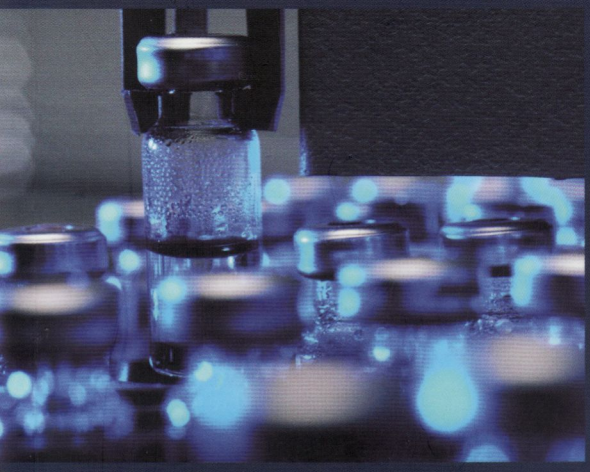
OXFORD Business English

English for the **Pharmaceutical Industry**

Michaela Büchler, Kathy Jaehnig,
Gloria Matzig & Tanya Weindler

EXPRESS SERIES



Includes MultiROM

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Michaela Bücheler · Kathy Jaehnig
· Gloria Matzig · Tanya Weindler

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Table of contents

About the book

English for the Pharmaceutical Industry has been specifically developed for people who need to communicate effectively in English in the pharmaceutical industry. The book will equip learners with the linguistic skills and specialist vocabulary necessary to understand daily situations in a work environment.

English for the Pharmaceutical Industry consists of six units and covers the full process of drug development. Unit 1 introduces topics specific to the field. Unit 2 deals with medical research and development, and Unit 3 covers quality control and auditing. Unit 4 looks at the various phases of trials, and then moves on to drug safety and regulatory requirements in Unit 5. The final unit deals with drug manufacture and packaging. The units are presented in a logical sequence.

Every unit begins with a **Starter**, a warm-up activity to introduce the topic. Each unit sets up realistic work scenarios, in which new technical knowledge and associated language skills can be communicated. Industry-specific vocabulary is practised through the analysis of authentic documents and listening exercises. The **Useful Phrases** boxes draw attention to industry jargon and phrases, while the **Did you know?** boxes bring together professional and lexical information relevant to the English-speaking pharmaceutical employee. Every unit finishes with the **Output** article, an authentic text which extends the unit topics and offers opportunities for discussion.

At the end of the book, there is a **Test yourself!** crossword on pages 74–75. In the appendix, the **Answer key** is provided for independent study, along with the **Partner Files**, which provide role-play exercises to practise the language learned in the units. There is also a **Useful Phrases** list to refer to and **Transcripts** of the listening exercises.

The MultiROM contains all the **Listening extracts** from the book. These can be played through the audio player on your computer or through a conventional CD player. The interactive exercises provide **Useful Phrases**, **Vocabulary**, and **Communication** practice and are all particularly valuable for independent study. There is also an **A–Z wordlist** with all the key words that appear in **English for the Pharmaceutical Industry**. This includes a column for phonetics and a space for you to write in the translations of the words in your own language.

1 The kick-off meeting

STARTER **Match what people are saying below with the department they work in.**

- ☐ Clinical Affairs
- ☐ Marketing and Sales
- ☐ Production
- ☐ R & D (Research and Development)
- ☐ Regulatory Affairs
- ☐ QA (Quality Assurance)

- Does your company have all of these departments?
- Which department do you work in? Which one would you like to work in?
- Which departments do you work with most often?

1 **Harvey Jones, project manager at Fab Pharmaceuticals, is preparing a kick-off meeting to discuss the development and launch of CoolHead, a new medicine. Read the memo.**

‹MEMO›

Fab Pharmaceuticals

From: Harvey Jones, project manager

To: Heads of departments

Re: 'CoolHead' – Kick-off meeting

Dear colleagues

The main reason I am writing to you today is to remind you that we still need you to propose people from your departments to work on our new soft gel capsule for headaches and to liaise with your departments. As you know, it will be a prescription drug, so people with experience in analgesics are the ones we'd most like to have on board.

Here is an update on the project. Since the conclusion of our successful feasibility study, we have also obtained very encouraging preclinical data. This means that we can soon start with the clinical trials and are now ready to get the project team together. The kick-off meeting will take place on 6 March in the Intercontinental Hotel. More details will follow soon.

You are probably aware that 'CoolHead' is just the working name of the new drug. The soft gel capsule will be followed soon afterwards by two other dosage forms also in the pipeline: patches and sugar-coated tablets. We plan to launch all of these products in Europe first and to apply for Food and Drug Administration (FDA) approval in the US the following year.

We still need project team members from R&D, Regulatory Affairs, and QA. As far as Marketing is concerned, Carole Marks will be flying in from France. She'll give us more information on the marketing claims and a target patient profile. From Clinical Affairs in Italy, Anna Edicola will present the clinical requirements. She, as well as Charley Wu from Production, will be connecting with us by video conference.

I'd like to get the team members' names you propose, as well as their contact details, and a brief bio on each one from you this week. Then I can invite them to the meeting. Let me know if you foresee any major difficulties at this stage.

Are the following statements true (✓) or false (✗)?

1 ☐ The most important reason for this memo is to give information about a new drug.

2 ☐ Patients who want to buy this drug will not need to see a doctor first.

3 ☐ There are three dosage forms planned at the moment.

4 ☐ The company plans to sell the drug in Europe and the United States.

5 ☐ Project members from Marketing, Production, and Clinical Affairs are already on board.

2 Match the term on the left with the definition on the right.

1 dosage form	a Medicine bought in a pharmacy and requiring a written note from the doctor.
2 feasibility study	b Future drugs, not yet on the market.
3 over-the-counter drug	c The final form of the medicine, e.g. tablet, powder, gel, spray, etc.
4 products in the pipeline	d An investigation to determine the advantages, practicality, and profitability of a proposed project.
5 prescription drug	e A product which can be sold without the patient seeing a doctor.

USEFUL PHRASES – PROVIDING INFORMATION

The main reason ...
Here is an update on the project.
As you know, ...
You are probably aware that ...
As far as ... is concerned, ...

3 Here is an extract from a memo sent by Harvey to the Head of Finance. Insert the expressions from the Useful Phrases box above in the gaps below.

_____[1] I am writing to you is to get your input on a new product. _____[2], we plan to market a new prescription drug for headaches.

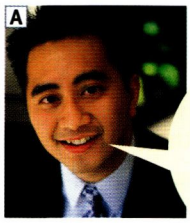
But first, _____[3]. The feasibility study has just been successfully completed. _____[4] it will be marketed in Europe first. _____[5] your input _____[6], we need the financial data from your department as soon as possible.

DATES

If someone writes to you and says the meeting will be on 05/04/12, what would you put in your calendar? In the UK, someone would write *5 April 2012*, whereas, in the US, they would write *May 4th, 2012*. For this reason, it is important to write out dates to avoid misunderstandings. Here are some useful forms: 2nd September, or shorter, 2 Sept.

4 Read the job profiles and match the words in italics with the definitions on page 9.

A



I collect drug safety information about patients *on our medications*. I must report any *serious adverse events* to the health authorities.

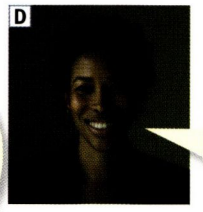
B

When a company starts to test drugs on live *subjects*, I work closely with the doctors to make sure that the studies are done correctly.

C

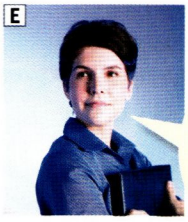
I operate complex scientific instruments and perform tests to determine whether *ingredients* in liquids, powders, or tablets meet requirements.

D



It's my job to research, write, and edit clinical and study reports before we submit them to regulatory authorities. I summarize and interpret clinical data.

E



I co-ordinate and manage the cross-functional teams that develop and launch a drug. It's not easy to get people to meet deadlines.

F

According to European law, I am personally responsible for the quality of each product that leaves the production line. I must manage all the processes in production, QA, and the labs to make sure *Standard Operating Procedures (SOPs)* are followed.

G

My job is to make sure that suitable, clean containers are used to get the product from the company to the patient. In general, I check for compliance with *health regulations*.

H

In my work, I develop pharmaceutical dosage forms. At the moment, I am changing a tablet formulation into *ointment* and gel forms.

1 _____ taking our medicine

2 _____ a substance in a drug

3 _____ a description of a working method or process

4 _____ a human or animal drugs are tested on

5 _____ any health problem which starts while on a new medicine

6 _____ rules or laws about health

7 _____ an oily substance like a cream

Now match the job profiles in A–H with the job titles below.

8 _____ clinical research associate

9 _____ formulation scientist

10 _____ laboratory technician

11 _____ medical writer

12 _____ packaging technician

13 _____ pharmacovigilance manager

14 _____ project manager

15 _____ qualified person

5 Underline the correct verb.

1 Companies must conduct / report serious adverse events to the health authorities.
2 New drugs are tested / determined on live subjects.
3 Laboratory technicians operate / perform complex scientific instruments and determine / perform whether liquids, powders, or tablets meet requirements.
4 Clinical research associates report / perform clinical trials. They must also summarize, interpret / regulate and process clinical data.
5 Regulatory Affairs reports / submits documents to regulatory authorities.
6 Formulation scientists develop / summarize pharmaceutical dosage forms.

AUDIO 2

6 Harvey Jones has got his project team together for the kick-off meeting via video conference. Listen to the dialogue and answer the following questions.

1 What is the main aim of the meeting? _____

2 Where does Anna work, and what does she do? _____

3 What is Walter's educational background? _____

4 What is Walter working on at present? _____

5 Where was Charley born and raised? _____

6 What did Charley help to plan and set up? _____

7 Listen to Anna in the dialogue again and fill in the gaps with the expressions below.

• assigned to this project • I did research on • I have been with this company for • I received my • I used to work • My professional background is in

Well, as you may know, I am from Milan and in case you are wondering, yes, like most Italians, I am a very good cook. _____[1] pharmacology, and in 2005 _____[2] master's degree at New York University and licence to practise pharmacy in the United States. _____[3] clinical methodology. As far as this project goes, I am the clinical trial manager _____[4] and am supported by two clinical research associates, who will work with test centres in northern Italy and in Slovenia. _____[5] about three years and _____[6] at Johnson & Johnson in their clinical department.

ACADEMIC DEGREES

The first scientific degree future pharmacists obtain is called a *bachelor's degree*. After receiving this degree, they continue their studies for several more years and get a *master's degree*, which usually involves research. However, before they become fully qualified, pharmacists have to take an examination to get a *licence to practise pharmacy*. After their master's degree, they can go on to do a doctorate.

Academic degrees

- bachelor's degree or bachelor of science degree (BS or BSc)
- master's degree or master of science degree (MS or MSc)
- licence (UK)/license (US) to practise pharmacy
- doctorate or doctor of philosophy degree in pharmacy (PhD)

USEFUL PHRASES – INTRODUCING YOURSELF, YOUR FIELD OF EXPERTISE, AND CURRENT PROJECT

Introducing yourself

I'm/My name is ...
I am from ...
I've been with the company for ... years.
I am ... (nationality), but originally I come from ... (country).
I am married / single.
I am based at ... (name of company/institute) in ... (city).

Educational background

My professional background is in ... (field).
I got/received/obtained my ... (degree) in ... (subject).

Experience

I used to work at ... (company/institute) in their ... department.
I then worked for ... (company/institute) and later for ... (company/institute).
I started as a ... (position) and worked my way up to ... (position).
I did research on ...

Expertise

I have experience in ... (field), and that's why I've been asked to join this project team.
I was on the team that ...
I was involved in ...

Describing current work and role in project

I am the ... (position) assigned to this project.
I am responsible for ...
I am supported by two ... (positions).
We are currently working on ...
At the moment, I am working on a project to ...

8 Use the Useful Phrases above to fill in the gaps.

Hi, everyone. Pleased to meet you all. _____[1] Charley Wu, and _____[2] plant manager at our manufacturing plant in Shanghai. I was also born and raised in China. I first _____[3] line worker and _____[4] to packaging technician. I later studied in the UK and _____[5] an MSc in Engineering there. More recently, _____[6] in the initial conceptual design phase, and at present _____[7] the planning and building of our second new pharmaceutical facility in Shanghai. In this new facility we will produce both liquid and solid dosage forms. In addition to this, at the moment _____[8] build a new analgesics production line, and that is why I was asked to join this project.

THE *TO DO* LIST

At the end of a meeting, the results of the meeting are often summarized in writing as action points. This is a 'to do' list. It gives the names of people and what each person should do. It often has sentences like this: 'Mary *is to write* to the regulatory authorities by Friday.'

9 Put information about yourself in the form below. Then use it to introduce yourself to the group.

Name:

Nationality:

Educational background:

Work experience:

Expertise:

Current position:

Responsibilities:

Current tasks:

AUDIO 3

10 Listen to Harvey summarize the decisions taken at the meeting. Match the list of action points with their deadlines to build sentences.

1	☐ Iris is to place all job ads for clinical research associates in trade journals	a	by Friday.
2	☐ Walter is to prepare a progress report on his work on the other dosage forms	b	within the next two weeks.
3	☐ Department heads are to estimate the time needed for their department's work	c	by the beginning of next week.
4	☐ Charley is to describe the technical equipment needed with a cost estimate	d	before the next meeting.
5	☐ Harvey is to work out the timelines, milestones, and budgeting	e	by the end of next month.
6	☐ Rasheed is to review any legal or regulatory issues	f	by the end of the month.

USEFUL PHRASES – SUMMARIZING ACTION POINTS

Before we close, I'd like to review ...
First of all, ...
... is to finish work by the end of the month.
... will be looking after the ...
... is going to find ...
Finally, ...
Each department needs to get back to me by ...

11 Put the words in the right word order to make sentences.

1 close, review Before we I'd like points to the action

_____

2 needed be Charley's the will team new equipment describing

_____

3 needs Each department me head get to to by back Friday

_____

4 look at any need Finally, regulatory issues addressed that to be is going to Rasheed

_____

5 from HR First will place in several pharmaceutical journals of all, job ads Iris Berger

_____

6 by the end to finish the other is dosage forms Walter of the month

_____

AUDIO 4

12 Georgina Beckham, the group leader of the clinical research team, needs her boss's approval to hire a new clinical research associate. She calls Anna, Head of Clinical Affairs, and reads out the job description. Compare her description to the advertisement below. Circle the five mistakes in the advert.

Large, multinational pharmaceutical company is searching for someone with experience in clinical trials to manage studies in a number of study centres in Eastern Europe.

CLINICAL RESEARCH ASSISTANT

DESCRIPTION

You will assist in the management of clinical drug development. You will be responsible for recruiting investigators and collecting study documentation.

You need to be able to write pharmaceutically and technically accurate protocols, study reports, clinical sections of dossiers, and other research documents in English. You will visit study centres, requiring up to 50 per cent travel.

REQUIREMENTS

- A BS in a life science is the minimum; a bachelor of science is preferable; a PhD is a plus.
- You must have at least two years' knowledge.
- In-depth knowledge of FDA regulations is essential to this job.
- You must work well independently and as part of a team.
- Top organizational and communication skills are a must.
- Excellent English is required. A working knowledge of Polish or Russian would be useful.

Fab Pharmaceuticals

USEFUL PHRASES – WRITING JOB ADVERTISEMENTS

... (company) is searching for a ... (position)
... will assist ... (person/position).
... is/are responsible for ...
... must have at least ... (number) years' experience.
... is preferable.
... is essential to this job.
... will need to be able to ...
... is/are required.

13 Use the expressions above to fill the gaps in the job advertisement.

JOB TITLE – CHEMIST

WJH

DESCRIPTION

CRO _____[1] someone to co-ordinate and perform analytical testing for stability studies of new products. You _____ _____[2] review data in accordance with Good Manufacturing Guidelines. You will be _____[3] checking laboratory documentation and chemical specifications. It is _____[4] to use a wide variety of physical and chemical analyses to support shelf-life studies of patented pharmaceutical products.

REQUIREMENTS

- At a minimum a BS in Chemistry or a related science is _____[5], an MSc is _____[6].
- You should have at least three _____[7] in pharmaceutical analytical techniques and test methods.

JOBS IN THE PHARMACEUTICAL INDUSTRY

PTA: Assistant or Technician?
Direct translations of job titles can be misleading. For example, if a PTA is described to someone in the US or UK as 'pharmaceutical technical assistant', it would sound as if this person has an entry-level position, possibly without any previous job training. In English, 'pharmaceutical technician' or 'pharmaceutical laboratory technician' would be better descriptions.

Junior vs. Senior; Scientist 1, 2, 3
The amount of training, the number of years of experience, and the salary scientists have, can often be seen in their job titles. Whereas a recent university graduate may start as a junior scientist, or scientist 1, the more experienced colleague would be a senior scientist, or scientist 2 or 3.

Associate
Many job titles include the word 'associate', for example, a research associate, a QA associate, an associate research scientist, or drug safety associate. This very general title roughly means 'partner'. In a pharmaceutical company, it usually refers to a professional with a degree, or specialized training, who has a certain area of responsibility.

14 Choose a job title and write an email to Iris. Describe the main points for the position.

Dear Iris
We will need to fill the position of _____ (job title) shortly.

I'd appreciate it if you could write up a job advertisement with the input below and place it in the pharmaceutical journal we normally use.

Here is a list of the main points:
Key duties / responsibilities

_____

_____

Educational background

_____

_____

Other skills needed

_____

_____

Let me know if you need any further information.

Thanks for your help.
Best regards

_____ (Name)

15 Each column contains a category and some terms listed under it. Cross out the term that does not fit in each category.

non-production pharmaceutical professions	dosage forms	What goes into drugs?	pharmaceutical documentation
clinical research associate	capsules	chemicals	clinical reports
formulation scientist	gel	formulation	dossiers
laboratory technician	ointment	ingredient	marketing claims
line worker	prescription drug	raw materials	protocols
pharmacovigilance manager	sugar-coated tablets	substances	study reports

16 Two colleagues, who have not yet met, are on the same project team. They call each other.

PARTNER FILES Partner A File 1, p. 76
Partner B File 1, p. 78

OUTPUT

Read the following newspaper article.

Cross-cultural differences in marketing drugs internationally

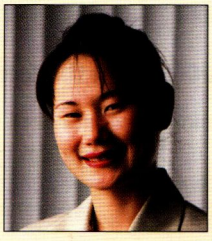
Some companies are successful at marketing their drugs all over the world without making any major changes to them. Others have different formulations, advertising, and packaging in each country, due to differences in customs and laws. See what various experts think about this topic.

Marie Simone, European marketing consultant: In France, medicines should not only cure a disease, but also look fresh and interesting. For example, pink eye drops have been popular here, which would be unthinkable in our subsidiary in Germany. There people expect medicine to look more 'clinical'.

Sabine Schmitz, Regulatory Affairs, Germany: The strength of medicine varies considerably depending on what health authorities allow. Here, health authorities prefer companies to sell drugs with only one active ingredient, rather than in combinations. They also prefer lower drug dosages as compared to those set by authorities in other places.

Brad Townsend, consumer specialist, Canada: Some people prefer to take several small tablets per day, whereas others prefer to swallow only one big one. In some countries they would take one look at such a large tablet and say, 'I'd give it to a horse, but there's no way that is going down my throat!'

Swetlana Sheremetieva, Russian pharmacist: In Russia, we prefer to buy over-the-counter products, like cold remedies or cough syrup, from people in pharmacies wearing white lab coats. So, when foreign companies try to introduce drugs here, we ask them for good in-pharmacy training programmes because our staff will have to answer many questions before people are willing to buy such cures.



Miko Tanaka, QA specialist, Japan: Quality is important all over the world, but in Japan we take it one step further. We will reject a whole shipment of drugs if we find the smallest scratch or imperfection in one single package, even if it makes no difference to the product at all.

Harry Hart, advertising agent, USA: US patients tend to self-medicate and buy drugs online. Unlike in many countries, you'll also find many cheerful, bright coloured ads in magazines, which promote anti-depressants and other prescription drugs in the US. Of course, the next page is always full of all the warnings, possible side effects and things to ask your doctor about.

OVER TO YOU

- Can you name any medicines that are marketed differently in different countries?
- Should companies try to keep their medicines as similar as possible wherever they are sold?
- Are there any cultural preferences in the way medicines are marketed throughout the world? Do you think any of these differences are important?

2 Substance discovery and product development

STARTER

Read the explanations and put the following words or expressions into the correct column.

Research – the process of testing chemical compounds, with the goal of finding a substance which has a beneficial effect on a targeted disease.

Development – the process of carrying forward scientific discoveries made during the research process, with the goal of producing a marketable drug.

analysis of disease • analytical testing • clinical trials • dosage forms • drug safety • discovery • new chemical entities (NCEs) • target identification

Research	Development
_____	_____
_____	_____
_____	_____
_____	_____

What kinds of R & D projects are there in your company at the moment?
Which process takes longer – research or development? Why?
What factors help pharmaceutical companies decide what drugs they should develop?

1 Read the memo and the information about Mensamint™.

MEMOMEMOMEMO

Caduceus Pharmaceuticals Ltd

Date: Tuesday

To: Pharmaceutical department – Chemists and Pharmacologists

From: John Keyes, Vice President R&D

Subject: Breakthrough in search for NCE for *Mensapatch*™ development

As some of you will already know, a new chemical entity has just been synthesized in our own labs, which we think may be useful in our *Mensapatch*™ development plans.

A meeting will be held tomorrow at 9.30 a.m. in conference room 308 to brainstorm ideas for this new substance, and to discuss the further development. Your participation would be appreciated.

JK

MENSAMINT™

Mensamint™ is a new dosage form of *Mensadent*™ (obtainable with physician's prescription only). It uses the newly synthesized active substance mensagitatum (Latin origin: the mind moves/animates).

The formulation for adult patients is in lozenge form (or as *Mensadent*™ in chewing gum form for young patients), and the indication is to stimulate brain activity and thinking power.

Known side effects often include loss of sleep if taken in the late afternoon or evening. Occasionally, an increase in blood pressure may occur. Rare instances of heart palpitations and headaches have also been reported. It is not possible to overdose and mensagitatum is non-addictive.

Answer the following questions.

1 What is the meeting about, and what needs to be discussed? _____

2 What kind of product is *Mensamint*™? _____

3 What do patients have to do to obtain it? _____

4 What are the dosage forms of this product? _____

5 Are there any known side effects? _____

AUDIO 5

2 An R & D meeting takes place, in which John answers questions about a new chemical substance. Read his answers below and write your own version of the questions. Then listen to the meeting and check your answers. Note: not every question is asked during the meeting.

1 _____

It is already available in lozenge and chewing gum form, but we hope to develop a time-release patch in the near future.

2 _____

We will have to test the bioavailability to be able to calculate dosages for non-intravenous routes of drug administration for this NCE.

3 _____

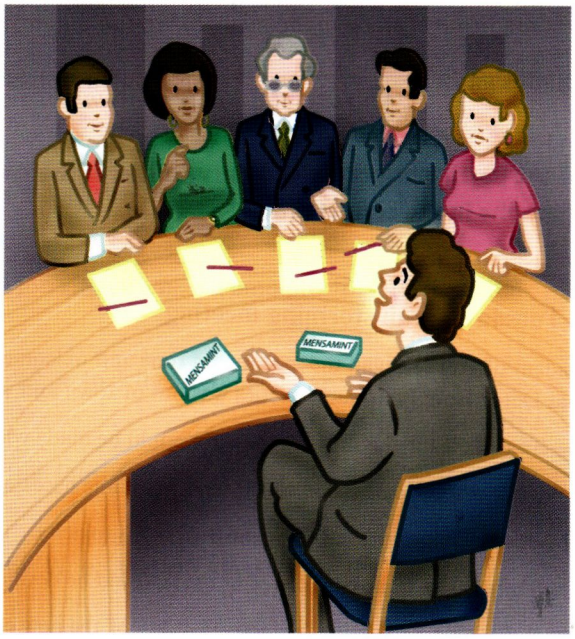
As you know, when substances are taken with alcohol or antibiotics, their chemical form could change and even cause harmful side effects. I'll keep you informed.

4 _____

Not completely. However, we do have a partner to help us develop a patch form which provides the desired effects for at least six hours.

5 _____

I'm afraid it may take a year or more before we can start the first tests on healthy humans.



ASKING ABOUT DRUG DISCOVERY AND DEVELOPMENT

Dosage
What kind of formulation could we develop?
What about using other forms?
Are tablets, capsules, or drops possible?
What about the dosage for these forms?

Development
What is the toxicity of this NCE?
What about the bioavailability of this NCE?
When can we start the first in-man study?
Do we have the technology to make patches?

3 Put the correct form of one of the vocabulary items from the box into the sentences below.

chemist • dosage form • formulation • in-man study • prescription • toxicology

1 A specialist or expert in the scientific field of chemistry is called a _____. In the UK, this word is also used for the person who prepares and sells medicine, also known as a pharmacist in the US.

2 Using the right _____ is especially important when giving medicine to children, because they often have problems swallowing pills.

3 The science of poisons, including their source, chemical composition, action, tests, and even their antidotes, is what we call _____.

4 If a drug or medicine is not available 'over-the-counter', it normally means that a _____ from a physician is needed to obtain it from a pharmacy.

5 Chemists and pharmacologists are also interested in how the medicine is administered, so they often ask about its _____.

6 Before drugs or medicines can be made available to the public, they have to be tested on human beings. We call this an _____. It is also called a phase 1, stage 1 study, or clinical trial.

4 A few days later, the participants received the minutes of the meeting. Listen again to exercise 2 and put the paragraphs in the correct order.

Minutes of Tuesday's brainstorming meeting

The Vice President of R&D began the meeting on time and welcomed all the participants. He also mentioned that Derek from Pharmacokinetics was out of town and was not able to attend.

A ☐ *Finally,* Brian asked if the new dosage form could be made with current technology.

B ☐ *Next,* there was some discussion about the time frame necessary for in-man studies.

C ☐ *Then* Marcus brought up the subject of the NCE's toxicity.

D ☐ Hilda *initially* asked what kind of formulation could be developed from the new NCE.

E ☐ *After that,* Frank asked about the bioavailability of the new chemical entity.

The meeting finished at 10.30 a.m. The next meeting for all participants, including Derek, will take place in one week. We will then decide how to proceed.

PHARMACOKINETICS VS. PHARMACOLOGY

Pharmacology is the study of drugs, how they work, and what they do in the body. Pharmacology can be divided into two separate areas: pharmacodynamics and pharmacokinetics. Pharmacodynamics studies what the drug does to the body, and pharmacokinetics studies what the body does to the drug.

AUDIO 6

5 Janet, a chemist, and Brian, a pharmacologist, meet to talk about the brainstorming meeting. Listen and decide if the statements are true (✓) or false (✗).

1 ☐ The side-effects research for the product is not finished yet.

2 ☐ There are other dosage forms which work better than the patch form.

3 ☐ It will only take a few months to further develop the patch form.

4 ☐ Cream, ointment, and suppository forms would also be possible for this product.

5 ☐ The company already has the technology to make tablets and pills.

TALKING ABOUT TIME PERIODS

We will *need a bit more time* to completely answer that question.
We *are still running tests* to find out what kinds of side effects are possible.
We can give you the answer *in about four weeks*.
It will take *from about six months to a year and a half*.
Not yet! But we're working on it.

6 Put the words in the right order to make questions and answers about substance discovery.

Question 1 formulation kind we What of develop could ?

Answer 1 yet, know on We we're it don't but working

Question 2 about forms What the dosage ?

Answer 2 answer yet don't have We a complete to question that

Question 3 NCE this is What toxicity of the ?

Answer 3 about give the four can We weeks you answer in

Question 4 can study the When we in-man start first ?

Answer 4 six year and a half We from need to months will a

Question 5 are What effects kinds possible of side ?

Answer 5 to still tests We running find are out

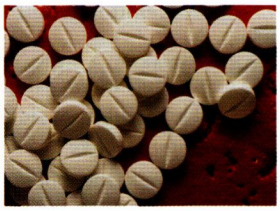
Talk about a drug in research at your company. Mention the following points:

development period • dosage form • study results • toxicity

7 Match the words from the box with the pictures, and fill in the gaps in the following text with the correct dosage form.

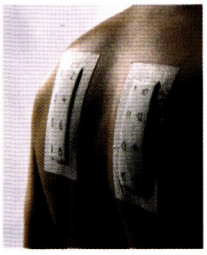
dosage • drops • patch • pills • suppository • syrup • tablets

a _____



b _____

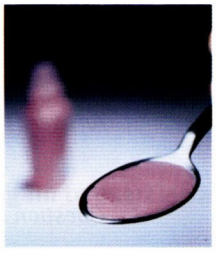
c _____



d _____

e _____

f _____



g _____

1 Calculating the correct _____ for some patients isn't always easy.

2 Children and older people often have trouble swallowing large _____ or _____.

3 Wearing a _____ may create problems for people with skin allergies.

4 Some medications are available in liquid form, such as _____ or _____.

5 We often use a _____ to administer medication to babies or other patients who are not able to take drugs orally.

AUDIO 7

8 Helen from Marketing Research calls John, Vice President of R & D, to discuss the results of a hospital in-patient survey on dosage forms for a new medication. The company needs to know which drug dosage forms patients prefer. Listen to the telephone call and fill in the form below.

Hospital In-patient Dosage Form Survey Results

1. Total number of in-hospital patients surveyed (a) _____
2. Male patients (b) _____ Female patients (c) _____
3. Average patient age (d) _____
4. Which of the following *oral* dosage forms are the patients *currently* using?

tablet (e)	_____	gel tablet (f)	_____	capsule (g)	_____	pill (h)	_____
solution	_____	drops	_____	syrup	_____	other(s)	_____

5. Which of the following dosage form(s) do the patients favour?

oral dosage forms

tablet	_____	gel tablet (i)	_____	capsule (j)	_____	pill	8 %
solution	_____	drops (k)	_____	syrup (l)	_____	other(s)	_____

inhaled dosage forms

aerosol (m)	_____	inhaler	_____	other(s) _____

topical dosage forms

cream (n)	_____	ointment (o)	_____	liniment	_____	lotion	_____
gel	_____	patch (p)	_____	other(s)	_____		

other dosage forms

nasal spray	_____	eye drops	_____	suppository _____

6. What kinds of side effects did the patients have with their current medication?
The following side effects were experienced:

allergic reactions	794	diarrhoea	29	dizziness	3
fever	75	headache	91	indigestion	422
insomnia	47	itching	70	nausea	253
skin rashes	59	vomiting	17	other(s)	

7. Do the patients have any suggestions for other future forms of medication?
List all suggestions here:

_____

8. Do the patients have any of the following chronic health conditions?

asthma	794	anaemia	121	bronchitis	805	diabetes	83	heart condition	21

9 Answer the following questions using the information in exercise 8.

1 How many patients were surveyed in all?

_____

2 Were more male or female patients interviewed?

_____

3 What kind of dosage form is most preferred by the patients surveyed?

_____

4 What kinds of side effects were experienced by the least number of patients?

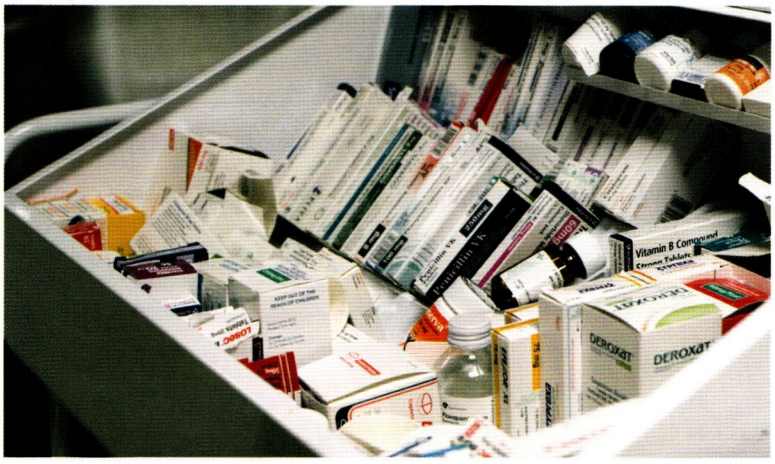
_____

5 What chronic health conditions did most patients have?

_____

10 Match the dosage form on the left to its definition on the right.

1	☐	aerosol	a	A very small amount of liquid that forms a round shape.
2	☐	drops	b	An smooth, thick substance to rub on the skin for healing.
3	☐	inhaler	c	An oily liquid to rub on painful body parts to reduce pain.
4	☐	liniment	d	A medication on material or cloth placed on the skin.
5	☐	ointment	e	A small, round piece of medicine to be swallowed without chewing.
6	☐	patch	f	A container with a liquid that is administered in spray form.
7	☐	pill	g	A liquid in which another substance has been dissolved.
8	☐	solution	h	A solid medicine which melts slowly in the rectum or vagina.
9	☐	suppository	i	A sweet, liquid medicine taken with a spoon or cup.
10	☐	syrup	j	A small device with medicine to breathe in through the mouth.



ASKING FOR AND GIVING OPINIONS

Asking for opinions
What do you think ... ?
What's your opinion on ... ?
What's your view of ... ?

Giving opinions
I think/I feel ...
In my opinion, ...
From my point of view, ...

Avoiding/Withholding opinions
I would rather not say ...
I'm sorry I cannot comment on ...
I'm afraid I am not in a position to answer that.

Giving strong opinions
I firmly believe ...
I feel very strongly that ...
I'm sure/certain/convinced ...

11 Rephrase the following statements for conducting or taking part in a survey. Use the Useful Phrases above.

1 A new drug has recently been developed to cure heart disease. (Ask for opinion)

_____

2 More than one dosage form is being considered: pill, and patch. (Ask for opinion)

_____

3 The in-man studies for this drug will take more than six months. (Give opinion)

_____

4 Additional clinical trials should be done in other countries. (Give opinion)

_____

5 This new formulation will be successful. (Give strong opinion)

_____

6 A third dosage form should be developed: nasal spray. (Give strong opinion)

_____

7 You don't have enough information to make a statement. (Avoid opinion)

_____

8 You don't want to share the information you have yet. (Avoid opinion)

_____

What kind of medication is often taken on a regular basis, and in what form?
Which side effects do you feel people dislike the most?
Do you prefer to take medication in a particular form? If so, which form, and why?

12 Two scientists meet to discuss the development of an NCE and its possible future formulation(s). They discuss and give their opinions on dosage, development, and time periods.

Partner A File 2, p.76
Partner B File 2, p.78

OUTPUT **Read the article below about different classes of drugs in different countries.**

How many drug categories do we need?

On the whole, countries establish specific rules and regulations not only on the type of drugs made available, but also on how they reach the consumer. On the one hand, medicine needs to be easily accessible. This is, of course, a question of public health. On the other hand, these same products can do harm if used incorrectly. This danger must be avoided.

For this reason, regulatory authorities in every country set the number of categories for drugs. For example, in Canada, there are four:

1) drugs available only with a prescription
2) those without a prescription, but only with the personal involvement of a pharmacist
3) medicine which customers can pick off open shelves, but only in a pharmacy, and
4) products which can be openly sold in any kind of retail outlet.

By contrast, the US only has two official categories: drugs needing a prescription and drugs that do not. The former are prescription drugs and are available in pharmacies and only by prescription. The latter are over-the-counter drugs which can be sold in any type of retail outlet that chooses to stock them.

In general, in the US, medication must meet four criteria in order to obtain the status of a non-prescription or over-the-counter (OTC) product. It must have:

- a large margin of safety
- low incidence of side effects
- low potential for misuse and abuse, and
- labelling that provides adequate directions for sale and effective use.

At present, the Food and Drug Administration is reviewing its current policy on the number of categories. It is discussing the introduction of a new intermediate category for the US market called 'behind-the-counter' (BTC) medicine. Drugs of this type would need no prescription, but would require a pharmacist's intervention and resemble category 2) in Canada. One reason is that consumers in many Western countries have found this new category beneficial.

In Europe, the concept of BTC has been practised with great success for years. People can just go to their local pharmacy and describe their medical need. The pharmacist simply recommends an appropriate drug without first requiring a doctor's prescription. He or she can also suggest a less expensive drug in generic form. The disadvantage, however, for many Europeans is that the cost of these drugs or medications is not taken on by the health insurance system.

Currently, the FDA is faced with a difficult decision. If it decides to add the category BTC, this will have definite consequences for the pharmaceutical industry in the US. In the short term, this change would immediately force the pharmaceutical companies to reorganize their marketing efforts. In the long term, companies and research institutes would need to reassess their own potential and reconsider which type of drugs are worth testing. ■

12

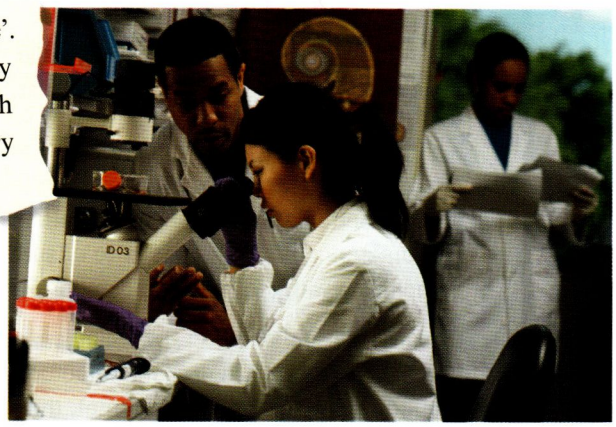
OVER TO YOU

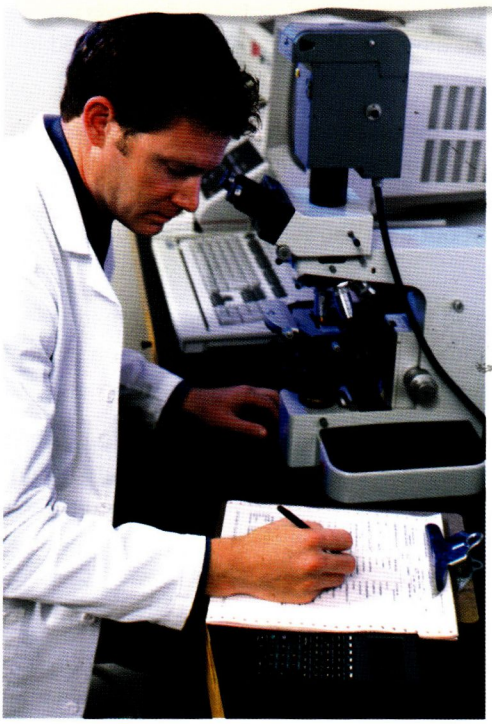
- What are the advantages of providing drugs and medications by prescription, BTC, and OTC?
- How are drugs and medications made available in your country?
- Which method(s) do you prefer?
- Should patients have the right to obtain drugs and medication online from other countries?

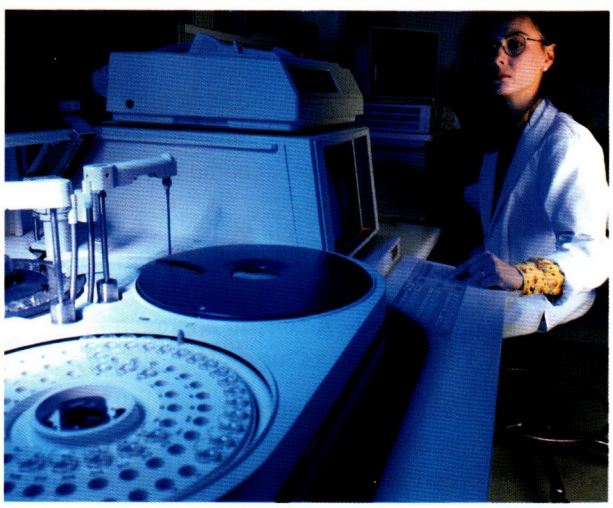
3 Quality assurance and auditing

STARTER **Read the definition of 'good practice', then match the words with the correct abbreviations.**

GxP is an abbreviation for 'good practice'. The 'x' is used to indicate the many different areas of 'good practice' which are required by international regulatory authorities.







GAP, GCP, GDP, GLP, GMP, GRP, GSP

auditing • clinical • documentation • laboratory • manufacturing • research • safety

It's good _____ *practice.*

- Which of these forms of good practice are you familiar with?
- Can you give examples of good practice requirements used in your company?

1 **Berner Pharmaceuticals Ltd provides employees with general information on GMP on its intranet. Read the following text and answer the questions.**

Berner Pharmaceuticals Ltd

Login **User:** **Password:**

In the pharmaceutical industry, different **quality assurance** processes are required for each area of good practice (GxP).

It is easiest to understand how good practice works in the area of manufacturing. The quality assurance process in good manufacturing practice (GMP) includes product **quality control**, sampling, and testing. Quality control ensures that the product quality remains high. The reason for interim testing, or **product sampling**, is to check the quality of pharmaceutical products. This is important to make sure that the product is **suitable** for its intended use and for sale. **Endpoint testing** is carried out at the end of every manufacturing process. This is to ensure that all procedures have been performed in compliance with industry and company standards.

Documentation is important and necessary at every step of the processes, activities, and operations involved in drug manufacturing. If the documentation is not in order, or if the required specifications are not met, then the product is considered **contaminated**. Proper documentation not only enables **traceability**, but also allows a complete **product recall** from the market, if necessary.

Inspection and **validation** are required to prove that the manufacturing and testing equipment is functional. All operational methods and procedures must also be inspected for accuracy. Most companies do this voluntarily through internal audit processes.

However, beyond the field of manufacturing, good practice must be adhered to in all processes in a pharmaceutical company. No process can be considered isolated from the others. For example, laboratory and manufacturing processes cannot be regarded separately. A **holistic approach** looks at all these environments to make sure that the entire process meets high industry standards.

Standard operating procedures (SOPs) are written and used by companies to make it easier for them to follow GxP. These are a set of written instructions to maintain performance and results. They are also the basis of every good quality assurance and quality control system.

According to the text, which answer is <u>not</u> correct?

1 Why is product sampling carried out?
a To introduce product quality.
b To check product quality.
c To make sure SOPs are followed.
d To meet high industry standards.

2 Which aspect of drug manufacturing enables traceability?
a quality assurance
b quality control
c holistic approach
d documentation

3 Why do operational methods and procedures have to be validated?
a To complete the quality assurance process.
b To make sure products perform their intended function.
c To complete the inspection process.
d To isolate products of high quality.

2 Complete the following sentences with the correct word or expression in bold from the text in exercise 1.

1 The documentation required for all research processes and development steps ensures the _____ of a drug.

2 A _____ considers laboratory and manufacturing processes and environments together and not individually.

3 Quality _____ involves all manufacturing processes in GMP which make sure the goods produced are kept at high standards.

4 Quality _____ involves interim and product sampling procedures, which are carried out to check product quality.

5 At the end of every stage of a product's manufacturing process, _____ is done to maintain quality standards.

6 Even a product that has been marketed for years might have to be taken off the market in a _____ if serious adverse reactions occur.

7 Manufacturing processes and procedures must go through periodic _____ to guarantee that they are still of an acceptable standard.

8 _____ products are no longer pure and acceptable for sale or public use and, therefore, must be returned to the manufacturer, or destroyed.

3 In order to comply with the internal audit requirements for Good Laboratory Practice (GLP) of the European Medicines Agency (EMEA) for pharmaceutical firms, Berner Pharmaceuticals Ltd needs to complete an audit of their current laboratory safety systems and procedures. Read the memo from the Quality Assurance Internal Auditing Department and answer the questions.

Berner Pharmaceuticals Ltd B|P

– Interoffice Memorandum –

Date:	Monday
To:	Philip Reuter, Laboratory Management
From:	Joseph Mason, Quality Assurance Internal Auditing
Subject:	Annual audit of SOPs for laboratory safety
Cc:	Richard Jacobs, Senior Quality Auditor; Gail Webber, Operations Auditor
Attachment:	Audit checklist for laboratory systems and procedures (see p. 86)

This memo is to advise you that your department has been scheduled for a periodic audit of the laboratory safety systems and procedures.
The timetable for the various laboratory audits is as follows:

Laboratory 1: Tuesday and Wednesday
Laboratory 2: Wednesday and Thursday
Laboratory 3: Thursday and Friday

Please make sure that all the laboratory staff are advised and prepared in accordance with standard audit procedure. Two members of our audit team (Richard Jacobs and Gail Webber) will begin this internal audit on Tuesday, two weeks from tomorrow, using the latest company-approved audit checklist (see attachment).

The completed checklist and original audit results will be reviewed with you and the Research and Development Vice President. Our goal is to identify any areas requiring corrective or preventive action before a summary report of the status of these actions is issued. This is done to assure compliance with industry standards, especially for safety procedures.

Please confirm receipt of this memo and send us a copy of all your correspondence with regard to this scheduled audit.

J. Mason

1 What kind of internal audit has been scheduled? _____

2 What is the objective of this audit? _____

3 How often does this type of audit have to be done? _____

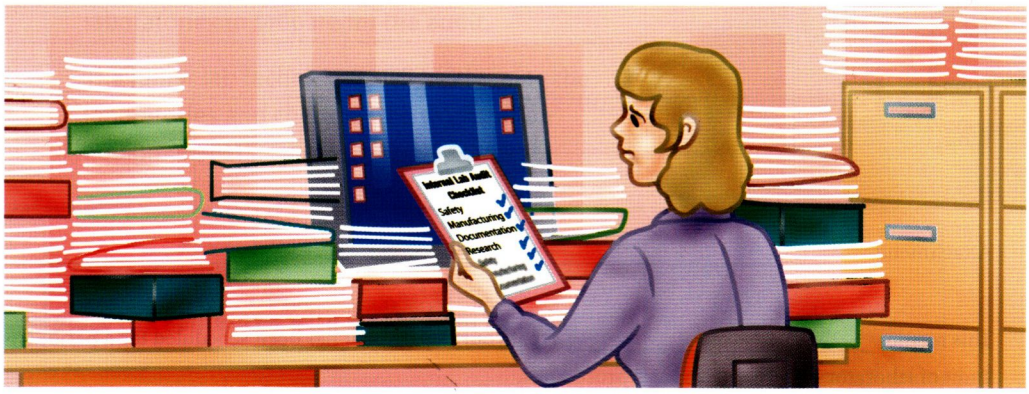
4 When will the audit take place? _____

5 What documentation is necessary for the audit? _____

- Does your company also have planned or scheduled audits? If so, for which areas and how often are they carried out?
- Have you ever been part of an internal audit? What did you do?
- What kind of special procedure(s) does your company follow for internal audits?

CAPA

Corrective Action/Preventive Action (CAPA) is a part of the overall Quality Management System (QMS) required for GMP. It focuses on the systematic investigation of non-conformance events (errors or deviations), to prevent their occurrence (for preventive action) or recurrence (for corrective action).



USEFUL PHRASES – INFORMING

This ... is to advise ... that ...	The ... is as follows: ...
The ... will be reviewed ...	Please make sure that ...
Our goal is to ...	Please send us ...
... department is scheduled for ...	Please confirm ...

4 Match the tasks on the left with the phrases on the right.

1 ☐	You state the reason for a memo.	a Please send us ...
2 ☐	You state the objective of a course of action.	b This memo is to advise you that ...
3 ☐	You say the planned schedule.	c Our goal is to ...
4 ☐	You ask for verification of some information.	d The laboratory procedures will be reviewed ...
5 ☐	You need to have a copy of something.	e Please confirm ...
6 ☐	You say which department in the company is involved.	f Please make sure that ...
7 ☐	You say what areas will be audited.	g The lab management department is scheduled for an audit ...
8 ☐	You say what should be done.	h The timetable is as follows ...

5 Complete the memo to your own staff. Let them know about an upcoming audit. Use the Useful Phrases from page 31.

_____
(your company)

– Interoffice Memorandum –

Date: _____

To: _____

From: _____

Subject: _____

Cc: _____

Attachment: _____

This memo _____[1] that your department has been scheduled for a periodic audit of laboratory safety systems and procedures.

The timetable for the various laboratory audits is as follows:

Building 1: Tuesday and Wednesday
Building 2: Wednesday and Thursday

Please _____[2] that all the employees are informed and prepared in accordance with standard audit procedure. Two members of our audit team (_____ (names)) will carry out this internal audit from _____ (date) to _____ (date), using the latest company-approved audit checklist.

The completed checklist and original audit results _____[3] with you and the Director of Laboratory Management, to identify areas requiring corrective or preventive action before a report of the status of these corrective or preventive actions is issued. _____[4] is to identify and correct any quality system defects and to assure compliance with industry standards, especially for laboratory procedures.

_____[5] receipt of this memo and _____[6] a copy of all your correspondence with regard to this scheduled audit.

AUDIO 8

6 Listen to a laboratory staff meeting in which preparations for an internal audit of laboratory safety procedures are discussed. Are the statements true (✓) or false (✗)?

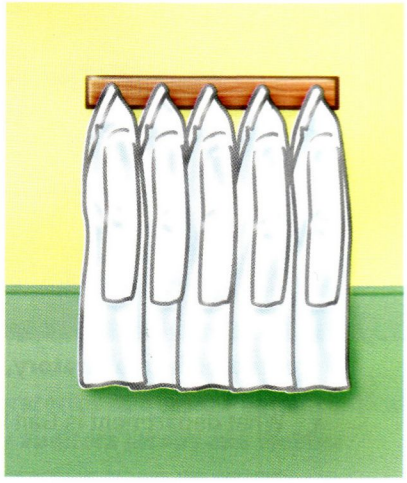
1 ☐ This is a planned audit.

2 ☐ The auditors will be giving information to the lab technicians during the audit.

3 ☐ One of the lab technicians will be in London during the audit.

4 ☐ The laboratory staff will only be cleaning the laboratories to prepare for the audit.

5 ☐ The junior lab technicians will be cleaning the laboratories and checking the workstation equipment lists.



7 Complete the sentences with words from the box.

checklist • finding • non-compliance • observe • safety • short • updated • up to date

1 Advance notice of this meeting was very _____.

2 _____ procedures make sure that the health and well-being of laboratory workers are guaranteed.

3 Auditors generally watch or _____ safety procedures in the lab.

4 To ensure that laboratory workers are asked certain questions about safety procedures, auditors use a _____.

5 If any _____ is observed during the audit, the department will be informed so they can take corrective action.

6 Standard operating procedures (SOPs) are _____ on a regular basis, often after an audit has been carried out.

7 Scientists often read journals and go to international conferences, because they need to stay _____ in their scientific fields.

8 Any observation or _____ noted by the auditors is categorized as either major, minor, or critical.

8 What kinds of questions about laboratory safety systems and procedures might be asked during an internal audit procedure? Write down examples from your own company.

1 _____

2 _____

3 _____

4 _____

5 _____

AUDIO 9

9 Listen to a conversation between an auditor and two lab technicians during an audit of safety procedures in a laboratory, and answer the questions.

1 What department is Gail Webber from, and what is her job?

_____

2 What must be done if non-compliance is observed?

_____

3 What are Charlie's and Jennifer's job titles?

_____

4 Name some items of protective clothing that must be worn in the laboratory.

_____

ASKING QUESTIONS DURING AN AUDIT

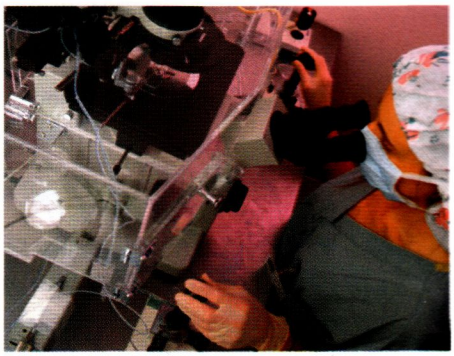
Talking to staff
What is your name?
What is your job?
What is your supervisor's name?
What is your supervisor's job?

Asking about processes and procedures
How have you been trained to perform this procedure?
How much time does it take to complete this part of the process?
What special procedures must be followed in a laboratory?
What special procedures must be followed for this process?

Asking about possible actions taken
How do you handle toxic waste in the lab?
How do you handle the transportation of animals in the lab?
What would you do if you got a toxic substance on your lab coat?
What would you do if you noticed non-compliance with safety procedures by a colleague?

10 **Practise asking and answering audit questions with a partner. Use the laboratory clothing and equipment from the list below and the Useful Phrases on page 34.**

- eye bath
- gas mask
- hairnet
- laboratory coat
- latex gloves
- overshoes
- safety glasses/goggles
- safety gloves
- bins for toxic substances



11 **Read part of the internal audit report done on the three laboratories at Berner Pharmaceuticals. There are five non-compliance areas which were observed by auditors Jacobs and Webber.**

Berner Pharmaceuticals Ltd Internal Audit Report – Friday 13 June 2010

Purpose and area description: Annual audit of safety procedures in all laboratories

Major facts: Although there were no serious instances of non-compliance, a number of incidents of undesirable conditions and practices were observed. These need to be corrected before the follow-up review in 30 days.

Observations:
a) Six laboratory technicians wore unsuitable clothing and safety equipment.
b) One lab assistant did not wash her hands after a procedure involving mice.
c) Times of the experiments were not entered on two of the daily lab reports.
d) Mice were transported in open cages (in public) to a second lab.
e) Improper disposal of toxic waste material was recorded.

Follow-up: A review of the procedures in Labs 1, 2, and 3 will be carried out …

Now match the areas of non-compliance found by the auditors with their observations.

Non-compliance areas	Auditors' observations
1 ☐ improper clothing/safety equipment	a chemicals found in normal waste bins
2 ☐ improper hygiene after handling animals	b lab mice moved outdoors in open cages
3 ☐ improper documentation	c safety gloves too big, no safety goggles
4 ☐ improper transportation of lab animals	d no recording of experiment times
5 ☐ improper disposal of toxic waste	e hand-washing or sanitizing forgotten

SUGGESTING CORRECTIVE ACTION

Neutral	Strong
I suggest you put 'No toxic waste' on the bin.	The only solution is to rethink the process.
My suggestion is that we redo the equipment list.	I strongly suggest that we try to prevent it in future.
My recommendation is to talk to the lab workers.	I'm convinced we must repeat the last tests.
It might be possible to relocate the equipment.	It is absolutely essential to learn the safety rules.

12 **Write five suggestions for corrective action to solve the safety problems in the Berner Pharmaceuticals labs (see exercise 11). Use the Useful Phrases above.**

1 _____

2 _____

3 _____

4 _____

5 _____

13 **Read excerpts from Berner Pharmaceuticals' SOP on laboratory procedures. Then match them to warning signs a–e.**

a 

b 

c 

d 

e 

1 ☐ All toxic waste materials must be disposed of properly.

2 ☐ Good sanitary hygiene must be practised by all lab staff.

3 ☐ Protective clothing must be worn in the labs at all times.

4 ☐ Lab animals must be transported in covered cages.

5 ☐ Eye protection must be worn as signposted.

DISCUSSING SOPS – PROCESSES, PROCEDURES, DOCUMENTATION, TIMING

Requesting information
Please describe the procedure for the ... process.
Would you please clarify how you ... ?
Could you explain the procedure for the documentation of ... ?

Asking questions
What are the guidelines for ... ?
How often do you have to ... ?
What special procedures do you follow for ... ?
How would you ensure good hygiene in the laboratory?

Formulating SOP guidelines
Proper protective clothing and safety equipment *must be worn* at all times.
Proper safety procedures *must be carried out* by laboratory staff.
Toxic or hazardous materials *must be disposed of* properly.

Note: SOPs often use the following structure: *must* or *should be* + verb.

14 Formulate SOP guidelines. Convert the following sentences.

Example: Use safety SOPs for working with laboratory animals.
Safety SOPs must be used for working with laboratory animals.

1 Perform all work with virus-infected animals in the bio-safety cabinet.

_____

2 Use disinfectant on equipment following any experiments with laboratory animals.

_____

3 Wipe up all chemical spills in the laboratory immediately.

_____

4 Wear laboratory gowns or lab coats, latex gloves, and safety glasses at all times.

_____

5 Cover small biological agent spills with a paper towel and treat them with bleach.

_____

6 Document all laboratory work in accordance with GLP.

_____

15 An internal auditor and a laboratory technician meet to discuss the standard operating procedures for safety in the laboratory.

PARTNER FILES Partner A File 3, p. 76–77
Partner B File 3, p. 78–79

OUTPUT **Read the following newspaper article.**

Drug contamination: lessons to be learned?

A few years ago, a well-known European pharmaceutical company was forced to recall one of its drugs due to claims of product contamination. The recall took place following reports from patients that their medication had a strange odour. Several patients from a number of different countries made the complaint within a short period of time. A few patients experienced nausea immediately after taking the medication. Unfortunately, the drug manufacturer was unable to say just how many patients were taking this drug at the time. However, it estimated the global figure at over 40,000 people.

Immediate investigations showed that samples of the tablets contained abnormally high levels of a harmful genotoxic substance. The contamination was traced back to its manufacturing plant. According to reports, it seems that an unanticipated reaction between the drug's active ingredient and the chemicals used as part of the cleaning processes at the site was the cause of the contamination.

The company claims that a cleaning error was the reason for the entire incident. This clearly underlines the danger of underestimating the importance of the cleaning process in pharmaceutical manufacturing. Validation of cleaning processes is essential in this industry, because chemical or bacterial contamination of drug products can potentially lead to severe public health risks. Regulatory bodies, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA), require validation of cleaning processes. In fact, if there is evidence that a company is trying to save money by reducing their cleaning activities, these agencies take action.

In the above case, no other products manufactured by the pharmaceutical company were affected by the mistake and the contamination error was quickly rectified. However, the recall left seriously ill patients without proper medicine. The World Health Organization recommended that patients try to find a suitable alternative.

OVER TO YOU

- What role did pharmaceutical manufacturing processes play in this incident?
- How could the company have avoided this recall? Consider the role of quality assurance, quality control, audits, and inspections.
- What effect do product recalls have on a pharmaceutical company?
- Has your company ever been involved in a product recall?

4 Ready for testing in live organisms

STARTER

Here are some opinions about preclinical and clinical trials. Do you agree or disagree?

		Agree	Disagree
1	An open day allows pharmaceutical companies to be more transparent about their animal testing policies.	☐	☐
2	Many people don't realize that animal trials are required by law, before testing in humans can take place.	☐	☐
3	Test animals often have better conditions than farm animals.	☐	☐
4	Participating in clinical trials is a good way to earn some extra money.	☐	☐
5	I wouldn't like to risk my health as a subject in clinical trials.	☐	☐
6	Heavy drinkers are more at risk than subjects in clinical trials.	☐	☐
7	Volunteers make a big contribution to the field of medicine, no matter what their motivation is.	☐	☐
8	If I were seriously ill, I would definitely take part in a clinical study. It could be my last hope!	☐	☐

1 **During an internship at Vine Pharmaceuticals, Miki, a lab technician, is learning about preclinical and clinical testing. She has found some general information on the Internet about requirements before an investigational drug can be tested in human volunteers. Complete the text with words from the box.**

active • administer • development • formulate • purity

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In the preclinical stage of drug development, an investigational drug must be tested extensively in the laboratory. This is to *ensure* it will be safe to _____[1] to humans. Testing at this stage can take from one to five years and must provide information about the pharmaceutical composition of the drug, its safety, and how the drug will be formulated and manufactured.

Preclinical Technology: During the preclinical _____[2] of a drug, laboratory tests document the effect of the investigational drug in living organisms (in vivo), and in cells in a test tube (in vitro).

Chemistry, Manufacturing and Controls (CMC)/Pharmaceutics: The results of preclinical testing are used by experts in pharmaceutical methods to *determine* how to best _____[3] the drug for its intended clinical use. For example, a drug that is intended to act on the sinuses may be formulated as a time-release capsule, or as a nasal spray. Regulatory agencies *require* testing that documents the characteristics – chemical composition, _____[4], quality, and potency – of the drug's _____[5] ingredient, and of the formulated drug.

Pharmacology/Toxicology: Pharmacology is the study of drugs and the body's reaction to drugs. Toxicology is the study of the *potential* risks to the body.

The results of all testing must be provided to the FDA in the United States and/or other appropriate regulatory agencies in other countries in order to *obtain* permission to begin clinical testing in humans. Regulatory agencies review the specific tests and documentation that are required in order to *proceed* to the next stage of development.

2 Use information from the text in exercise 1 to answer the following questions.

a How long can it take to finish the preclinical stage?

_____

b What needs to be documented in laboratory tests?

_____

c What do regulatory agencies require?

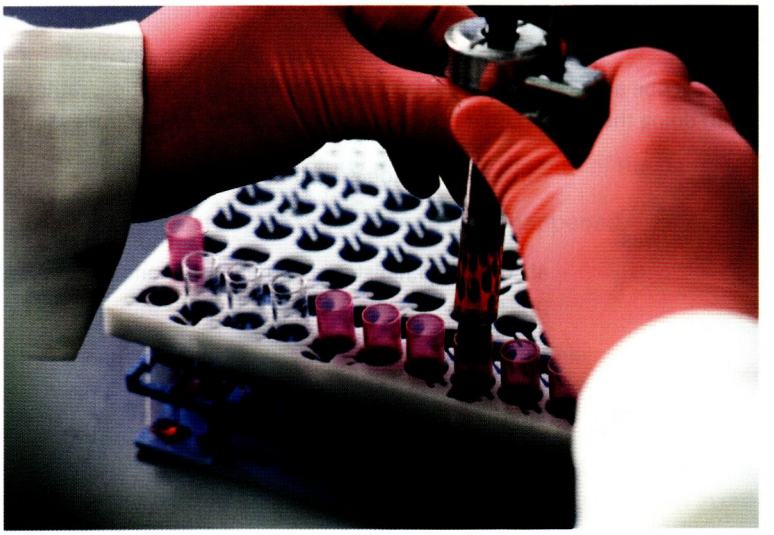
_____

d What is the difference between pharmacological and toxicological studies?

_____

e When can a pharmaceutical company start clinical testing in humans?

_____



3 Find the word in italics in the text on page 40 which means:

a receive, get _____

b demand _____

c make sure _____

d fix conclusively _____

e possible _____

f go on _____

4 Complete the table using a word from the text in exercise 1.

verb		document		intend		inform
noun	permission		administration		formulation	

5 Miki is informing a new trainee about what she has learned regarding a certain investigational drug at Vine Pharmaceuticals. Complete the excerpt using the correct form of the words in exercise 4.

First of all, it is the _____[1] of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give _____[2] to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to _____[3] the active pharmaceutical ingredient into a suitable administration form. We have to _____[4] each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The _____[5] must show that the _____[6] of the investigational drug is safe for our subjects.

AUDIO 10

Now listen and check your answers.

DESCRIBING A PROCESS (PART 1)

The passive is often used to describe a process. We use it because it focuses on the action, rather than on the person or thing (agent) doing the action. Often the agent is unclear, unknown, or irrelevant.

An experiment A trial/study	is/was	carried out/conducted/done/performed.
A drug		absorbed/administered/formulated/manufactured/prescribed/taken.
The data	are/were	provided/transmitted.
A number of experiments Several tests		conducted/done/performed.
The criteria	can must be will	met.
A study		carried out/ conducted/done/performed.

6 Complete the sentences about preclinical development using the correct form of the verbs in the box.

be administered • be conducted • be determined • be formulated • be provided • be used

1 We started the trial after tests on investigational drugs _____ in vivo and in vitro over a period of up to five years.

2 Last year, results of preclinical testing _____ to come up with the best formulation of the intended drug.

3 Extensive documentation must _____ to the appropriate regulatory authorities.

4 A drug intended to act on the skin can _____ as a cream.

5 Potential risks to humans _____ in toxicity studies.

6 The requirements of drug bioavailability determine how it will _____ to humans.

Now describe an SOP or process in your company using the phrases above.

AUDIO 11

7 Miki has been invited to join an impromptu lab meeting about drug substance MPP 010098, which is being tested in dogs. Miki, Linda, an animal caretaker, Jake, a biological lab technician, and their supervisor, Roger, are talking about a problem. Listen to the conversation and decide if the statements below are true (✓), false (✗), or not mentioned (–).

1 Someone told Linda that the dogs were vomiting. ☐

2 Some dogs were not affected negatively by the drug substance. ☐

3 Linda doesn't know if the animals in the control group are affected. ☐

4 Dogs are more sensitive than mini-pigs. ☐

5 The study protocol will have to be changed. ☐

6 Roger will contact the study director by the end of the day. ☐

7 Miki is going to write the report on what happened. ☐

THE INS AND OUTS OF CLINICAL TRIALS

A **chemistry lab technician** assists chemists and chemical engineers using chemicals and related products, whereas a **biology lab technician** works with living organisms.

A **control group** in preclinical studies is a group of test animals that is not exposed to the medication under study. In an experiment, this group is treated just like the other animals, but does not receive the active ingredient. This group is then compared with the treated animals in order to validate the results of the test.

Low-dose/mid-dose/high-dose groups are three groups of animals which receive different concentrations of the medication under study.

In preclinical trials, at least **two different animal models** are necessary:
1 Testing is done in rodents (e.g. mice, rats, but also rabbits, and/or guinea pigs).
2 Testing is then carried out in animals which have systems more similar to humans, e.g. dogs, mini-pigs, and/or monkeys.

The active ingredient can be tested in humans only after these tests have been successfully completed and authorization has been given.

GETTING INFORMATION AND MAKING SUGGESTIONS

Asking for and clarifying information	Making suggestions	Responding to suggestions
Could somebody fill me in on ... ? I'd like to know what has happened. Does that mean ... ? I have heard ... . Is that correct?	I suggest making ... I suggest we take ... We could consider trying ... So, we'd better test ...	I'll let you know what we come up with. I'm not sure I agree with you on that.

8 Unscramble the words. Make questions or sentences to ask for and clarify information, make suggestions, and respond to suggestions. Note that each time there is one word you do not need.

1 fill in me Could somebody is what on the problem there's please ?

2 correct does it the dogs Is responding that aren't to the drug

3 need to figure we which animal group First, out is receiving what concentration

4 could We consider testing group without another animals of

5 would know to prefer mini-pigs I use dogs instead of Personally,

6 later know we come with I'll trials let up you what

7 we put have the would to I change study protocol imagine

9 Choose one of the situations below, or think of one at your company. Then follow the flowchart to discuss this subject with a partner. Use the Useful Phrases above.

Situations: – The amendment to a study protocol has not been signed.
– The body weight of the animals has not been filled out for Day 3.
– All the mice in the study have started scratching themselves.

Partner A		Partner B
Ask what is wrong	→	Explain
Ask for clarification	→	Give details and suggest a solution
Reject the solution OR Agree and summarize		

10 **Roger needs to write the required amendment. Here are Linda's notes, which sum up the points in the meeting. Read her notes, and match the sentence halves to make a summary of the meeting.**

Notes

The general health of the dogs was regularly checked. In addition, the overall appearance and behaviour of each animal was assessed twice a day. On Day 2, however, abnormalities regarding food consumption were observed shortly after administration in the high-dose group. The dogs' food consumption was lower, whereas their water consumption was higher. The dogs started retching and vomiting and were separated to allow closer observation. No other clinical symptoms were observed, though.
In comparison with the high-dose groups, animals in the low-dose and mid-dose groups showed no clinical symptoms at all.

1	☐ The animals that showed clinical symptoms	a	were checked twice a day.
2	☐ Clinical symptoms in the high-dose group	b	were separated to be watched more intensively.
3	☐ The general health and behaviour of the dogs	c	were found in the low- and mid-dose groups.
4	☐ No major clinical symptoms	d	were discovered soon after administration.

Now write a short summary of the situation you discussed in exercise 9.

LINKING IDEAS

Certain words are added to make additional points, or to compare or contrast ideas.

Adding a relevant point	**Making a comparison or a contrast**
In addition,/Additionally, ...	... , whereas ...
... not only... , but also ...	... , while
Besides, ...	... (even) though
Furthermore, ...	However, .../But ...

11 **Underline the linking words and phrases in Linda's notes in exercise 10.**

12 Use the word or phrase in brackets to link the two ideas. In some cases you will still have two sentences.

1 There were no clinical findings in the mid-dose group. The high-dose-group animals showed clinical symptoms. (while)

2 The pulse rate was increased. The blood pressure was high. (not only ... but also)

3 There were no clinical findings in the oral administration studies. There were clinical findings in the intravenous-dose studies. (however)

4 Mini-pigs are easy to handle. Rhesus monkeys are difficult to work with. (whereas)

5 The drug was well tolerated by rats. It did not have any effect on blood pressure. (furthermore)

13 After getting a close insight into preclinical testing, Miki would like to know what comes next, and asks a colleague for help. She gets the following email.

From: jill.sanders@VinePharmaceuticals.com
To: miki.takashi@VinePharmaceuticals.com
Re: Phases in Clinical Testing

Dear Miki
At lunch yesterday you asked me to send you some general information on clinical trials. Here is a rough summary that might be useful.

Phase I Trials: These are studies which are performed to evaluate the safety of drugs in healthy people, and to determine the pharmacological properties of drugs. They are done to find out how the drug reacts in the body. Toxicity, metabolism, absorption, and excretion are observed and documented.

Phase II Trials: These are controlled studies conducted to evaluate the effectiveness of the drug in a particular indication and to determine possible side effects and risks. These studies are performed on volunteers and a number of patients with the target disease or disorder. In this phase, testing determines the safety and efficacy of the drug in treating the condition and establishes the minimum and maximum effective dose.

Phase III Trials: After gaining evidence that the drug is effective, these controlled and uncontrolled trials are carried out to obtain additional information to evaluate the overall benefit–risk relationship of the drug. In this phase, a large group of patients is studied and closely monitored by physicians for efficacy and any adverse events after long-term exposure to the drug.

Phase IV Trials: These are post-marketing studies after getting approval for general sale. They are carried out in order to gather further information about the drug's safety, efficacy, and optimal use.

Hope this helps. Call me if you need anything else.

Best wishes
Jill

Which phase does each description belongs to?

1 Phase _____ is performed after there is preliminary evidence that the drug is effective.

2 In phase _____, the lowest and highest doses are determined.

3 Phase _____ is the first phase in which patients with the target disease or disorder take part.

4 In phase _____, further information regarding the ideal use of the drug is collected.

5 Phase _____ is the final phase before getting marketing approval.

INSIDE CLINICAL TRIALS

An adverse event is any abnormal medical occurrence in a patient or clinical trial subject after a medicinal product has been administered. It does not necessarily have a causal relationship with the medicinal product.

Adverse reaction refers to all abnormal and unintended responses to an investigational medicinal product related to any dose administered.

In a **controlled study**, one group of test subjects is exposed to the substance, while the control group is not. Test subjects in the treatment group receive the medication under study, whereas the control group receives either a standard medication or a placebo. The results are then compared to determine the health effects of the substance being studied. **Uncontrolled clinical trials** do not have a comparison group.

AUDIO 12

14 The clinical trials for RFI 100089 were successful and the documents can be submitted. For this reason, Vine Pharmaceuticals has arranged a mock inspection to prepare for an upcoming visit by the regulatory authorities. Listen to part of the inspection and circle the correct ending to the sentences below.

1 The inspector wants to look at
   a an instruction manual.
   b the detailed data gathered during the clinical trial.

2 The inspector
   a did not accept the documentation about the change in temperature.
   b considered the incorrect change to the documentation to be minor.

3 In order to solve the problem
   a the temperature was increased.
   b the temperature was decreased.

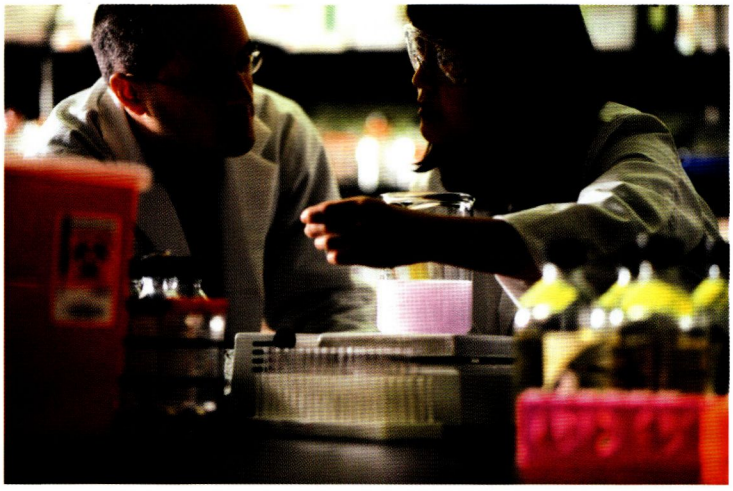
REQUESTING INFORMATION AND RESPONDING DIRECTLY

Giving information at inspections
Here are the documents you requested.
I'll get it immediately.
You can find this on page three.
The change is crossed out, initialled, and dated.
Let me explain in more detail ...
I can give you more specific information on ...

Explaining and justifying decisions
Let me demonstrate ...
We had no alternative but to ...
I assure you ...
You can rest assured that we will ...
That led to ...
This way, you can/will avoid ...

15 Who would say this during an inspection, the expert (E) or the inspector (I)?

1 I'll send for that immediately. ☐
2 How do you account for the change? ☐
3 You can rest assured that this won't happen again. ☐
4 If you check page six you'll find it at the bottom of the page. ☐
5 It was initialled and dated by Dr Svenson. ☐
6 Where can I find the change that was made? ☐



16 Find a phrase in the dialogue in exercise 14 which means:

1 Have a look at ... _____
2 What's your explanation for ...? _____
3 I assure you ... _____
4 We have made a change due to ... _____
5 Do I understand correctly? You want me to ... _____
6 This is how you stop ... _____

Richard Thompson, the expert responsible for the project, is hosting Paul Williams, a consultant, for a mock inspection. Work with a partner and role-play the inspection.

Paul Williams	Richard Thompson
Ask for current study protocol	Hand over document
Ask about documentation of a change	Say where to find it
Refer to a mistake in documentation	
Warn about possible problems with authorities	Accept warning
Ask for explanation of the change	Double-check request
Confirm	Explain the change
Show satisfaction with explanation	
Move on to next subject	

18 The following words are often confused. Put the correct one into the sentences. If necessary, look back in the unit. At least one word of each pair has been used in this unit.

illness/disease

1 There is a history of lung _____ in the family.

2 He missed five days of work because of _____.

sensitive/sensible

3 Dogs are more _____ to drugs than mini-pigs.

4 It was a _____ decision to cancel the trial.

affect/effect

5 I felt the _____ of the new ointment right away.

6 The active ingredient currently being tested seems to _____ the kidneys.

shortly/briefly

7 The adverse event occurred _____ after the injection.

8 The trial director spoke _____ to his staff about the current status of the trial.

19 Work with a partner. Read out the definitions in your Partner File, but do not read out the term in bold. Can your partner give you the correct term?

PARTNER FILES Partner A File 4, p. 77 Partner B File 4, p. 79

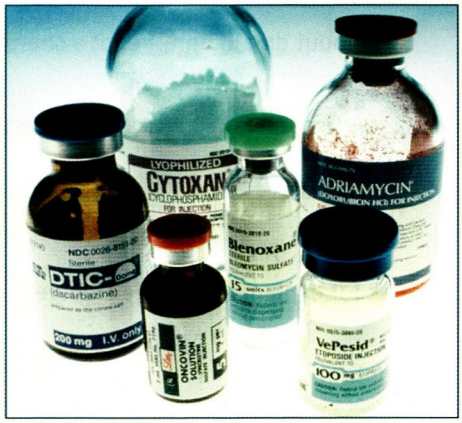
OUTPUT **Read the following newspaper article.**

Experimental Drugs on Trial

The parents of a 21-year-old woman challenged the FDA. They took the authority to court after their daughter had died of cancer. The parents firmly believe that their daughter might have had a chance of surviving if she had been given access to a potentially life-saving experimental cancer drug that her doctor had recommended.

Many terminally ill people fall victim to the 'therapeutic misconception' that the objective of trials is to cure them. In truth, clinical trials are mainly aimed at answering scientific questions. In general, their goal is to gather statistics to determine whether an experimental drug is safe and effective.

On the whole, subjects in a trial must be willing to be randomly assigned to either the group which receives the unapproved medication or the one which gets a placebo. This is the only way to make sure clinical trials serve a scientific purpose. Subjects also have to be aware that the pharmaceutical company which is sponsoring the clinical trial can stop the trial at any time.



Do terminally ill patients have the legal right to try to prolong their lives by taking experimental drugs? The FDA has a clear position on this subject. It maintains that it would be difficult to find a sufficient number of patients to participate in clinical trials if it were possible to obtain the drug without actually being a subject in a trial. The safety and efficacy of a drug can only be determined by conducting rigorous clinical trials, according to the FDA.

OVER TO YOU

- Is it ethically justifiable to deny terminally ill patients access to potentially life-saving, experimental drugs and medicine?
- Would easier access to experimental drugs have an effect on obtaining reliable data on the safety and efficacy of the drugs?
- What can authorities do to provide terminally ill patients with drugs that could help them?

5 Drug safety and regulatory affairs

STARTER

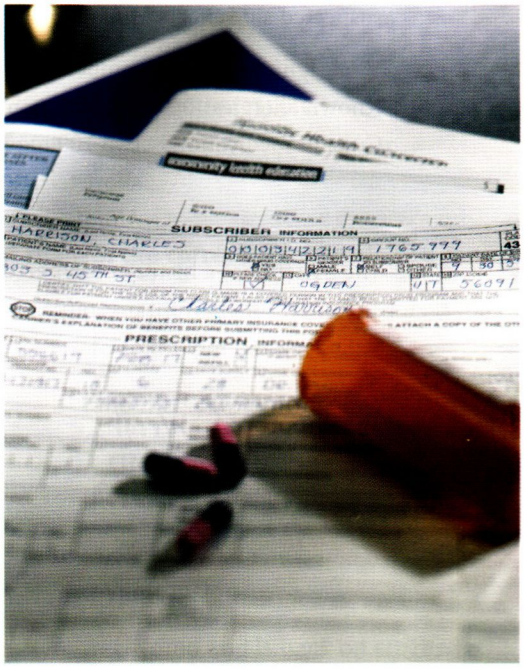
Tick the department which is responsible for each of the following tasks:

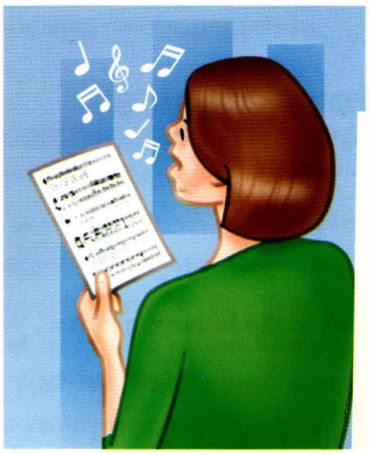
		Drug Safety	Regulatory Affairs
1	Reporting an adverse drug reaction to health authorities.	☐	☐
2	Submitting documents needed to obtain marketing approval for a drug.	☐	☐
3	Monitoring and evaluating suspected side effects.	☐	☐
4	Responding to a physician's report.	☐	☐
5	Compiling dossiers for submission to authorities.	☐	☐
6	Writing the drug information for the patient.	☐	☐

Why do healthcare professionals and pharmaceutical companies keep records of unexpected reactions to drugs?
How much should patients know about possible side effects before taking medication? Why?

WHAT IS PHARMACOVIGILANCE?

The Greek word 'pharmaco' (medicine) and the Latin term 'vigilantia' (watchfulness) were put together to form the word *pharmacovigilance*. Government agencies, pharmaceutical companies, and healthcare professionals work together to monitor and evaluate suspected side effects of medicines to improve the safety of drugs in use.





ADDITIONAL EFFECTS OF TAKING DRUGS

Side effect – any unintended reaction caused by a drug or medical treatment. This term is used by the general public, but is often avoided by medical authorities.

Adverse event – an unwanted medical occurrence which a patient experiences during treatment. This may or may not be a side effect of a drug.

Serious adverse event (SAE) – an adverse event that threatens life, requires or prolongs hospitalization, or results in death.

1 Read the following report.

Doctor's report:

On 24 Dec 2010, a woman of unknown age, Maria Gallois, fainted after developing a sudden, severe skin **rash** and **inflammation** all over her body.

Ms Gallois, the well-known opera singer, lost consciousness 30 minutes before she had planned to go on stage. She was taken to hospital and regained consciousness an hour later. She reported that she had not had anything to eat except some chocolate four hours before. In addition to small, red, **itching** spots all over her body, she also reported a racing heart, a headache, and **insomnia** after starting on *Mensamint*™ three weeks previously. At the hospital, the patient showed evidence of hyperactivity, accompanied by confusion and agitation. Subsequently, *Mensamint*™ was discontinued, but the symptoms **persisted** until a strong sedative was administered. After 24 hours, all symptoms except for a mild skin **irritation** had subsided and the patient was discharged from hospital. Some symptoms are suspected side effects of *Mensamint*™.

Vital signs:	temperature 100 °F (38.8 °C) and blood pressure 160/110
Known allergies:	peanuts, penicillin
Current medications:	two 100 mg *Mensamint*™ lozenges taken once daily for improved short-term and long-term memory.
	Mimifem oral contraceptive 0.2 mg daily.

The patient has a history of **hypertension**, mild heart **palpitations**, high adrenalin levels, and often suffers from insomnia.

Frederick M. Wright

Frederick M. Wright, MD
Attending Physician

Now answer the following questions.

1 What were the patient's symptoms before she was admitted to hospital?

_____

_____

2 How was she treated by her physician?

_____

_____

3 What was her condition when she was discharged from the hospital?

_____

_____

What evidence points to *Mensamint*™ as the cause of the symptoms?
What evidence suggests that other factors may be responsible for the symptoms?

2 Match the following symptoms in bold in the doctor's report with their definitions.

1	☐ hypertension	a	sleeplessness
2	☐ rash	b	general discomfort, bad feeling
3	☐ palpitation	c	red, warm, and swollen
4	☐ insomnia	d	you feel like you want to scratch
5	☐ inflammation	e	heart racing
6	☐ itching	f	high blood pressure
7	☐ irritation	g	a lot of spots on the skin

3 Connect the following sentence halves. Then put them in the correct order to make a case report.

1	☐ A report received from the patient's sister	a	the attending physician reduced the dosage to 10 mg per day.
2	☐ After having taken *Mensamint*™, the patient experienced	b	and the symptoms cannot be ruled out.
3	☐ A correlation between *Mensamint*™	c	headaches and insomnia.
4	☐ The patient has now completely	d	indicated that she had a history of hypertension.
5	☐ After examining the patient,	e	recovered and is back on stage.

Correct order: __ __ __ __ __

REPORTING SEVERE ADVERSE EVENTS TO HEALTH AUTHORITIES

Pharmaceutical companies use details from doctors' reports to inform the authorities in a case report.

Patient history

The patient has a history of ...
A report was received from the physician indicating that ...
Before the event, the patient was on the following medication: ...

Description of adverse event

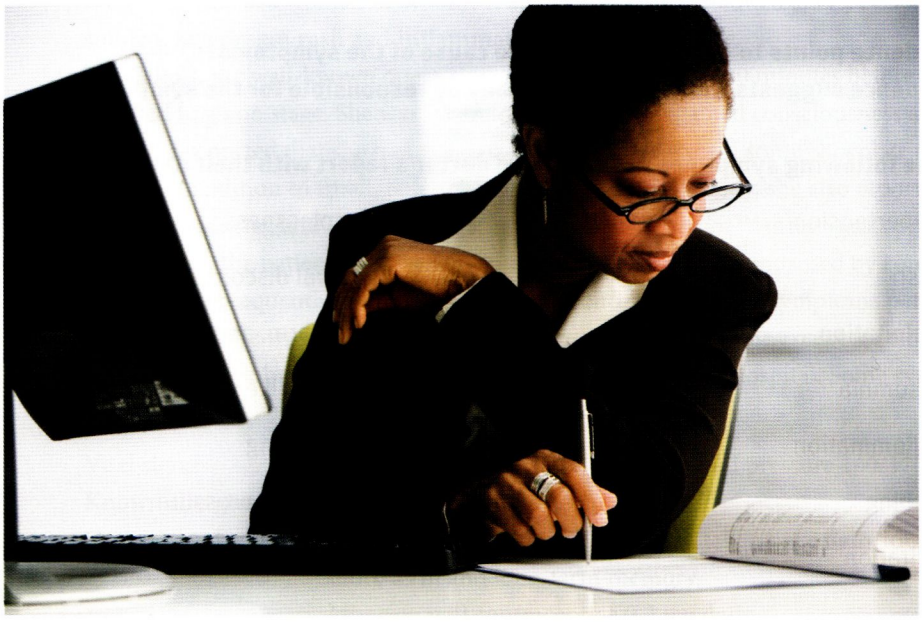
After examining the patient, the physician ...
After taking (drug), the patient experienced ...
At the time of the report, the patient's condition was/remained unchanged.
At the time of the report, the patient was recovering/had completely recovered.
This event led to the patient's death.

Drug information

... are known/suspected side effects of this drug.
(Drug) was administered for (condition).
Eye drops were instilled.
A bandage/cream/lotion/ointment was applied (to the skin).

Assessment of adverse event

(Drug) is (not) believed to be related to the event.
An interaction between (drug x) and (drug y) was suspected.
A correlation between (drug) and (symptom) can/cannot be ruled out.



4 Pharmaceutical companies have to submit a Safety Information and Adverse Event Report to the FDA and to the local authorities immediately. The medical director of your company asks you to complete the form based on the doctor's report on page 52. Complete section B. 5 of the FDA form using the phrases below.

a a history of
b a report was received
c after examining the patient
d all symptoms had subsided
e be ruled out
f was concomitantly taking
g correlation between
h showed evidence of
i suspected side effects
j the patient reported
k vital signs

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
Maria G In confidence	unknown	☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☒ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/24/2...	12/26/2...

5. Describe Event, Problem or Product Use Error

2. Dose or Amount	Frequency	Route
#1 2 x 100 mg	once a day	Lozenges
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 started medication 3 weeks
#2 prior to SAE

4. Diagnosis or Reason for Use *(Indication)*
#1 memory enhancement
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 12345678	#1 June 2...	unknown
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

---

5. Describe Event, Problem or Product Use Error

____[1] from a physician indicating that a woman had fainted after developing a sudden, severe skin rash and inflammation all over her body. She was taken to hospital and regained consciousness 30 minutes later. ____[2] not having had anything to eat but a chocolate candy bar 4 hours beforehand. In addition to small, red, itching spots all over her body, she also reported suffering from mild heart palpitations, headaches, and insomnia after starting on *Mensamint*™ three weeks previously. The patient ____[3] the following medication: *Mimifem* oral contraceptive pill 0.2 mg daily. As to her emotional state after hospital admission, the patient ____[4] hyperactivity, accompanied by confusion and a feeling of agitation. ____[5], the attending physician discontinued *Mensamint*™ and administered a strong sedative. After 24 hours, ____[6] except for a mild skin irritation and the patient was released from hospital. Symptoms are ____[7] of *Mensamint*™, although a ____[8] her peanut allergy, *Mensamint*™ and this event cannot ____[9].

____[10]: temperature 100 °F (38.8 °C); blood pressure 150/110.

Known allergies: peanuts, penicillin.

The patient has ____[11] hypertension, heart trouble, and insomnia.

---

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

- allergy to peanuts
- heart palpitations
- headaches
- insomnia

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Name: Mensamint
Strength:
Manufacturer:
#2 Name:
Strength:
Manufacturer:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
Mimifem - dates unknown

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: CARDUCEUS PHARMACEUTICALS
Address: Mecklenburgische Straße 53
City: Berlin State: ZIP: 14197

Phone #	E-mail
0049-30-89785807	

2. Health Professional?	3. Occupation	4. Also Reported to:
☒ Yes ☐ No	PV Officer	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

HEALTH AUTHORITIES AND USEFUL TERMS

The names of health authorities and other terms used in pharmacovigilance are often shortened. Here are some typical examples:

EMEA European Medicines Agency (EU)
FDA Food and Drug Administration (US)
MHRA Medicines and Healthcare Products Regulatory Agency (UK)

PSUR Periodic Safety Update Report
SAE Serious Adverse Event
QPPV Qualified Person Responsible for Pharmacovigilance

5 The FDA form has been submitted to the authorities. A meeting with the Chief Executive Officer (CEO), the Medical Director, and the Regulatory Affairs Manager is planned to discuss this SAE. Tick the topics which you think they will discuss at the meeting.

- ☐ approval process
- ☐ clinical trial
- ☐ doctor's report
- ☐ last audit report
- ☐ Quality Assurance
- ☐ SOPs

AUDIO 13

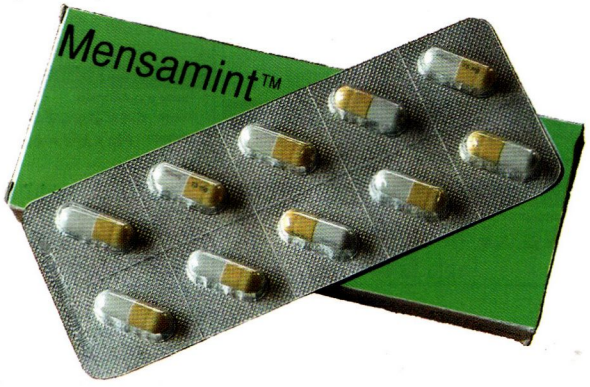
6 Now listen to the meeting in which Karl (CEO), Fred (Head of Regulatory Affairs), and Caroline (Head of Pharmacovigilance) discuss the SAE and its implications for the company. Are the following statements true (✓) or false (✗)?

1 ☐ There are two dosage forms of *Mensamint*™ currently on the market.

2 ☐ The serious adverse event is clearly linked to *Mensamint*™.

3 ☐ The documentation for the new dosage form of *Mensamint*™ will be submitted to the authorities soon.

4 ☐ Heart trouble is a known side effect of *Mensamint*™.



DISCUSSING CAUSES OF SAES	ASKING ABOUT IMPLICATIONS FOR A DRUG
It could have been due to ...	How did the clinical trials go?
It is due to pre-existing conditions.	What is the status of approval?
The evidence is conclusive/inconclusive.	How far is it from approval?
A reaction to the product cannot be ruled out.	Could it jeopardize other products?
	What does it mean for the products in the pipeline?

7 Rewrite the following statements and questions using the Useful Phrases above.

1 It resulted from an old illness.

2 Will it cause problems for other products?

3 Maybe the side effect was a result of taking this product.

4 How soon will we get permission to put the product on the market?

5 Were the clinical trials successful?

6 The facts neither prove nor disprove this.

7 How will this affect other products which are not yet on the market?

8 This product may or may not have caused the reaction.

8 In order to get approval to sell a new drug, a company has to compile detailed documentation with all the information required by the drug authorities. Match the following sections with their descriptions.

1 ☐ Administrative Data

2 ☐ Common Technical Document Summaries

3 ☐ Quality

4 ☐ Non-clinical Study Reports

5 ☐ Clinical Study Reports

a biological, chemical, and pharmaceutical documentation with manufacture, quality control, and testing data

b overviews of quality, clinical, and non-clinical data

c documentation about clinical trials and post-marketing information

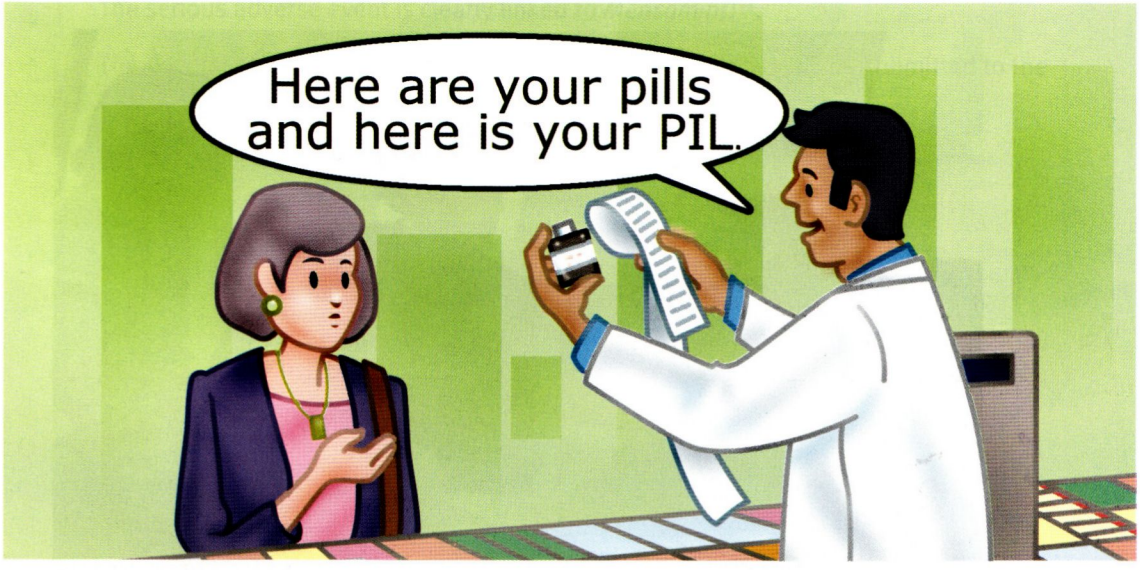
d general information, such as the marketing authorization application form, as well as product characteristics and labelling

e study reports, pharmacology, pharmacokinetics, toxicology, and references

PIL VS. PILL

Important information for any person taking a drug can be found in the 'PIL' or patient information leaflet. Such information is also called the patient leaflet, patient packet, or package insert. In the US, it is also referred to as a patient information sheet (PIS), or medication guide.

Note: When you talk about PILs, say each letter. If not, it might be confused with 'pills'.



9 Read the email from the Head of Regulatory Affairs and answer the questions below.

From: Fred Crow, Head of Regulatory Affairs
To: Regulatory Affairs staff, especially medical writers
Re: Recent audit, readability, and warnings

Dear RA staff

I just wanted to give you a brief update on the self-inspection conducted last week by QA. Most of the results were very positive. It seems our documentation is of a high standard, especially with respect to completeness and technical details. However, in terms of readability, we can still make some improvements in future patient information leaflets. We need to remember that not only healthcare professionals read these PILs, but also patients.

In addition, I have noticed something which, I think, some of you can improve on. It has to do with drug warnings. Yes, we do need to let patients know of any possible side effects. But, no, it is not necessary to alarm them unnecessarily. In other words, in future when describing possible side effects for products in the pipeline, we will need to differentiate more clearly between frequent and rare risks. In the case of the latter, we will need to be less direct in order to increase patient compliance.

Let's talk about these two points at our department meeting on Friday. I will also be asking Wendy, our senior medical writer, to coach junior staff members.

Best regards
Fred

1 What are the strong points in this department's documentation?

_____

2 How could it improve its documentation?

_____

3 What effect could a change in the style of language have on patients?

_____

AUDIO 14

10 Wendy, the senior medical writer in the Regulatory Affairs department, is training Mark, a junior staff member. Both write and translate patient information leaflets. Listen to the dialogue and add the following headings to the PIL for *Mensamint*™.

Before you take this product • Further information • How to store • How to take/use • Read this leaflet carefully because it contains information you need to know • Possible side effects • What the product is, and what it is used for

PATIENT INFORMATION LEAFLET

MENSAMINT™

1 _____

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor, pharmacist, or healthcare professional. This medicine has been prescribed for you personally. Do not pass it on to others, even if their symptoms are similar to yours.

2 _____

Mensamint™ is a lozenge to support increased concentration. Regular use can lead to a marked improvement of both short-term and long-term memory and logical thinking skills. The active substance is mensagitatum. Other ingredients are peppermint, oil, sugar, talcum, and a preservative.

3 _____

Do not take *Mensamint*™ if you are allergic to peanuts.
If you have a history of heart trouble, consult your doctor before taking.

4 _____

Take two lozenges a day, mornings and early afternoons.

5 _____

Some patients may experience loss of sleep if the lozenges are taken too late in the day.

6 _____

Store below 25 °C in a dry place.

7 _____

Caduceus Pharmaceuticals
154 Freshfield Street
Milton Keynes

GIVING GENERAL ADVICE	GIVING STRONG WARNINGS
Mensamint™ may cause dizziness.	*Do not* use/take *Mensamint™* if ...
Mensamint™ can interact with other medicines.	*Stop use* and ask a doctor if ...
Like all drugs, this medicine can cause side effects.	*Keep out of reach* of children.
Use Mensamint™ with caution while driving or undertaking dangerous activities.	*Tell your doctor* immediately/right away if ...
It is possible that you may receive this medicine, or an alternative may be used.	You *must not* drive while taking this drug.
	You *should not* take *Mensamint™* if you have a history of ...

11 **Here is some information from the PIL for a new drug called *Pogolox™*. Match the following sentences halves used in the leaflet.**

1	*Pogolox™* may cause	a	are allergic to any antibiotics.
2	Tell your doctor right away if	b	your temperature continues to rise.
3	You must not	c	operate machinery while taking this drug.
4	Do not take *Pogolox™* if you	d	this medicine can cause diarrhoea.
5	Stop use of *Pogolox™* immediately	e	serious liver damage.
6	Like all antibiotics,	f	if you experience any chest pain.

12 **Choose a medicine you know. Write some general advice (GA) and some strong warnings (SW). Mark each sentence either GA or SW.**

1 ☐ _____

2 ☐ _____

3 ☐ _____

4 ☐ _____

5 ☐ _____

6 ☐ _____

7 ☐ _____

13 **A patient speaks to a drug safety specialist about current symptoms possibly related to a drug.**

Partner A File 5, p. 77
Partner B File 5, p. 79

Write up a report on the above adverse event. Use the doctor's report on page 55 as a model.

OUTPUT **Read the following newspaper article.**

Fatal fakes – counterfeit medicines

Imagine that it is your job to monitor drug safety. One day a report with a very unusual adverse event lands on your desk. It has to do with one of your well-established blockbuster drugs. Such an event has never happened to either test subjects in clinical trials or to any patients recorded in post-marketing surveillance. Of course, you investigate this occurrence by looking for similar side effects in the documentation and report it to the authorities. Still, nothing even vaguely similar can be found for either the API (active pharmaceutical ingredient) or any of the excipients. The patient's reaction to this prescription drug does not even make medical sense, given the chemicals involved.

Just a freak reaction? Perhaps. Or maybe it has nothing to do with your medicine. It has the same packaging, same colour coating, same bitter aftertaste, but not the same ingredients inside the pill. Is this a fake drug?

Fake drugs may contain

- a worthless placebo
- a lower concentration of the same active ingredient
- a similar, but different substance
- a totally different, potentially dangerous substance.

With the advent of online pharmacies, open borders and uncontrolled chemical laboratories all over the world, the number of counterfeit drugs is on the rise, not only in developing but also in industrialized countries. This lucrative, organized 'pharmaceutical crime' poses a substantial threat to public health. For this reason, some countries are passing stricter regulations and implementing tagging systems to help trace the sources. They are also developing better chemical analysis equipment to quickly determine tablet content. There is also a danger that fake pharmacopeias (the pharmacist's 'bible') with incorrect information could be used. Therefore, in Europe, for example, steps have been taken to use holograms to prove a pharmacopeia's authenticity.

Despite more international co-operation in the fight to stop counterfeit drugs, some countries have unfortunately not taken action. They are still treating this problem as if it were about imitation designer bags, fake watches, or alligators on T-shirts.

OVER TO YOU

- In your opinion, how high is the risk of counterfeit prescription drugs?
- Who should try to stop such criminal activity? The industry? The government?
- Should online pharmacies be banned, or more tightly regulated?
- Are drugs in your company also tested for authenticity in the case of adverse events?

6 Production and packaging

STARTER

Which of these signs would you expect to find when you visit a pharmaceutical company? Do you know what they mean?





AUDIO 15

1 A self-help group for cardiac diseases is visiting RRB Pharmaceuticals. Henry Naylor, a representative from Public Relations (PR), welcomes them. Listen and answer the questions.

1 What did RRB produce originally?

_____

2 What are the visitors not allowed to do?

_____

3 What do they have to do?

_____

4 When can the visitors ask their questions?

_____

EXPRESSING MOMENTS IN TIME

Past
When the company was founded, it only sold one product.
In the past we produced everything ourselves.

Present
Nowadays/Today many of our products are produced ...
Meanwhile, .../In the meantime, ...

Specifying particular moments
While watching the film, ...
During the tour, ...

Putting events in order
After the meeting has finished, we will ...
Once you have seen the company, you will ...
By the time we met them, the company had ...

2 Underline the most suitable expression to complete the sentences.

1 In the past, / In the meantime, requirements have reached a very high standard.
2 When it was founded, / Nowadays, the company only had one production site.
3 In the meantime, / When it was opened, they have developed a number of well-known products.
4 While / During you are waiting, you can look at these brochures.
5 In the past, / Meanwhile, our company is one of the ten largest drug companies in Europe.
6 By the time / During the safety film, I will give you more detailed information on the company.
7 Once / While the tour is finished, you will have seen the most important production areas.

Now talk about your company and job. Use as many of the Useful Phrases above as possible.

3 Put the words into the correct order to make sentences.

1 effervescent company to The used powder only produce

_____

2 and process uncomplicated simple The be production to used

_____

3 documented use clothing The didn't be specifications to

_____

4 regulations strict to company's The safety be didn't so use

_____

5 inspections didn't so authorities be There use many by to

_____

4 Now look at these signs. Match them to the terms below.

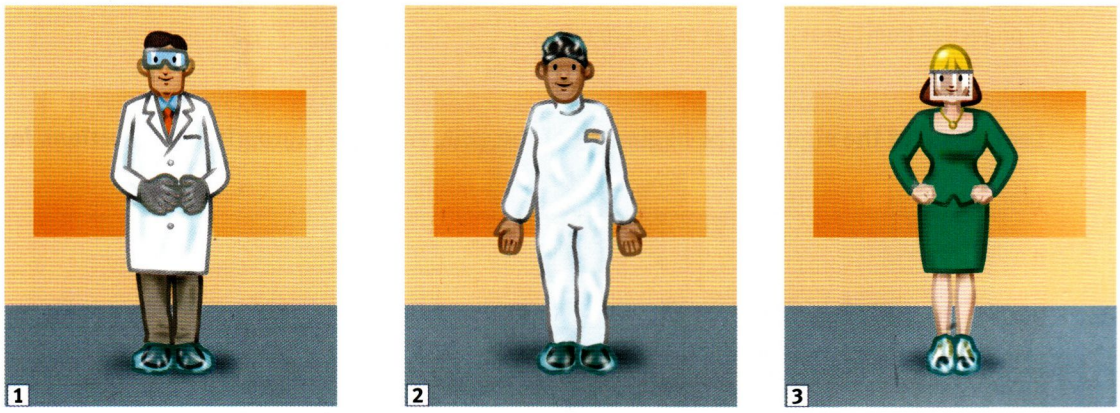
1	_____	face mask ☐	5	_____	overshoes ☐
2	_____	hair covering ☐	6	_____	protective shoes ☐
3	_____	lab coat ☐	7	_____	rubber gloves ☐
4	_____	overalls ☐	8	_____	safety goggles ☐

Do you or others at your company have to wear any protective clothing? Why?

AUDIO 16

5 Listen to Stephanie Baker take the self-help group on a tour of the production facilities. Tick the protective clothing items mentioned in the list above.

6 Which diagram shows the person dressed correctly, according to Stephanie's instructions?



GIVING INSTRUCTIONS

If you give instructions in a very direct way, it may sound impolite. Therefore, it is important to watch your tone of voice, and how you phrase your instructions.

Note that when you tell people to do something mandatory, if you add a simple 'please', it makes your instructions sound much nicer.
e.g. *Please remember that the overshoes are only allowed to touch the white area.*

Note that 'mustn't' means that you are *not* allowed to do something.
e.g. *There mustn't be more than three people in the gowning room at a time.*

Polite instructions

Could you please ... ?	Please remember/Don't forget ...
Would you please ... ?	Please keep in mind ...
Please make sure that ...	I/We need you to ...

AUDIO 17

7 Listen to the instructions. Are they polite ☺, or impolite ☹? Tick the correct answer.

1	☺ ☐	☹ ☐	4	☺ ☐	☹ ☐
2	☺ ☐	☹ ☐	5	☺ ☐	☹ ☐
3	☺ ☐	☹ ☐			

Rewrite the impolite sentences in a polite way. Practise saying the sentences politely.

1 _____

2 _____

3 _____

Listen to the tour again. What should Stephanie do differently?

SAFETY VS. SECURITY

Safety is the freedom from danger or harm, whereas security is the protection from threats, such as attacks or crime.

8 Look again at the signs at the beginning of the unit, and give appropriate instructions for them.

1 _____

2 _____

3 _____

4 _____

5 _____

Now look at these signs. Give appropriate instructions for each one.

1 

2 

3 

4 

5 

1 _____

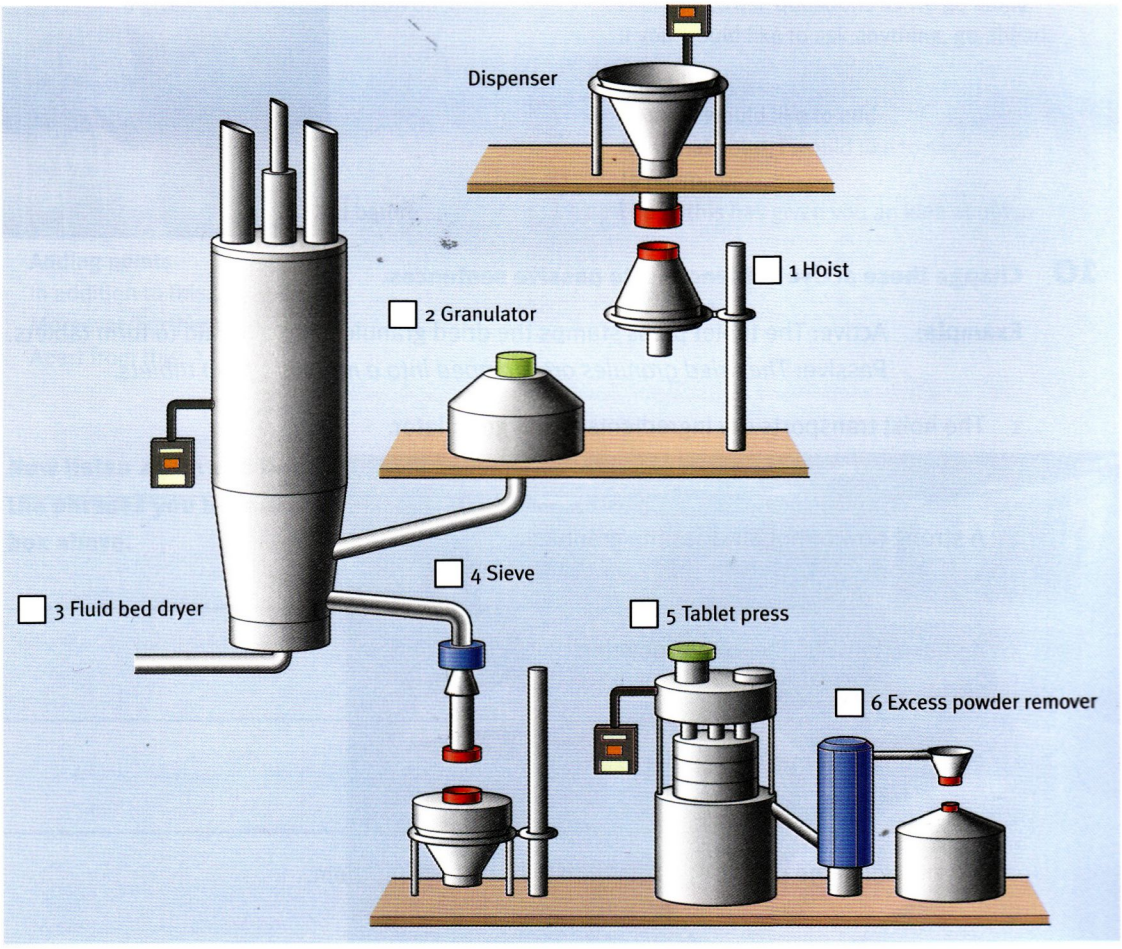
2 _____

3 _____

4 _____

5 _____

9 The group moves on to see the tablet production unit at RRB. Look at the diagram below.



Read the description of the production process, and number the steps according to the diagram.

A ☐ As the tablets go up a spiral, they are shaken, and the excess powder is vacuumed off. The pressed tablets are put into a drum and stored until it is time to coat them.
B ☐ In the granulator, the ingredients are mixed to create a wet mixture.
C ☐ The wet granules are pressed through a sieve on their way to the fluid bed dryer.
D ☐ The granules are air-dried.
E ☐ The dried granules are stamped into a mould to form tablets.
F ☐ Dry ingredients are weighed and transported to the granulator by the hoist.

DESCRIBING A PROCESS (PART 2)

The passive can also be used when the agent is known or relevant.
For this, *by + agent* is added.

The moisture	is	removed	by the hot air in the fluid bed dryer.
The granules	are	transported	by the hoist.

10 Change these active sentences into passive sentences.

Example: Active: The tablet press stamps the dried granules into a mould to form tablets.
Passive: *The dried granules are stamped into a mould to form tablets.*

1 The hoist transports dry ingredients to the granulator.

_____

2 A strong flow of hot air dries the granules.

_____

3 A shaker loosens the excess powder.

_____

4 A vacuum system sucks up the excess powder.

_____

5 A drum holds the pressed tablets until it is time to coat them.

_____

AUDIO 18

11 **After the tour of the tablet production area, the visitors are given a presentation on some different aspects of the pharmaceutical industry. Listen to part of the presentation Henry Naylor is giving to the self-help group on one aspect of compliance. Decide whether the statements are true (✓) or false (✗).**

1 ☐ Henry wants the visitors to ask their questions at the end of his presentation.

2 ☐ Pharmaceutical companies have to comply with GMP guidelines.

3 ☐ The different colour zones on the floors indicate the separation of certain functions.

4 ☐ Authorities sometimes come unannounced.

5 ☐ Production equipment does not need to be validated until it is taken into operation.

GIVING PRESENTATIONS

Welcoming the audience
Good morning/afternoon, ladies and gentlemen. ☐
I'm happy to welcome you to our company. ☐

Introducing your topic
Let me give you a brief overview of ... ☐
I'm here to give you some information on ... ☐
Today, I'll be talking about ... ☐

Signposting
Moving on to the next point, ... ☐
As I mentioned earlier, ... ☐
Coming back to ... ☐
Let me come back to what I said before ... ☐

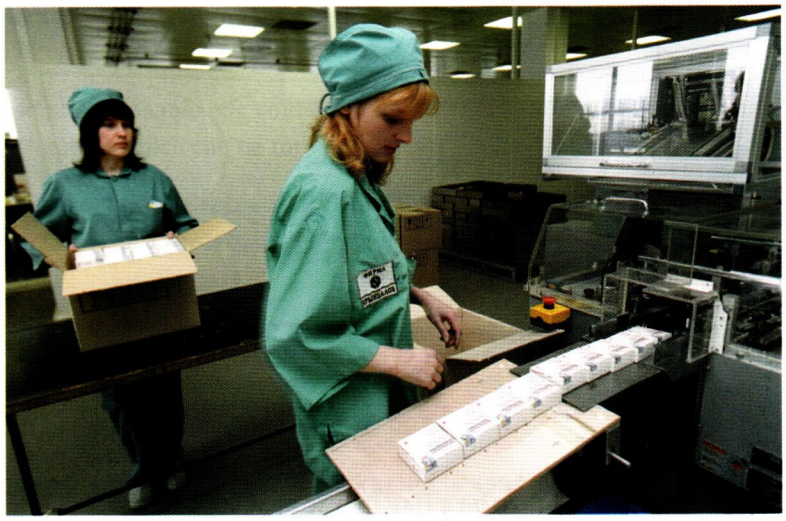
Adding points
In addition to this, ... ☐
Moreover/Furthermore, ... ☐
Apart from this, ... ☐

Dealing with interruptions
Could I please finish what I was saying? ☐
If I could just finish what I was saying ... ☐

Dealing with questions
There will be time for questions after my talk. ☐
Feel free to ask questions as we go along. ☐
If you would like to ask anything, go ahead. ☐

Finishing
Finally, I would like to add ... ☐
As a final point, I would like to say ... ☐
To recap, ... ☐
I hope this has given you an idea about ... ☐

12 **Now listen again and tick the phrases you hear in the box above.**



13 **Here are Henry's handwritten notes. Which part of the presentation do they belong to?**

a) Enjoying tour so far?

b) Continue on to packaging

c) Buildings, clothing, training

d) What is GMP?

e) Interrupting OK

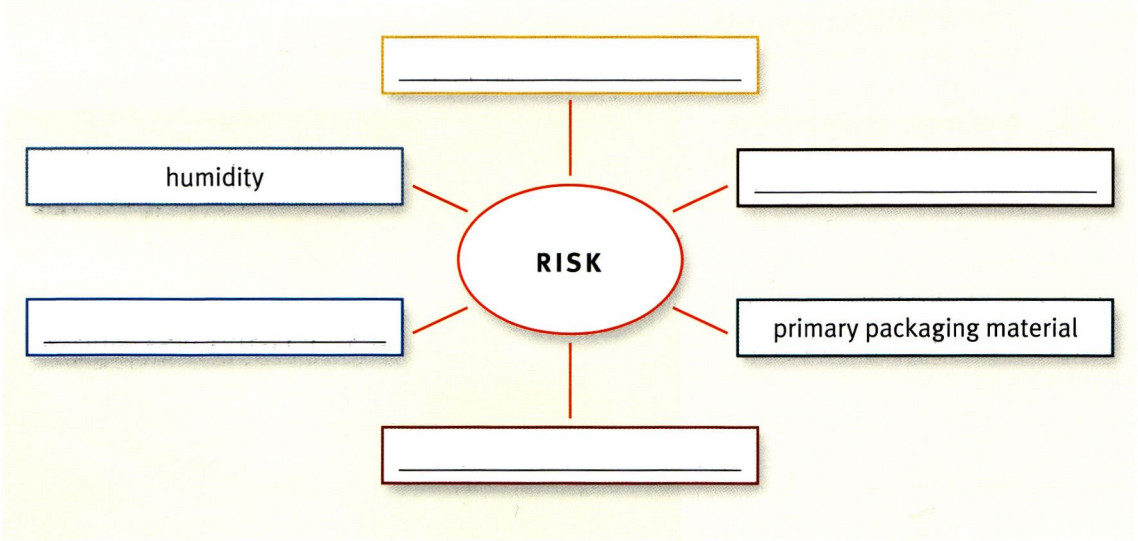
f) Recap

Parts of a presentation: a checklist

1) Welcome and introduction – ☐
2) Handling questions – ☐
3) State the topic – ☐
4) Main body – ☐
5) Summarize – ☐
6) Invite final questions – Open questions?
7) Finish – ☐

14 **Now it's your turn. Choose a topic from any of the previous units, or from your field of expertise, and prepare a short presentation. Use the checklist.**

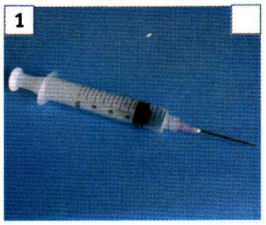
15 **After Henry's presentation, the visitors see the packaging area. He explains that packaging protects the quality of the products during shipping and storage. However, there are always risks involved. Look at the diagram below. What risks would you add?**

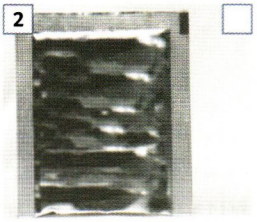


Why would they be a risk for the product quality?

16 Are these primary or secondary packaging materials? Could they be both? Write P for primary, S for secondary, or B for both.

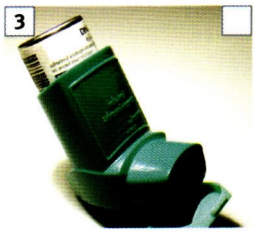
PRIMARY AND SECONDARY PACKAGING

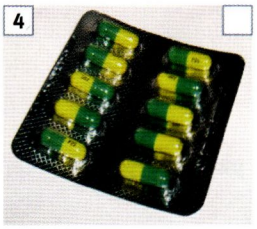


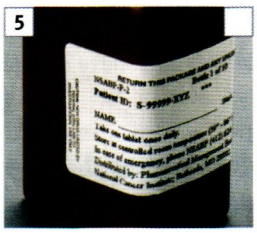


Primary packaging is the material which is in direct contact with the product.

Secondary packaging is any packaging material that is not in direct contact with the product.







17 Match the types of packaging from exercise 16 with their descriptions below.

1 A(n) _____ is an aerosol dispensing device which releases medication into the mouth of the patient. The medication is breathed deeply into the lungs, or stays in the mouth or throat.

2 A(n) _____ is a type of single-use plastic container, and is used for pharmaceutical products as well as for other consumer goods. The product is placed in the formed cavity and sealed by lidding foil. The product is removed by pushing it through the foil.

3 A(n) _____ is a needle attached to a plastic tube used for putting medicine into the body or removing blood.

4 A(n) _____ is a multi-use glass container with a twist-on lid. It can hold pharmaceuticals, or any kind of fluids or solids. It can be opened and closed several times until the contents are used up. Sometimes a desiccant is integrated into the cap so that the contents remain dry.

5 A(n) _____ is a small disposable bag containing an individual dose of the medicine. It often has a lengthwise perforation which can be torn open.

6 A(n) _____ is a piece of paper attached with adhesive to the primary packaging to identify it and give details concerning its ownership, nature, and/or use.

Which primary packaging would you recommend for the following medicine?

cough syrup • nose drops • ointments • suppositories • tablets

What products does your company have? What type of packaging is used?

18 Which of the verbs in the box are used with the following primary packaging forms? Why?

press • push through • remove • tear • twist

1 syringe _ _ _ _ _ _
2 sachet _ _ _ _
3 blister pack _ _ _ _ _ _ _ _ _ _
4 jar _ _ _ _ _
5 inhaler _ _ _ _ _

CHILDPROOF VS. ELDERLY-ACCESSIBLE

A lot of research is done to make packaging *childproof*, i. e. a child cannot open it alone. However, at the same time, the elderly must have easy access to their medication, i. e. it needs to be *elderly-accessible*.

19 Read the following text about childproof packaging and unscramble the letters in the brackets to find the correct word.

The latest *i* _____ [1] (vatinionson) in childproof packaging nowadays entail sophisticated *m* _____ [2] (sacnihmsem) that are physically easy to open, even for the *e* _____ [3] (dyelerl) or infirm, but that require actions to be thought through in a way small children would not be *c* _____ [4] (aaclbep) of. Psychologists, *e* _____ [5] (gieneesrn), and designers have *c* _____ [6] (bocallradeto) and come up with the following state-of-the-art features.

Now match each container system type to the action needed to use it.

1 ☐ slide
2 ☐ poke
3 ☐ push-screw
4 ☐ squeeze-screw
5 ☐ peel-push system

a A closure must be pushed down before it can be unscrewed.
b A first layer must be peeled off a blister before the drug can be pushed through the second layer.
c A closure must be squeezed between two fingers before it can be unscrewed.
d A container with three buttons that must be aligned in order to slide off the lid.
e A tube that can only be released by an adult-length finger by pushing an internal catch.

Do you think these types are really elderly-accessible?

20 A group of scientists and technicians are interested in the production and packaging facilities at your company. Discuss the visit on the phone.

PARTNER FILES Partner A File 6, p. 77 Partner B File 6, p. 79

OUTPUT **Read the article.**

5

BOY KILLED BY POTENT PAIN PATCH

A few years ago, a mother was convicted of negligence leading to her son's death. It was claimed that he had died from a pain medication overdose. Now the woman has taken measures to ensure that other children do not die the same way.

A four-year-old boy was found dead after he had stuck a highly potent, pain-relieving patch to his leg. His mother was sentenced to several years' community service for leaving a used patch in a place where her young son could have access to it. The patches had been prescribed for her as treatment for a serious intestinal disorder.

She claimed that she always put her used patches into an empty soda can, whenever possible. One day, however, she did not have one available, so she put the used patch directly into the garbage. Her son later found it and stuck it onto his leg, just the way he had seen his mother do it.

The authorities became interested in this case. The boy's death highlighted a problem that no one had anticipated up to that time. Because of her son's death, the young mother demanded that safe-disposal boxes be included in the packages of medicated patches. These boxes should have a small slit at the top to discard used patches and it should be impossible to open them.

In the meantime, many medications, especially those that involve needles, come with disposal boxes for discarding them. However, besides a warning about the effects of the medication, authorities have unfortunately not made the requirements regarding the disposal of potentially dangerous materials any stricter. Fortunately, though, many pharmaceutical companies have recognized the problem and now supply boxes for disposal with their products. ◆

OVER TO YOU

- Who do you think is responsible for the boy's death? The mother? The pharmaceutical company? Someone else?
- Do you know of any similar cases involving pharmaceutical products?
- Pharmaceutical companies are required to package their products in a childproof, but elderly-accessible way. Why is this so difficult?

Test yourself!

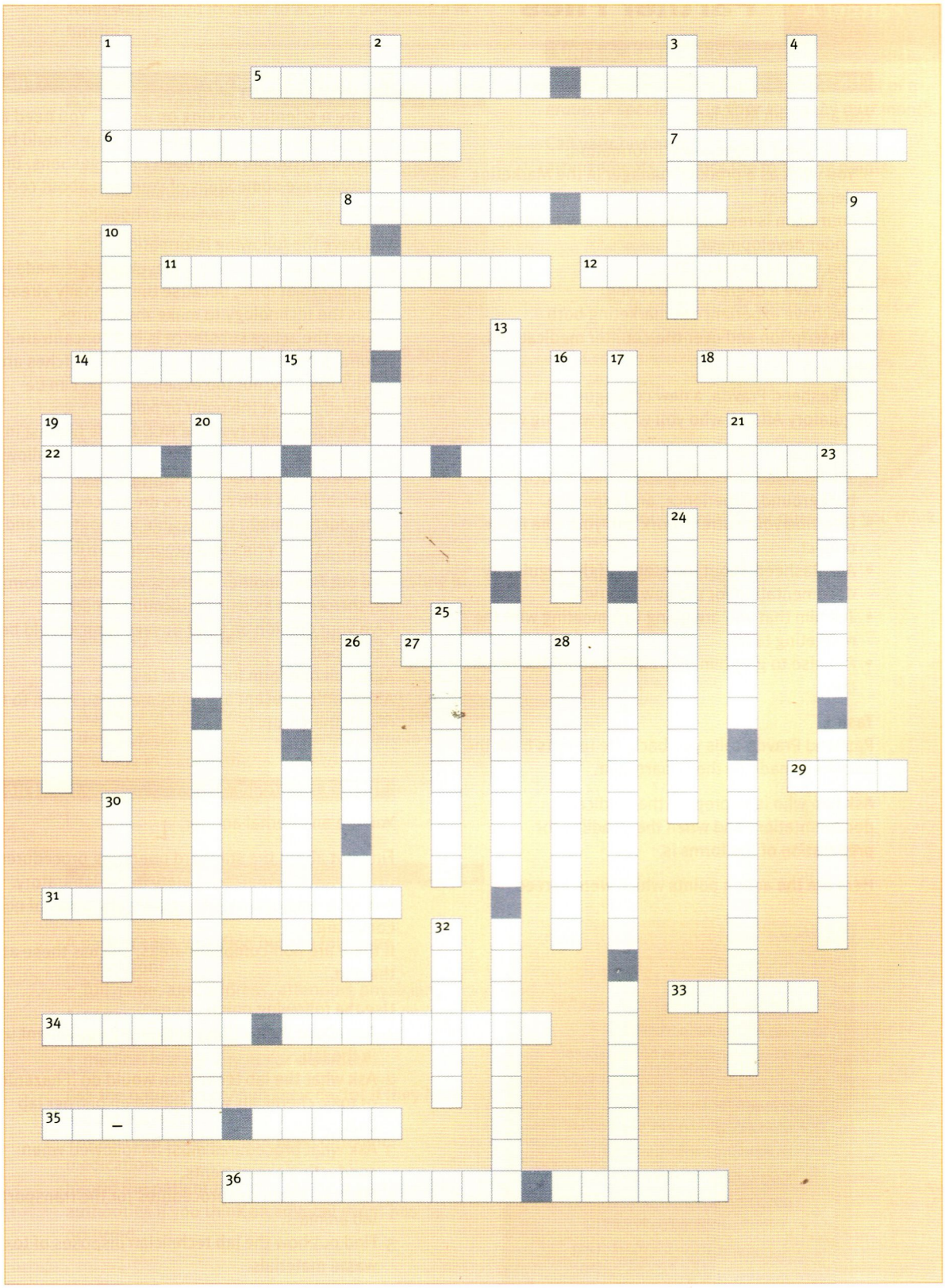
See how much vocabulary you have learned. Use the clues to complete the crossword puzzle.

Across

5 A task performed to fix something wrong.
6 A condition in which a part of the body becomes red, warm, and swollen.
7 A place where a company has its offices and/or factories.
8 An unwanted medical occurrence during a clinical trial.
11 Paperwork necessary to provide evidence or proof.
12 A careful study of a substance done before medicine is developed.
14 A written description of changes to a study or trial protocol.
18 To give or hand in, e.g. a documentation to an authority to obtain authorization.
22 An American drug authority.
27 Following rules and regulations made by people in authority.
29 To put a cover over tablets.
31 A written note from a doctor for medicine.
33 Equipment used to lift something.
34 The practice of making sure that goods and services fulfil defined standards.
35 Trials to test a drug in humans.
36 A task performed to stop something bad from happening.

Down

1 An examination of processes, procedures, and standards.
2 Medicine provided by a chemist or pharmacist without a prescription.
3 A mechanism which releases its contents in defined amounts.
4 A mechanism or piece of equipment designed to perform a special function.
9 A difference from a specification, not within the accepted range.
10 Monitoring or evaluating suspected side effects.
13 A fixed working method, often written down.
15 A substance recently developed.
16 The ability of a drug to treat the illness for which it was developed.
17 An information sheet explaining how to take a drug.
19 Giving off small bubbles of gas when added to liquids.
20 Permission to sell and distribute a new drug.
21 A person trained to do tests on drug ingredients.
23 Medicine obtained in retail outlets without a prescription.
24 Features or characteristics of a drug.
25 A person who agrees to participate in a clinical trial.
26 A type of medicine, e.g. tablets, powder, gel, spray.
28 A substance in a drug.
30 A small animal used as a subject in the earlier stages of preclinical trials, e.g. mouse or rat.
32 A prescribed amount of a medicine or drug.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Partner A Partner Files

UNIT 1, Exercise 16 File 1

You are Sarah Manders.

Here is some biographical information:
- You work as a product manager in the Marketing department.
- Your team is responsible for the new product under development.
- You live in London.
- You have a degree in marketing.
- You have experience in marketing both prescription and over-the-counter medications.

Task 1
Call Rasheed Pravda, a new colleague from Regulatory Affairs, who you will be working with.

- Introduce yourself.
- Tell Rasheed something about your educational background, experience, and expertise.
- Describe your current work and your role in the project.
- Ask Rasheed about the status of the regulatory documentation for the new product.
- Tell him that you are going to a meeting with the marketing team.
- Promise to give him information about the results later.

Task 2
Rasheed Pravda calls you back. He reports back the decisions made by the department.

Ask him who is to prepare the medical documentation, and when the deadline for preparation of the forms is.

Here are the action points which were agreed:

Action points:

- Sarah Manders is to ask Rasheed Pravda about a possible date for marketing authorization.
- Sarah Manders is to lead a team of two marketing assistants to prepare for launch.
- Marketing is to set the actual launch date. Information from Regulatory Affairs must be obtained first.
- John Carlton is to check the documentation for marketing.

UNIT 2, Exercise 12 File 2

You are a scientist working on an NCE. You need to decide what dosage form of a new drug should be developed. You are fairly open to suggestions. But you also have some ideas of your own about certain forms.

You have the following information:
- The drug will cost less to develop if it is made in a pill or tablet form, because the company already has the technology to make these forms.
- Since the active substance is in a concentrated form, a patch might be a good idea. Patches are easy to apply, not too expensive, and can be placed right at the point of pain.
- The bioavailability of the NCE will be highest in a capsule form and capsules are easy to swallow. Therefore, you would favour this form. If the clinical trials with capsules are successful, full production might be possible in about two and a half to three years for European distribution.

Find out from another scientist what dosage forms he/she prefers as pain medication for adults.
Give your opinion on what dosage form should be developed.
Agree on one form for clinical testing.
Afterwards, present any agreement you reach to the rest of the group.

UNIT 3, Exercise 15 File 3

You are an internal auditor.

Find out about the standard operating procedures (SOPs) for all aspects of safety in the laboratory.
Ask follow-up questions to clarify any areas of non-compliance.
If there are non-compliant areas, discuss these at the end.

Use the following points:
1 Ask about the clothing and safety equipment used in the lab.
2 Ask what the lab technician would do if hazardous or toxic chemicals were spilled on his/her lab coat.
3 Ask what procedures must be followed when conducting experiments.
4 Find out about the procedures for the transport of lab animals.
5 Find out how the lab technician disposes of toxic waste materials.

Report back to the group any areas of non-compliance that were identified.
What was agreed in order to achieve compliance in future?

UNIT 4, Exercise 19 — File 4

Systematic testing done in animals before humans are allowed to receive a substance. **preclinical trials**	The drug substance that has the capacity to have a pharmacological effect. **active pharmaceutical ingredient**
The quantities and combinations of different substances used to make medicine. **formulation**	A type of small animal used in preclinical trials, such as mice and rats. **rodent**
A person who receives an investigational drug or a placebo in a clinical trial. **subject / volunteer**	The right given by authorities to begin with clinical testing in humans. **permission**
A period of time spent doing practical training in a company. **internship**	A formal word for a change made to a trial protocol. **amendment**

UNIT 5, Exercise 13 — File 5

You are a drug safety specialist.

A patient calls you. Find out the following information:

- full name, age, address, attending physician
- name of all drugs taken, period of time, dosage
- description of symptoms, period of time
- medical history, any major disorders.

Ask the patient to consult their doctor if they have not yet done so.
Suggest the patient might need different medication.
Inform the patient that this will be reported to the authorities if you think an adverse event has occurred.

Make a note of the implications for the drug and for your company.

UNIT 6, Exercise 20 — File 6

You are responsible for organizing the visit of a group of specialists to your company next month.

Call your business partner regarding the arrangements. Discuss the following points:

- *How many visitors?*
- *Outline the company tour (no sterile areas)*
- *Offer to show training centre – if requested*
- *Mention company rules (dos and don'ts)*
- *Confirm meeting with head of production after lunch*
-
-

Add any other information or questions you think necessary.

Try to find compromises.

Partner B Partner Files

UNIT 1, Exercise 16 File 1

You are Rasheed Pravda.

Here is some biographical information:
- You work in Regulatory Affairs.
- You are going to lead a team responsible for the marketing authorization of a new product.
- You are originally from India, but have lived in Switzerland for about eight years.
- You have a master's degree in pharmacy from Aston University in Birmingham, England.
- You have experience in preparing the documentation necessary to obtain marketing authorization in Europe.

Task 1
Sarah Manders, a new colleague from the Marketing department, will call you.

- Introduce yourself.
- Tell Sarah something about your educational background, experience, and expertise.
- Describe your role in the project.
- Tell her you have a meeting with your boss and new department tomorrow.
- Promise to call Sarah back with more information.

Note: You do not know the current status of the regulatory documents.

Task 2
You have been to a meeting with your boss and your new team. Call Sarah back to inform her of the results, and ask her for an update on the marketing authorization and launch date.

The action points decided at the meeting are:

Action points:

- Manuela Fritz is to prepare medical documentation by 15 March.
- Margit Anton is to prepare all forms needed for dossier by 10 April.
- Rasheed is to co-ordinate everything so that the dossier can be submitted by May 5th.

UNIT 2, Exercise 12 File 2

You are a scientist working on an NCE. You have very strong opinions about effective dosage forms for pain relief. Using the following information, present arguments in favour of your preferred dosage form(s).

- The company is already successful with its tablets and suppositories and therefore you are strongly in favour of these forms.
- However, you will have the technology to make drops and syrups in a year. These forms are a good substitute for people who cannot swallow solid oral forms. They would be your second choice as a dosage form for the treatment of pain.
- The company does not have the technology to produce patches. You have read that it can be complicated to dispose of used patches, and that they are highly toxic for children or animals.
- You currently produce suppositories, ointments, and creams in a joint-venture project with a Japanese firm. If you choose suppositories as the dosage form, you could work with your joint-venture partner again, and travel to Japan. Production might be possible in a year-and-a-half to two years.

Find out from another scientist what dosage forms he/she prefers as pain medication for adults.
Give your opinion on what dosage form should be developed.
Agree on one form for clinical testing.
Afterwards, present any agreement you reach to the rest of the group.

UNIT 3, Exercise 15 File 3

You are a laboratory technician.

Answer the questions which your company's internal auditor asks you about the standard operating procedures (SOPs) for safety in the laboratory.

If there are non-compliant areas, discuss these with the auditor at the end.

Use the following points:
1 Animals must be transported in disposable cardboard boxes and as quickly as possible.
2 Name the usual laboratory clothing and equipment.

3 Contaminated laboratory clothing must be removed immediately. Explain how direct skin contact can be avoided *(see exercise 14 for help)*.
4 Special containers are provided for the disposal of toxic waste materials. Name some kinds of materials these containers could be made out of. Say how the containers can be recognized.
5 Only the results of experiments are documented. This does not necessarily have to be done immediately.

Report back to the group any areas of non-compliance that were identified.
What was agreed in order to achieve compliance in future?

UNIT 4, Exercise 19 — File 4

A pharmaceutical form of an active ingredient which is tested in a clinical trial. **investigational drug**	Systematic testing of a drug in humans to determine its pharmacological effectiveness and safety. **clinical trial**
The amount of a drug administered to an animal, healthy volunteer, or patient. **dosage**	Records of a trial, including information on dosages, methods, results, factors, and actions taken. **documentation**
The action of giving someone a drug. **administration**	A simulated audit to prepare for an inspection by regulatory authorities. **mock inspection**
The short form of a signature using the first letters of your name. **initials**	A person who performs tests in a biology or chemistry laboratory. **lab technician**

UNIT 5, Exercise 13 — File 5

You are a patient.

Read the patient information leaflet.

Possible side effects

Common side effects of CAREFREEDO are:
- nausea
- vomiting
- abdominal pain (pain in your stomach or intestines).

In rare cases, the following may occur:
- dizziness
- allergic reactions (for example, a rash)
- elevated blood pressure.

Further information

Call 0041 30 388 9222

You have been taking this medication for two weeks. Since then you have begun to feel dizzy. Yesterday you actually fainted and were taken to hospital. You were able to leave after five hours.
You have a history of dizziness whenever the weather changes. At the moment the weather is stable. You also have hay fever and are allergic to several pollens. This is the reason you take this medication. You think that your fainting and dizziness are a result of taking this drug.
Call the pharmaceutical company and describe your situation.

UNIT 6, Exercise 20 — File 6

You are organizing a visit to your business partner's company next month for a group of specialists.

Your partner calls you.

Use the following notes to clarify a few details:

- *Confirm size of group (7)*
- *Go into sterile area?*
- *Lunch with Head of Production?*
- *Visit packaging area?*
-
-

Add any other questions you may have.

Try to find compromises.

Answer key

UNIT 1

page 5

Starter

5 Clinical Affairs
4 Marketing and Sales
1 Production
2 R & D
3 Regulatory Affairs
6 QA

page 6

1 1 F 2 F 3 T 4 T 5 T

page 7

2 1 c 2 d 3 e 4 b 5 a

3 1 The main reason
2 As you know
3 here is an update on the project
4 You are probably aware that
5 As far as
6 is concerned

page 9

4 1 on our medications
2 ingredient
3 standard operating procedure (SOP)
4 subject
5 serious adverse event
6 health regulations
7 ointment
8 B
9 H
10 C
11 D
12 G
13 A
14 E
15 F

5 1 report
2 tested
3 operate, determine
4 perform, interpret
5 submits
6 develop

page 10

6 1 To meet and discuss a new headache medicine.
2 Milan, Italy; the clinical trial manager.
3 He has a PhD in Pharmaceutical Chemistry.
4 Two new dosage forms.
5 Shanghai, China.
6 The new pharmaceutical facility in Shanghai.

7 1 my professional background is in
2 I received my
3 I did research on
4 assigned to this project
5 I have been with this company for
6 I used to work

page 11

8 1 I'm/My name is
2 I'm the
3 started as a
4 worked my way up
5 got/received/obtained
6 I was involved
7 I am responsible for
8 I am working on a project to

page 12

10 1 b 4 f
2 e 5 d
3 a 6 c

page 13

11 1 Before we close, I'd like to review the action points.
2 Charley's team will be describing the new equipment needed.
3 Each department head needs to get back to me by Friday.
4 Finally, Rasheed is going to look at any regulatory issues that need to be addressed.
5 First of all, Iris Berger from HR will place job ads in several pharmaceutical journals.
6 Walter is to finish the other dosage forms by the end of the month.

12 CLINICAL RESEARCH ASSOCIATE
· clinical drug trials
· scientifically and technically accurate protocols
· a master of science
· two years' experience

page 14

13 1 is searching for
2 will need to be able to
3 responsible for
4 essential to this job
5 required
6 preferable
7 years' experience

page 15

15 line worker
prescription drug
formulation
marketing claims

UNIT 2

page 17

Starter

Research	*Development*
analysis of disease	analytical testing
clinical trials	dosage forms
discovery	drug safety
new chemical entities (NCEs)	target identification

page 18

1 1 breakthrough in the search for an NCE for Mensapatch™ development, ideas for new substance and further development
2 a new lozenge form of the product Mensadent™ to stimulate brain activity and thinking power
3 see a physician and get a prescription
4 lozenges and chewing gum
5 yes: loss of sleep, increased blood pressure, heart palpitations, and headaches

page 19

2 suggested answers:
1 What kind of formulation could we develop from this NCE?
2 What is the bioavailability of this NCE?
3 Is there some information available on the toxicity of the substance?
4 Are we in a position to make this new dosage form with our current technology?
5 What kind of time frame are we talking about for the first in-man study?

page 20

3 1 chemist
2 dosage form
3 toxicology
4 prescription
5 formulation
6 in-man study

4 A 5
B 4
C 3
D 1
E 2

page 21

5 1 T
2 F
3 F
4 F
5 T

6 Q 1 What kind of formulation could we develop?
A 1 We don't know yet, but we're working on it.

Q 2 What about the dosage forms?
A 2 We don't have a complete answer to that question yet.

Q 3 What is the toxicity of this NCE?
A 3 We can give you the answer in about four weeks.

Q 4 When can we start the first in-man study?
A 4 We will need from six months to a year and a half.

Q 5 What kinds of side effects are possible?
A 5 We are still running tests to find out.

page 22

7 a pills
b tablets
c dosage/syrup
d patch
e suppository
f drops
g syrup/dosage

1 dosage
2 pills, tablets
3 patch
4 drops, syrup
5 suppository

page 23

8 a nearly 2,000
b 54%
c 46%
d 50
e 20%
f 0%
g 22%
h 26%
i 30%
j 32%
k 12%
l 8%
m 2%
n 5%
o 2%
p 1%

page 24

9 1 nearly 2,000
2 males
3 32% preferred capsules
4 dizziness, vomiting, and diarrhoea
5 bronchitis and asthma

10 1 f
2 a
3 j
4 c
5 b
6 d
7 e
8 g
9 h
10 i

page 25

11 suggested answers:
1 What do you think about the new drug which has recently been developed to cure heart disease?
2 What's your opinion on whether a pill or patch dosage form should be considered?
3 In my opinion, the in-man studies for this drug will take more than six months.
4 I feel that additional clinical trials should be done in other countries.
5 I'm convinced this new formulation will be successful.
6 I feel very strongly that a nasal spray should be developed as a third dosage form.
7 I'm afraid I don't have enough information to make a statement on that.
8 I would rather not say just yet what information I have.

UNIT 3

page 27

Starter

good auditing practice (GAP)
good clinical practice (GCP)
good documentation practice (GDP)
good laboratory practice (GLP)
good manufacturing practice (GMP)
good research practice (GRP)
good safety practice GSP)

page 29

1 1 a 2 c 3 d

2 1 traceability
2 holistic approach
3 assurance
4 control
5 endpoint testing
6 product recall
7 validation
8 Contaminated

page 30

3 1 laboratory safety SOPs
2 to identify any areas requiring corrective or preventive action
3 annually
4 from Tuesday to Friday (Lab 1 on Tuesday and Wednesday, Lab 2 on Wednesday and Thursday, and Lab 3 on Thursday and Friday)
5 the audit checklist

page 31

4 1 b
2 c
3 h
4 e
5 a
6 g
7 d
8 f

page 32

5 suggested answers:
1 is to advise you
2 make sure
3 will be reviewed
4 Our goal
5 Please confirm
6 send us

page 33

6 1 T 2 F 3 F 4 F 5 T

7 1 short
2 Safety
3 observe
4 checklist
5 non-compliance
6 updated
7 up to date
8 finding

page 34

9 1 Internal Auditing.
2 A checklist of points is made so that corrective or preventive action may be taken later.
3 Charlie is a junior chemical lab technician; Jennifer is a senior chemical lab technician.
4 Safety goggles or glasses, lab coats, safety gloves, hairnets, overshoes.

page 35

11 1 c 2 e 3 d 4 b 5 a

page 36

12 suggested answers:
1 I suggest you dispose of toxic waste in the bins provided for this purpose.
2 It is absolutely essential to move lab mice outdoors in closed cages.
3 The only solution is to make sure all safety gloves are available in all sizes (S, M, L, XL), and that all lab staff use safety goggles in future.
4 My recommendation is to review with all lab staff the procedures for recording experiments.
5 I strongly suggest that all staff comply with the proper rules for hand-washing and sanitizing in future.

13 1 b 2 c 3 e 4 d 5 a

page 37

14 suggested answers:
1 All work with virus-infected animals must be performed in the bio-safety cabinet.
2 Disinfectant must be used on all equipment following any experiments with laboratory animals.
3 All chemical spills in the laboratory must be wiped up immediately.
4 Laboratory gowns or lab coats, latex gloves, and safety glasses must be worn at all times.
5 Small biological agent spills must be covered with a paper towel and treated with bleach.
6 All laboratory work must be documented in accordance with GLP.

UNIT 4

page 40

1 1 administer
2 development
3 formulate
4 purity
5 active

page 41

2 a One to five years.
b The effect of a drug in vivo and in vitro.
c Testing that documents the characteristics and chemical composition of the API and formulated drug.
d Pharmacological studies look at the body's reaction to the investigational drug. Toxicological studies concentrate on the possible negative effects that could harm the body.
e When the regulatory authorities authorize the commencement of clinical studies.

3 a obtain
b require
c ensure
d determine
e potential
f proceed

4 permit
documentation
administer
intention
formulate
information

page 42

5 1 intention
2 permission
3 formulate
4 document
5 documentation
6 formulation

pages 42–43

6 1 were conducted
2 were used
3 be provided
4 be formulated
5 are/were determined
6 be administered

page 43

7 1 F – She discovered it herself.
2 T
3 F – Only animals in the high-dose group are affected.
4 T
5 T
6 (–) – He only says he will talk to the study director, but not when.
7 F – She is going to help Linda.

page 44

8 1 Could somebody (please) fill me in on what the problem is(, please)?
2 Is it correct that the dogs aren't responding to the drug?
3 First, we need to figure out which animal group is receiving what concentration.
4 We could consider testing another group of animals.
5 Personally, I would prefer to use (dogs/mini-pigs) instead of (mini-pigs/dogs).
6 I'll let you know (later) what we come up with (later).
7 I imagine we would have to change the study protocol.

page 45

10 1 b 2 d 3 a 4 c

11 In addition, however, whereas, though

page 46

12 1 While there were no clinical findings in the mid-dose group, the high-dose group animals showed clinical symptoms.
2 Not only was the pulse rate increased, but also the blood pressure was high.
3 There were no clinical findings in the oral administration studies. However, there were clinical findings in the intravenous-dose studies.
4 Mini-pigs are easy to handle, whereas rhesus monkeys are difficult to work with.
5 The drug was well tolerated by rats. Furthermore, it did not have any effect on blood pressure.

page 47

13 1 III 2 II 3 II 4 IV 5 III

14 1 b 2 b 3 b

page 48

15 1 E
2 I
3 E
4 E
5 E
6 I

16 1 If you check ...
2 How do you account for ... ?
3 You can rest assured ...
4 ... led to the change.
5 You mean, ... ? Is that right?
6 You will prevent ...

page 49

18 1 disease
2 illness
3 sensitive
4 sensible
5 effect
6 affect
7 shortly
8 briefly

UNIT 5

page 51

Starter

Drug safety 1, 3, 4
Regulatory Affairs 2, 5, 6

page 53

1 1 She fainted and had small, red, itching spots all over her body, a skin rash, and inflammation, a racing heart, high blood pressure, a headache, and insomnia.
2 The doctor gave her a strong sedative and took her off the medication.
3 She only had a mild skin irritation.

Evidence pointing to *Mensamint™*:
- Her symptoms occurred after taking *Mensamint™* and stopped 24 hours after she discontinued it.
- Some of her symptoms are known side effects of *Mensamint™*: loss of sleep if taken in the late afternoon or evening, increase in blood pressure, heart palpitations, and headaches.

Other factors:
- Patient is allergic to peanuts and penicillin and had eaten a candy bar, which could have contained peanuts.
- She is taking another drug, an oral contraceptive, and has a history of hypertension, mild heart palpitations, high adrenaline, and insomnia.

2 1 f 2 g 3 e 4 a 5 c 6 d 7 b

3 1 d 2 c 3 b 4 e 5 a
Correct order: 2 1 5 4 3

pages 54–55

4 1 b 2 j 3 f 4 h 5 c 6 d 7 i 8 g 9 e 10 k 11 a

page 56

5 Topics discussed: approval process.
Topics mentioned: clinical trial, doctor's report, Quality Assurance.

6 1 F 2 F 3 T 4 T

page 57

7 suggested answers:
1 It is due to pre-existing conditions.
2 Could it jeopardize other products?
3 The side effect could have been due to (taking) this product.
4 How far is it from approval?
5 How did the clinical trials go?
6 The evidence is inconclusive.
7 What does it mean for the products in the pipeline?
8 A reaction to the product cannot be ruled out.

page 58

8 1 d 2 b 3 a 4 e 5 c

page 59

9 1 The strong points are its completeness and technical details.
2 They could improve readability and differentiate when describing frequent and rare risks by being more or less direct in language.
3 Better style could increase patient compliance.

page 60

10 1 Read this leaflet carefully, because it contains information you need to know.
2 What the product is, and what it is used for
3 Before you take this product
4 How to take/use
5 Possible side effects
6 How to store
7 Further information

page 61

11 1 e 2 b 3 c 4 a 5 f 6 d

UNIT 6

Starter

page 63

1 1 effervescent powder drink flavouring
2 take photographs/smoke
3 keep visitor's pass visible
4 any time

page 64

2 1 In the meantime,
2 When it was founded,
3 In the meantime,
4 While
5 Meanwhile,
6 During
7 Once

3 1 The company used to only produce effervescent powder.
2 The production process used to be simple and uncomplicated.
3 The clothing specifications didn't use to be documented.
4 The company's safety regulations didn't use to be so strict.
5 There didn't use to be so many inspections by authorities.

page 65

4 1 F 2 C 3 A 4 B 5 E 6 H 7 D 8 G

5 hair covering, overalls, and overshoes

6 diagram 2

page 66

7 1 ☺ 2 ☹ 3 ☺ 4 ☹ 5 ☹

suggested answers:
1 The rest of you, please wait here.
2 Please sit/have a seat on the bench.
3 Please stay with the group.

pages 66–67

8 suggested answers:
1 Please mind the corrosive substances, which could cause severe burns.
2 Please be careful, this substance is toxic.
3 We would like to remind you that smoking is not permitted.
4 Please be careful, as there are radioactive substances here.
5 A hard hat must be worn at all times in this area.
1 Animals are not permitted in this area.
2 Taking photographs is not permitted.
3 The speed limit is 30 kph.
4 Protective glasses/goggles must be worn at all times in this area.
5 Entering this area is not permitted.

pages 67–68

9 1 F 4 C
2 B 5 E
3 D 6 A

page 68

10 1 Dry ingredients are transported to the granulator by the hoist.
2 The granules are dried by a strong flow of hot air.
3 The excess powder is loosened by a shaker.
4 The excess powder is sucked up by a vacuum system.
5 The pressed tablets are held in a drum until it is time to coat them.

page 69

11 1 F – They can ask their questions any time.
2 T
3 T
4 F – Authorities always announce their visits.
5 F – The equipment has to be validated before production can start.

12 I'm here to give you some information on ...
Let me give you a brief overview of ...
Moving on to the next point, ...
Coming back to ...
In addition to this, ...
Feel free to ask questions as we go along.
As a final point, I would like to say ...

page 70

13 1 a 4 c
2 e 5 f
3 d 7 b

15 suggested answers:
light/temperature/shipping time/shipping conditions/exposure to oxygen

page 71

16 1 P 4 B
2 P 5 S
3 P 6 B

17 1 inhaler 4 jar
2 blister pack 5 sachet
3 syringe 6 sticky label

page 72

18 1 remove 4 twist
2 tear 5 press
3 push through

19 1 innovations
2 mechanisms
3 elderly
4 capable
5 engineers
6 collaborated

1 d 2 e 3 a 4 c 5 b

pages 74–75

Test yourself!

Across

5 corrective action
6 inflammation
7 premises
8 adverse event
11 documentation
12 research
14 amendment
18 submit
22 food and drug administration
27 compliance
29 coat
31 prescription
33 hoist
34 quality assurance
35 in-man study
36 preventive action

Down

1 audit
2 behind the counter
3 dispenser
4 device
9 deviation
10 pharmacovigilance
13 standard operating procedure
15 new chemical entity
16 efficacy
17 patient information leaflet
19 effervescent
20 marketing authorization
21 laboratory technician
23 over the counter
24 properties
25 volunteer
26 dosage form
28 ingredient
30 rodent
32 dosage

Berner Pharmaceuticals Ltd

Internal Audit Checklist – Laboratory Systems

Date: _____ **Audited by:** _____ **and** _____

Objective:
To monitor the laboratory quality system and take any needed corrective or preventive action to assure industry compliance in laboratory procedures.

Interviews with personnel (who?):

_____

_____

_____

Examination of documentation (what?):

_____

_____

_____

Observation of activities and conditions (list these on separate page):

Review of quality and technical procedures (list these on separate page):

Results (write preliminary report with suggested corrective action with copies to head of audited department):

Action (list of corrective or preventive action taken by whom and when):

_____

_____

_____

_____

_____

Date of next audit (six months from now):

_____

_____

_____

Transcripts

UNIT 1, EXERCISE 6

2

Harvey Good morning, and welcome everyone. Great that everyone on the project team could make it to our kick-off meeting. Now that we are using video conferencing even Charley Wu from China and Anna Edicola from Milan can fully take part. Just one more thing before we start. Please keep in mind that, although we can see each other, we have no direct eye contact. So please remember to say your own name and the first name of the person you are addressing. OK? That will save time and avoid confusion.
The aim of our meeting today is to meet each other and to discuss the new analgesic, a headache medicine with the working name of CoolHead. By the end of the meeting I hope we will have come up with deliverables for getting the project off the ground and a full to do list. However, before we get started on the project itself, I would like you to introduce yourselves and say something about your professional background, area of expertise, and so on. Anna, would you mind starting?

Anna Of course not, Harvey. Well, as you may know, I work in Milan. My professional background is in pharmacology and in 2005 I received my master's degree at New York University and licence to practise pharmacy in the United States. I did research on clinical methodology. As far as this project goes, I am the clinical trial manager assigned to this project and am supported by two clinical research associates who will work with test centres in northern Italy and in Slovenia. I have been with this company for about three years and I used to work at Johnson & Johnson in their clinical department.

Harvey Thanks, Anna. Walter, could you go next?

Walter I'd be glad to. Hi, everyone. For those of you who don't know me, I'm Walter Pawel. Well, I'm married and we have a new-born son. So if I look tired, it's not bad reception on your screen. That's the way I look. As for my background, I got my PhD in Pharmaceutical Chemistry at the Free University in Berlin and then worked for Pharmafix in their R & D department and left there to join this company. I am the formulation scientist whose team developed the soft capsule for this project. We are currently working on the other two dosage forms.

Harvey Thanks Walter, and now, Charley, could you ... ?

Charley Hi, everyone. Pleased to meet you all. My name is Charley Wu. I am based at our manufacturing plant in Shanghai and was also born and raised there. I first started as a line worker and worked my way up to packaging technician. I later went abroad to study in the UK and obtained a Master of Science in Engineering there. More recently, I was involved in the initial conceptual design phase, the planning and building of our new pharmaceutical facility in Shanghai, and now I am the plant manager. At this facility, we produce both liquid and solid dosage forms. At the moment I am working on a project to build a new analgesics production line, so that is why I was asked to join this project.

UNIT 1, EXERCISE 10

3

Harvey So that just about finishes up our first meeting. Before we close, I'd like to review the action points and the timelines just to make sure each person's role is clear at this stage.
First of all, Iris Berger from HR will place job ads in several major pharmaceutical journals **within the next two weeks** to look for two new clinical research associates to conduct the trials in the test centres in France.
Anna will work with her on writing up the requirements and description of duties.
Walter is to prepare a progress report on the development of the other dosage forms **by the end of next month**.
Department heads need to get back to me **by Friday** with an estimate of how much time they'll need for their part of the project.
With your input, I'll be able to finalize the timelines for planning and implementation and decide on milestones **before our next meeting**. I'll get the budgeting worked out by then, as well.
Charley's team will be responsible for describing the new equipment and machinery needed for the new dosage forms and for making a list of any technical changes in production which need to be addressed at this stage. He will give us a cost estimate **by the end of the month**.
Finally, Rasheed is going to review any legal or regulatory issues that need to be addressed **by the beginning of next week**.

UNIT 1, EXERCISE 12

4

Large, multinational pharmaceutical company is searching for someone with clinical trials experience to manage studies in a number of study centres in Eastern Europe.
CLINICAL RESEARCH **ASSOCIATE**

DESCRIPTION
You will assist in the management of clinical drug **trials**. You will be responsible for recruiting investigators and collecting study documentation.

You need to be able to write **scientifically** and technically accurate protocols, study reports, clinical sections of dossiers, and other research documents in English. You will visit study centres, requiring up to 50 per cent travel.

REQUIREMENTS
A BS in a life science is the minimum; a **master** of science is preferable; a PhD is a plus.
You must have at least two years' **experience**.
In-depth knowledge of FDA regulations is essential to this job.
You must work well independently and as part of a team.
Top organizational and communication skills are a must.
Excellent English is required. A working knowledge of Polish or Russian would be useful.

UNIT 2, EXERCISE 2

5

John Thanks to all of you for coming at such short notice. This will be more a brainstorming session to start off. What do you think you will need to know about the new substance before we can get to work on our new project?

Hilda First of all, could you tell us what kind of formulation we could develop from this NCE?

John Well, we firmly believe we may have a good substance to help us develop a time-release patch form of Mensamint™. Are there any other questions?

Frank Yes, I'd be interested in knowing more about the bioavailability of this NCE.

Marcus I am sure there must be some information available on the toxicity of the substance. Am I right?

Janet Are you in a position to answer the question about what kind of time frame we are talking about for the first in-man study?

Brian In your opinion, are we in a position to make this new dosage form with our current technology?

John ... Wait a minute! I'll be happy to answer all your questions – but one at a time! OK, Frank, what did you want to know?

UNIT 2, EXERCISE 5

6

Janet I'm not convinced that we will be able to come up with a viable patch form of Mensamint™. I'm afraid we are still running tests to find out what kinds of side effects are possible. What do you think about the situation?

Brian It's true that we don't have a complete answer to that question yet. We'll need a bit more time. But it seems to me that it's the time needed to develop the patch form that we have to worry about. I'm sure that some other dosage forms would work just as well or maybe even better.

Janet What did you have in mind?

Brian Well, developing a patch would take anything from six months to a couple of years. I think we should consider either a gel tablet or a pill. We already have the technology for both. Of course, even a liquid form would be better than a patch.

Janet And Brian, regarding drops or syrup – we don't have the technology perfected yet – but we're working on it. We should be able to come up with an answer in about four weeks.

Brian That's good news, Janet. Let's get together with Dr Steinmetz in Production and see what he thinks. Then we can present our ideas for other dosage forms to John at the next meeting.

Janet That's a great idea. I'll call Dr Steinmetz right away and get back to you later.

UNIT 2, EXERCISE 8

7

John Hi, Helen. Thanks for calling. Can I get a little bit of information on the patient survey you just completed in Switzerland about hospital in-patient medication dosage forms?

Helen Sure, John, I've got most of the results right here. What do you want to know?

John I'm looking at a copy of your questionnaire now – how many patients were interviewed altogether? How many male and how many female?

Helen Well, we conducted the survey in four different hospitals and have results for nearly 2,000 hospital patients, most of whom were between 37 and 63, with an average age of 50. 54% were male, and 46% female.

John Right. Now what about the current oral dosage forms?

Helen 68% of them currently take either tablets, pills, or capsules for various ailments. 20% tablets, 26% pills, and 22% capsules.

John What dosage forms do they seem to prefer?

Helen Well, many patients find it difficult to swallow solid oral dosage forms and they prefer drops (12%) or syrup (8%). Few patients would prefer aerosols (2%), creams (5%), ointments (2%), and patches (1%). Most patients, however, prefer gel tablets (30%) or capsules (32%), because they say they go down more easily.

John That's just what I was hoping to hear! Now could you just give me an idea of some of their chronic health problems?

Helen It may sound strange, but actually most of the patients were not in hospital because of their chronic health problems but were being treated for such things as broken bones, pneumonia, serious infections, or septic wounds.

John Well, I'd still like to know if any of them had any other major health problems.

Helen Why don't I simply email you a copy of my final analysis later this afternoon?

John Good idea, then I can have a closer look at the results. Thanks again, Helen. See you.

Helen You're welcome, John. Goodbye.

UNIT 3, EXERCISE 6

8

Philip Sorry about the short notice. I strongly suggest we talk about who needs to do what to prepare for the laboratory safety procedures internal audit in two weeks. As this is a regular part of good laboratory practice, I don't expect any problems. But do any of you have any questions?

Charlie Well, I've never been involved in an audit before. Do I need any special training for it?

Philip Not really. You already know the correct laboratory procedures. My suggestion is that we all review these procedures again with the laboratory technicians. But each of you also has to be prepared to answer the auditors' questions, just in case. First of all, though, make sure all our laboratory staff are here on audit day and are able to answer questions.

Jennifer One of my lab technicians will be in Vienna at a conference during the audit. If that's a problem, we can cancel the trip.

Philip That's not necessary. But I recommend that at least two lab technicians are present during the audit, just to be on the safe side.

Charlie What kinds of questions do you think the auditors will ask?

Philip They will probably just observe the lab technicians working and possibly ask you or the lab technicians questions from the company's internal audit checklist. Did you get a copy with my memo?

Charlie Yes, I did. What if they ask me a question that I can't answer? Should I ask them to talk to you in that case? What if you're not in on that day?

Philip If there's a question you can't answer, I suggest that you send someone to get me. Don't worry! I plan to be here on all the audit days. If the auditors observe any non-compliance, they'll write it down on their checklist and we'll be informed so that we can take corrective or preventive action. So there's no reason to panic!

Ina One of my lab technicians is out of the country on holiday until the day of the audit. How can I prepare her in time?

Philip Well, the only solution is to reassign her to Charlie's lab on Thursday and Friday, since it's being audited last. You'll have time to bring her up to date by then. The important point is to review all the procedures given in SOP-37-2008b-rev2. Read through it again and let me know if you have any questions. Do you all have a copy?

Julia We've just moved offices again and all our SOPs are still in boxes. Do you have a copy I could look at in the meantime?

Philip Here you are. You can use my extra copy until you've unpacked. Any last questions? If not, I have just a couple of final points. If I may make a suggestion: we should tell the lab staff to double-check that all the labs are spotlessly clean and that all lab devices and equipment are where they should be – at every single workstation. I suggest that they also check the equipment lists to make sure each workstation has all the correct equipment. May I just suggest that the junior lab technicians take care of these two items?

UNIT 3, EXERCISE 9

9

Gail Good morning, I'm Ms Webber, Gail Webber, from Internal Auditing and I need to ask you some questions about your work here in our laboratories. While we're talking, I'll write the information down on the company checklist. Have you seen our checklist?

Charlie Yes, I have a copy.

Jennifer Me too.

Gail Don't look so worried! I'm here to check that good laboratory practice is being followed in the laboratories. If I observe any non-compliance, I'll write it on my checklist and later some corrective or preventive action may need to be taken. Do you have any questions before we start?

Jennifer No.

Charlie We're ready when you are.

Gail OK, would you please tell me your names and job titles? I also need the name of your supervisor and his or her job title.

Charlie Well, I'm Charlie Newman and I'm a junior chemical lab technician. I've been with the company for about three months now. My supervisor is Dr Ina Richter, Lab 1 Manager.

Jennifer Good morning, Ms Webber. I'm Jennifer Kremer – with a K – and senior chemical laboratory technician. I've been with the company for nearly six years. Dr Richter is also my supervisor.

Gail OK, you need to show me what projects you're working on now and what procedures you have to follow. I need to know what kind of training you've had for these procedures and how much time you need to perform them.

Charlie Um ... I'm working on trying to find a new substance which we hope to develop for pain relief. I'm doing a lot of throughput testing at the moment. It takes a lot of time – maybe even months – and it's not really very exciting. I'll tell you about the training later. If you'd like to watch now ...

Gail Before you start, would you please tell me what special procedures must be followed in the laboratory?

Jennifer Charlie, I'll answer for you so you can show Ms Webber the throughput procedure. First, we have to wear the proper protective clothing and safety equipment and observe all the safety rules for the laboratory. Of course, clothing and equipment such as safety goggles or glasses have to be worn in the lab at all times. We also have to wear special lab coats, safety gloves, hairnets, and overshoes in this laboratory.

Charlie Naturally, there's no smoking here and absolutely no drinking or eating is allowed here, either. Some of the other procedures have to do with the particular project we're working on, like ...

10

UNIT 4, EXERCISE 5

First of all, it is the **intention** (1) of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give **permission** (2) to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to **formulate** (3) the active pharmaceutical ingredient into a suitable administration form. We have to **document** (4) each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The **documentation** (5) must show that the **formulation** (6) of the investigational drug is safe for our subjects.

11

UNIT 4, EXERCISE 7

Linda Good morning, everybody.

Jake Hi, Roger. Hi, Miki. How's the internship going? Still enjoying your stay here?

Miki Yes, thanks. Everyone has been very helpful.

Jake Roger, could you please fill me in on what this is about?

Roger Certainly, Jake. Well, hi, everyone. Do take a seat! I suggest that Linda first tell us what problem she observed. I hear you noticed something wrong with the dogs that got the new drug. Is that correct?

Linda Yes, it is. This morning when I wanted to take the blood and urine samples, I saw that some of the dogs had been vomiting. They looked pretty bad.

Miki You said – some of the dogs. Does that mean they are not all affected?

Linda That's right. Some of them had vomited and were still retching, whereas the others appeared to be fit and healthy.

Roger Is the reaction restricted to any particular dosage group?

Linda As far as I can tell, the control and low-dose groups are not affected at all. The animals affected are only in the high-dose group.

Jake So, that pretty much means the drug substance is the cause. What did the study in rodents show?

Linda There were none of these reactions, but, of course, rats can't vomit. There were no clinical findings at all, not even chewing – which is a clinical finding in rats. You can read all the details in the study report.

Jake If you ask me, I think we should consider using mini-pigs instead of dogs, since they're not as sensitive.

Roger I'm not sure I agree with you on that. How long have the dogs been treated with the substance?

Linda For two days now and the individual doses were adjusted to the most recently recorded body weight.

Jake It seems to be the concentration of the drug. So we'd better cancel the highest dose, if the dogs are too sensitive.

Miki If we did that, would the complete study protocol have to be changed?

Roger Yes, it would. But first we need to figure out which dose we are going to use and then write the amendment. Personally, I would prefer to keep going for another three days – without the high-dose group, of course. In the meantime, just carry on with the other groups and I'll let you know what we come up with after talking to the study director. Please inform me immediately if any other animals start showing similar symptoms. Also, could you please send me a copy of your report on the clinical observations as soon as possible?

Linda Sure, no problem. Miki, would you like to help me with that?

Miki Yes, I've never done that before.

12

UNIT 4, EXERCISE 14

Inspector All right. May I have a look at your documentation now?

Expert Yes, of course. Here it is.

Inspector Where can I find details of storage temperatures?

Expert If you check the third page, you'll find them at the bottom of the page.

Inspector I'm afraid I can't read the original text, as the original information has been made illegible. You know, it should only be crossed out with a single line so that the original text can still be read. Who is responsible for that? You know this is a deviation, don't you? More of these could result in a major finding.

Expert Yes, and we certainly don't want that. Umm, let me see. It's initialled and dated by Dr Frensen. He's new here. But I see here on this document that he has now had training, so you can rest assured that this won't happen again.

Inspector Well, I'll accept that, since training has been done. Just make sure that all changes are made according to Good Manufacturing Practice standards and you will prevent major findings.

Expert You're right.

Inspector So, how do you account for the temperature change?

Expert You mean, the changes we made in the storage temperature? Is that right?

Inspector That's correct.

Expert The reason for that is simple. Our stability studies showed that the storage temperature had an unwanted effect on the substance. The original temperature was too high, which led to a value that was outside the standard curve.

Inspector All right, that sounds plausible. Let's move on to the safety regulations. I would like to start with the documentation of the safety training of the staff.

13

UNIT 5, EXERCISE 6

Karl Glad you could all make it here, even though it's Christmas Eve. Marv from the Legal Department is on his way, too. Shall we start? First, I'd like to say that although *Mensamint*™ is only being marketed in capsule form at present, it has already proved to be our biggest blockbuster in years. So, what about this case with Maria, uh, Ms Galois? Is it serious?

Caroline I'm afraid it is. Even though the patient has fully recovered, this is a high-profile case and Ms Galois is thinking about going to the press. She did give us approval to call the attending physician to find out what had happened. In addition to what he put in his report, he said it could have been due to her peanut allergy and the chocolate she had eaten or to other pre-existing conditions.

Karl I'm trying to forget what an explosive diva Ms Galois is, both on and off stage. Sorry! I didn't say that!

Caroline Although the evidence is inconclusive, a reaction to *Mensamint*™ cannot be completely ruled out.

Fred So, what were her symptoms?

Caroline Well, she had a severe, inflamed rash all over her body, high blood pressure, a headache, and had reported insomnia beforehand. She then fainted and after she woke up 30 minutes later, she was confused about whether or not she was still supposed to go on stage. She was supposedly very annoyed by all the questions the emergency room staff asked her!

Karl So, what does this all mean for the other dosage form in the pipeline, the chewing gum, targeted at young people who have to concentrate during exams? How far is that from approval?

Fred Well, as you know, after the clinical trials – which, I might add, went well – getting approval is always the next obstacle. I'm afraid this reported event could jeopardize the whole approval process for any other dosage forms of *Mensamint*™, especially in the EU and the US.

Karl What is the status of approval?

Fred We are still completing the submission documentation and have finished all preclinical and clinical data, as well as the administrative data with the patient information leaflets and labelling, safety data sheets, and environmental risk assessment. However, we're still working on the Quality Assurance and expert statements. We hope to submit the dossier to the FDA early next month.

Karl I see. Well, back to Maria, uh – Ms Galois. So what is your conclusion? Is there a connection between *Mensamint*™ and her symptoms?

Caroline The contraindications and warnings in the PIL clearly state that patients like Ms Galois with a history of hypertension should avoid taking *Mensamint*™. Some of the side effects she experienced are known. Luckily, after they took her off *Mensamint*™, the symptoms seemed to go away.

Karl That's good news!

UNIT 5, EXERCISE 10

14

Mark So we've survived another internal audit by QA. What were they checking this time?

Wendy It was mainly about the readability of our leaflets, you know. They were checking to see if the average man on the street easily understands our instructions.

Mark Is that really an issue?

Wendy Well, actually it is. The patients must know exactly when, how, and how much to take, so the leaflets must give very simple, clear instructions that anyone can immediately understand, even if they're in a hurry. They shouldn't have to look anything up in a dictionary, either.

Mark We do get used to our own medical jargon, don't we? Words such as 'indications', 'contraindications', etc. can be confusing.

Wendy That's exactly the point. Think about the instructions you'd like to read when you're trying to do something with your computer or to put furniture together.

Mark So, what should we be writing instead?

Wendy Shall we just go through a typical leaflet?

Mark Sounds like a good way to start.

Wendy To start off, we need to insert a standard warning. It's generally the following: 'Read this leaflet carefully because it contains information you need to know.'

Mark That's pretty straightforward.

Wendy Anyone can understand that one. Next comes the section called 'What the product is, and what it is used for'.

Mark That's the contraindications, right?

Wendy Actually, it's the indications section, which lists the illness or condition it aims to treat.

Mark Sorry, that's what I meant. But this looks a bit different, because it also has the active ingredients' strength here, doesn't it?

Wendy That's right. They are now put in the same section. After that comes the contraindication information, where we write in which cases the patient should definitely not use the product and some general warnings about taking it. This part is simply called 'Before you take this product'. The actual list of side effects comes in a later section.

Mark Well, that should be easy enough. So that fits in with what Dr Crow meant in his email when he said we should be less direct in our warnings.

Wendy Right. Our patients shouldn't be so alarmed that they are afraid to actually put the pills in their mouth and swallow them. The PIL just needs to reflect the probability of side effects.

Mark So how do we do that?

Wendy Well, basically for side effects that are not common, you don't just use 'this leads to'. Instead, say 'this may, might, or can lead to'. You should also be careful to say 'if' instead of 'when', and so on. However, in the case of common side effects and real warnings, it is really necessary to be direct.

Mark I see.

Wendy Anyway, the next section actually tells the user about drug administration and is called 'How to take/use', followed by the name of the product. 'Possible side effects' is the name of the following section and categorizes unwanted, known side effects according to their frequency.

Here, again you must be direct if the risk is great, and less direct if it isn't.

Mark OK.

Wendy The next to last section in the PIL is the 'How to store' section. Finally, we put general information, such as the name and address of the pharmaceutical company producing the drug, in the 'Further Information' section.

Mark Wait a minute. I thought these leaflets were called patient information sheets. You keep talking about PILs.

Wendy Whereas Europeans tend to call them PILs, patient information leaflets, the FDA in the United States usually calls them patient information sheets. Now, as I was saying ...

15

UNIT 6, EXERCISE 1

Henry Good morning, ladies and gentlemen. On behalf of the Public Relations Department, I'd like to welcome you to RRB Pharmaceuticals. My name is Henry Naylor, and I work in the Public Relations Department here at RRB. Prior to your tour of the production facilities, I'll tell you a bit about the history of the company. When the company was founded in 1948, there were just 17 employees producing effervescent powder to flavour drinks. In the meantime, RRB Pharmaceuticals has grown to have about 28,000 employees worldwide. Nowadays, RRB is a research-driven, innovative pharmaceutical enterprise that develops new drugs, produces them, prepares them for sale, and markets them worldwide.

Visitor Um. Excuse me. Can I take flash pictures?

Henry I'm afraid not. As a matter of fact, we have to ask you to leave your cameras in the lockers at reception. Unfortunately, taking pictures is strictly forbidden and you are not allowed to smoke anywhere on the premises. And I would like to remind you that, for security reasons, your visitor's pass must be visible at all times.

The clothing requirements didn't used to be as tough as they are nowadays. But, in the meantime, the regulations have become so strict that in the heart of some production areas staff members are wearing three layers of clothing and they can't recognize each other any more. However, we won't be getting quite that far into the heart of it today. By the time we finish today, I hope to have answered all of your questions. But if you wish to ask anything during the tour, you can interrupt me at any time.

Please remember, once you have entered the clean area it won't be possible to use the toilet facilities. So, while we're waiting for Stephanie Baker to pick you up for the actual tour, feel free to use the facilities at the end of the hall. Oh, here she is now.

16

UNIT 6, EXERCISE 5

Stephanie So, if everybody is with us again, follow me. Be sure to stay with the group! This is the gowning room. Not more than three people are allowed to be in there at a time. I'll take the first two with me. The rest of you, wait here until I come to get you.

Wash and disinfect your hands here, like this. Now pull a hair covering out of the dispenser and put it on your head. You've got some hair sticking out. Be sure everything is inside the covering!

Here are your overalls. Don't allow them to touch the floor! Sit on the bench to put them on if this is easier for you. Now, sit on the bench! Stop. Don't move! Here are your overshoes. Notice how the floor is two colours? The black floor is the 'dirty' floor, and the white floor on the other side of the bench is the 'clean' floor. Once you've got one overshoe on, swing that leg over the bench. The overshoe is only allowed to touch the white area. Then do the same with the other foot. Go out that door and wait there for the rest of the group. Don't wander off!

1st group member Wow, she was rude, wasn't she?

2nd group member Oh, really? I didn't notice.

17

UNIT 6, EXERCISE 7

1 Would you please follow me?
2 The rest of you, wait here.
3 Please make sure that they don't touch the floor.
4 Sit on the bench.
5 Don't wander off!

18

UNIT 6, EXERCISE 11

Henry Ladies and gentlemen, welcome back.

I hope you have enjoyed your tour so far. You have been on your feet for a while, so we've prepared a little break for you. You can sit down and rest while I give you some information on certain requirements pharmaceutical companies have to meet. Feel free to interrupt me and ask questions as we go along. What are these requirements? There are many, many rules that people who work in pharmaceutical companies have to follow, and they are regularly checked by the regulatory authorities. Following these rules is called compliance. So, let me give you a brief overview of what that means for our people in production. Compliance means following the rules, but the rules themselves are known as GMP, or good manufacturing practice. They provide a very high standard, which people have to follow during the manufacturing of pharmaceutical products. For example, GMP covers how to design and construct buildings so that the flow of materials is optimized, and so that they can be cleaned easily.

Visitor 1 Excuse me, what do you mean by optimize the flow of materials?

Henry Well, we have to make sure that there are no mix-ups of materials throughout the whole manufacturing process. On your tour you probably noticed the different colours of the separate areas, or the markings on the floor. This ensures that there is always adequate space for a particular function, and it minimizes the chances of mistakes happening. The building is just one aspect of GMP. In addition to this, GMP also covers areas such as the type of clothing to wear while working, the documentation that is necessary, and the training that employees get on a regular basis.

Visitor 2 May I ask a question, please?

Henry Yes, go ahead!

Visitor 2 How can authorities check that? Do they make surprise visits?

Henry No, they announce their visits to the company about eight weeks in advance. That gives us time to prepare everything that they need to see. This way we ensure that neither the inspectors' nor our time is wasted. Coming back to compliance, for us that means we always wear appropriate clothing and we check that equipment is clean or sterile and calibrated before using it. And last, but definitely not least, we keep a very close eye on our documentation. Moving on to my next point, I'd like to say a few words about another aspect of GMP. In order to receive valid and reliable results, all devices and methods have to undergo a validation process. Before a device can be used, we have to ensure that it works properly. The same is true for methods. This validation process has to be repeated on a regular basis.

Visitor 3 Excuse me. One question. How often is 'on a regular basis'? Is that every three months, or every five years?

Henry That really depends on what's being validated. But, in general, you could say once a year. As a final point, I'd like to mention the many people who do all the lab work as required by GMP. Without all these technicians it would be impossible to bring safe products onto the market. These technicians perform tests on the raw materials used in drugs to make sure they meet the high-quality specifications. Active ingredients, as well as all the excipients, are tested. Some of the work the technicians do for the production department includes various interim analyses during the process. Testing at this stage shows how long the product will hold up under certain conditions, like temperature and humidity. During production, samples are taken at critical stages and tested to make sure, for example, that no contamination has occurred. Technicians also check the samples for content uniformity, content weight, and so on. The list of tests done during the production process is, however, long. To be honest, if I went into detail about each of these very important tasks, we'd be here for at least a week.

So, that brings me to the end of this brief overview of GMP requirements, compliance, and the implications for pharmaceutical companies. Are there any further questions? ... No? All right, then. Would you like to follow me to the packaging area now?

Useful phrases

PROVIDING INFORMATION

The main reason ...
Here is an update on the project.
As you know, ...
You are probably aware that ...
As far as ... is concerned, ...

INFORMING

This ... is to advise ... that ...
The ... will be reviewed ...
Our goal is to ...
... department is scheduled for ...
The ... is as follows: ...
Please make sure that ...
Please send us ...
Please confirm ...

GETTING INFORMATION AND MAKING SUGGESTIONS

Asking for and clarifying information
Could somebody fill me in on ... ?
I'd like to know what has happened.
Does that mean ... ?
I have heard ... . Is that correct?

Making suggestions
I suggest making ...
I suggest we take ...
We could consider trying ...
So, we'd better test ...

Responding to suggestions
I'll let you know what we come up with.
I'm not sure I agree with you on that.

ASKING FOR AND GIVING OPINIONS

Asking for opinions
What do you think ... ?
What's your opinion on ... ?
What's your view of ... ?

Avoiding/Withholding opinions
I would rather not say ...
I'm sorry I cannot comment on ...
I'm afraid I am not in a position to answer that.

Giving opinions
I think/I feel ...
In my opinion, ...
From my point of view, ...

Giving strong opinions
I firmly believe ...
I feel very strongly that ...
I'm sure/certain/convinced ...

SUMMARIZING ACTION POINTS

Before we close, I'd like to review ...
First of all, ...
... is to finish work by the end of the month.
... will be looking after the ...
... is going to find ...
Finally, ...
Each department needs to get back to me by ...

GIVING PRESENTATIONS

Welcoming the audience
Good morning/afternoon, ladies and gentlemen.
I'm happy to welcome you to our company.

Introducing your topic
Let me give you a brief overview of ...
I'm here to give you some information on ...
Today, I'll be talking about ...

Signposting
Moving on to the next point, ...
As I mentioned earlier, ...
Coming back to ...
Let me come back to what I said before ...

Adding points
In addition to this, ...
Moreover/Furthermore, ...
Apart from this, ...

Dealing with interruptions
Could I please finish what I was saying?
If I could just finish what I was saying ...

Dealing with questions
There will be time for questions after my talk.
Feel free to ask questions as we go along.
If you would like to ask anything, go ahead.

Finishing
Finally, I would like to add ...
As a final point, I would like to say ...
To recap, ...
I hope this has given you an idea about ...

LINKING IDEAS

Certain words are added to make additional points, or to compare or contrast ideas.

Adding a relevant point
In addition,/Additionally, ...
... not only... , but also ...
Besides, ...
Furthermore, ...

Making a comparison or a contrast
... , whereas ...
... , while
... (even) though
However, .../But ...

DESCRIBING A PROCESS (PART 1)

The passive is often used to describe a process. We use it because it focuses on the action, rather than on the person or thing (agent) doing the action. Often the agent is unclear, unknown, or irrelevant.

An experiment A trial/study	is/was	carried out/conducted/done/performed.
A drug		absorbed/administered/formulated/manufactured/ prescribed/taken.
The data	are/were	provided/transmitted.
A number of experiments Several tests		conducted/done/performed.
The criteria	can must be	met.
A study	will	carried out/conducted/done/performed.

DESCRIBING A PROCESS (PART 2)

The passive can also be used when the agent is known or relevant. For this, *by + agent* is added.

The moisture	is	removed	by the hot air in the fluid bed dryer.
The granules	are	transported	by the hoist.

TALKING ABOUT TIME PERIODS

We will *need a bit more time* to completely answer that question.
We *are still running tests* to find out what kinds of side effects are possible.
We can give you the answer *in about four weeks*.
It will take *from about six months to a year and a half.*
Not yet! But we're working on it.

ASKING ABOUT DRUG DISCOVERY AND DEVELOPMENT

Dosage
What kind of formulation could we develop?
What about using other forms?
Are tablets, capsules, or drops possible?
What about the dosage for these forms?

Development
What is the toxicity of this NCE?
What about the bioavailability of this NCE?
When can we start the first in-man study?
Do we have the technology to make patches?

REQUESTING INFORMATION AND RESPONDING DIRECTLY

Giving information at inspections
Here are the documents you requested.
I'll get it immediately.
You can find this on page three.
The change is crossed out, initialled, and dated.
Let me explain in more detail ...
I can give you more specific information on ...

Explaining and justifying decisions
Let me demonstrate ...
We had no alternative but to ...
I assure you ...
You can rest assured that we will ...
That led to ...
This way, you can/will avoid ...

ASKING QUESTIONS DURING AN AUDIT

Talking to staff
What is your name?
What is your job?
What is your supervisor's name?
What is your supervisor's job?

Asking about processes and procedures
How have you been trained to perform this procedure?
How much time does it take to complete this part of the process?
What special procedures must be followed in a laboratory?
What special procedures must be followed for this process?

Asking about possible actions taken
How do you handle toxic waste in the lab?
How do you handle the transportation of animals in the lab?
What would you do if you got a toxic substance on your lab coat?
What would you do if you noticed non-compliance with safety procedures by a colleague?

SUGGESTING CORRECTIVE ACTION

Neutral
I suggest you put 'No toxic waste' on the bin.
My suggestion is that we redo the equipment list.
My recommendation is to talk to the lab workers.
It might be possible to relocate the equipment.

Strong
The only solution is to rethink the process.
I strongly suggest that we try to prevent it in future.
I'm convinced we must repeat the last tests.
It is absolutely essential to learn the safety rules.

DISCUSSING SOPS – PROCESSES, PROCEDURES, DOCUMENTATION, TIMING

Requesting information
Please describe the procedure for the ... process.
Would you please clarify how you ... ?
Could you explain the procedure for the documentation of ... ?

Asking questions
What are the guidelines for ... ?
How often do you have to ... ?
What special procedures do you follow for ... ?
How would you ensure good hygiene in the laboratory?

Formulating SOP guidelines
Proper protective clothing and safety equipment *must be worn* at all times.
Proper safety procedures *must be carried out* by laboratory staff.
Toxic or hazardous materials *must be disposed of* properly.

Note: SOPs often use the following structure: *must* or *should be* + verb

GIVING INSTRUCTIONS

If you give instructions in a very direct way, it may sound impolite. Therefore, it is important to watch your tone of voice, and how you phrase your instructions.

Note that when you tell people to do something mandatory, if you add a simple 'please', it makes your instructions sound much nicer.

e.g. *Please remember that the overshoes are only allowed to touch the white area.*

Note that 'mustn't' means that you are not allowed to do something.

e.g. *There mustn't be more than three people in the gowning room at a time.*

Polite instructions
Could you please ... ?
Would you please ... ?
Please make sure that ...
Please remember/Don't forget ...
Please keep in mind ...
I/We need you to ...

REPORTING SEVERE ADVERSE EVENTS TO HEALTH AUTHORITIES

Pharmaceutical companies use details from doctors' reports to inform the authorities in a case report.

Patient history
The patient has a history of ...
A report was received from the physician indicating that ...
Before the event, the patient was on the following medication: ...

Description of adverse event
After examining the patient, the physician ...
After taking (drug), the patient experienced ...
At the time of the report, the patient's condition was/remained unchanged.
At the time of the report, the patient was recovering/had completely recovered.
This event led to the patient's death.

Drug information
... are known/suspected side effects of this drug.
(Drug) was administered for (condition).
Eye drops were instilled.
A bandage/cream/lotion/ointment was applied (to the skin).

Assessment of adverse event
(Drug) is (not) believed to be related to the event.
An interaction between (drug x) and (drug y) was suspected.
A correlation between (drug) and (symptom) can/cannot be ruled out.

DISCUSSING CAUSES OF SAES

It could have been due to ...
It is due to pre-existing conditions.
The evidence is conclusive/inconclusive.
A reaction to the product cannot be ruled out.

ASKING ABOUT IMPLICATIONS FOR A DRUG

How did the clinical trials go?
What is the status of approval?
How far is it from approval?
Could it jeopardize other products?
What does it mean for the products in the pipeline?

GIVING GENERAL ADVICE

Mensamint™ may cause dizziness.
Mensamint™ can interact with other medicines.
Like all drugs, this medicine can cause side effects.
Use Mensamint™ with caution while driving or undertaking dangerous activities.
It is possible that you may receive this medicine, or an alternative may be used.

GIVING STRONG WARNINGS

Do not use/take *Mensamint™* if ...
Stop use and ask a doctor if ...
Keep out of reach of children.
Tell your doctor immediately/right away if ...
You *must not* drive while taking this drug.
You *should not* take *Mensamint™* if you have a history of ...

English for the **Pharmaceutical Industry**

EXPRESS SERIES

English for the Pharmaceutical Industry is part of the EXPRESS SERIES. It is the ideal quick course for anyone who needs English to communicate with colleagues and contacts in the pharmaceutical sector. It can be used to supplement a regular coursebook, on its own, as a stand-alone intensive specialist course, or for self-study. Whichever part of the industry you work in – Research, Development, Manufacturing, or Marketing – **English for the Pharmaceutical Industry** will give you the English you need to communicate across this complex sector.

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