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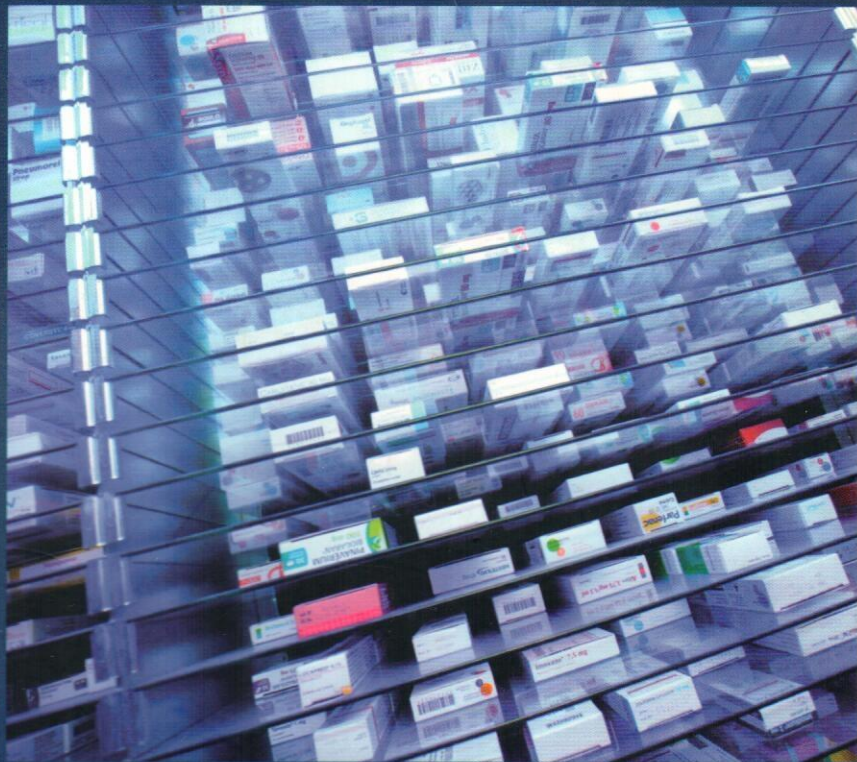
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OXFORD Business English

# English for the Pharmaceutical Industry

Michaela Büchler, Kathy Jaehnig,  
Gloria Matzig & Tanya Weindler

EXPRESS SERIES



Includes MultiROM



OXFORD



# English for the **Pharmaceutical Industry**

EXPRESS SERIES



-3073-

Michaela Bücheler · Kathy Jaehnig  
· Gloria Matzig · Tanya Weindler

„საფარმაცო ინდუსტრია“ ს. ლტმ

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## 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.

1  
We compound the raw materials into drugs, package them, and put in the leaflets for the patients. We also keep careful records of all the steps in this process.

2  
We find new substances to make new drug formulations or change existing dosage forms, for example, from tablets to capsules.

3  
We compile the drug documentation and send it to the regulatory drug authorities so we can get authorization to market the product.

4  
We plan the promotion and distribution of drugs which will be launched, and make decisions about the packaging or tablet colour of new products.

5  
We test or organize testing on live subjects, and make sure that our drugs are safe and effective for the patients.

6  
We ensure that products meet the standards which the law requires, and contain the active ingredients advertised.

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 (X)?**

- 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.

\_\_\_\_\_ <sup>1</sup> I am writing to you is to get your input on a new product. \_\_\_\_\_ <sup>2</sup>, we plan to market a new prescription drug for headaches.

But first, \_\_\_\_\_ <sup>3</sup>. The feasibility study has just been successfully completed. \_\_\_\_\_ <sup>4</sup>

it will be marketed in Europe first. \_\_\_\_\_ <sup>5</sup> your input \_\_\_\_\_ <sup>6</sup>, 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.

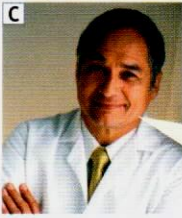
4 Read the job profiles and match the words in italics with the definitions on page 9.



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



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.



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



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.



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.



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.



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*.



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.



**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. \_\_\_\_\_<sup>1</sup> pharmacology, and in 2005 \_\_\_\_\_<sup>2</sup> master's degree at New York University and licence to practise pharmacy in the United States. \_\_\_\_\_<sup>3</sup> clinical methodology. As far as this project goes, I am the clinical trial manager \_\_\_\_\_<sup>4</sup> and am supported by two clinical research associates, who will work with test centres in northern Italy and in Slovenia. \_\_\_\_\_<sup>5</sup> about three years and \_\_\_\_\_<sup>6</sup> 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. \_\_\_\_\_<sup>1</sup> Charley Wu, and \_\_\_\_\_<sup>2</sup> plant manager at our manufacturing plant in Shanghai. I was also born and raised in China. I first \_\_\_\_\_<sup>3</sup> line worker and \_\_\_\_\_<sup>4</sup> to packaging technician. I later studied in the UK and \_\_\_\_\_<sup>5</sup> an MSc in Engineering there. More recently, \_\_\_\_\_<sup>6</sup> in the initial conceptual design phase, and at present \_\_\_\_\_<sup>7</sup> 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 \_\_\_\_\_<sup>8</sup> 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: \_\_\_\_\_



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

- |   |  |   |                                |
|---|--|---|--------------------------------|
| 1 | <input type="checkbox"/> Iris is to place all job ads for clinical research associates in trade journals | a | by Friday.                     |
| 2 | <input type="checkbox"/> Walter is to prepare a progress report on his work on the other dosage forms    | b | within the next two weeks.     |
| 3 | <input type="checkbox"/> Department heads are to estimate the time needed for their department's work    | c | by the beginning of next week. |
| 4 | <input type="checkbox"/> Charley is to describe the technical equipment needed with a cost estimate      | d | before the next meeting.       |
| 5 | <input type="checkbox"/> Harvey is to work out the timelines, milestones, and budgeting                  | e | by the end of next month.      |
| 6 | <input type="checkbox"/> 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

---



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

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

## JOB TITLE – CHEMIST



## DESCRIPTION

CRO \_\_\_\_\_<sup>1</sup> someone to co-ordinate and perform analytical testing for stability studies of new products. You \_\_\_\_\_  
 \_\_\_\_\_<sup>2</sup> review data in accordance with Good Manufacturing Guidelines.  
 You will be \_\_\_\_\_<sup>3</sup> checking laboratory documentation and chemical specifications. It is \_\_\_\_\_<sup>4</sup> 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 \_\_\_\_\_<sup>5</sup>, an MSc is \_\_\_\_\_<sup>6</sup>.
- You should have at least three \_\_\_\_\_<sup>7</sup> 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



-3073-

**Research**

**Development**

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**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?**

.ცემოკაბიზენიკი" ს. ლტე

## 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.

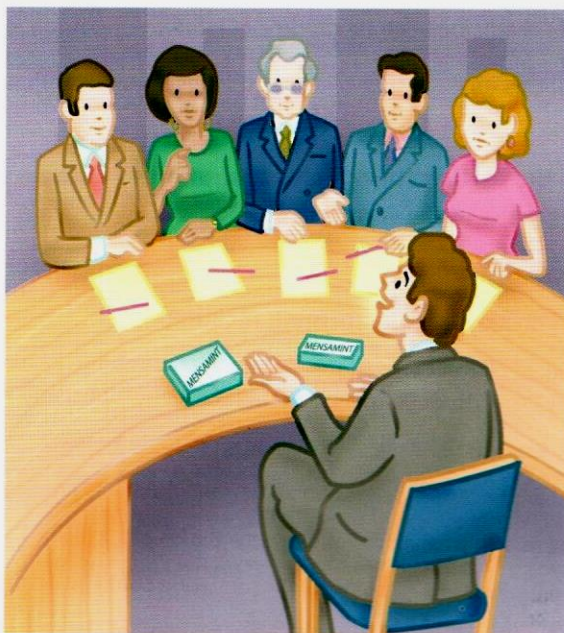
- 1 What is the meeting about, and what needs to be discussed? \_\_\_\_\_
- 2 What kind of product is *Mensamint*™? \_\_\_\_\_
- 3 What do patients have to do to obtain it? \_\_\_\_\_
- 4 What are the dosage forms of this product? \_\_\_\_\_
- 5 Are there any known side effects? \_\_\_\_\_





**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.





**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 (X).**

- 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.**

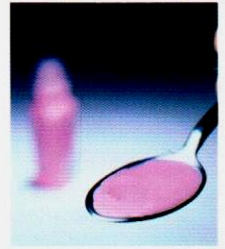
dosage • drops • patch • pills • suppository • syrup • tablets



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.





- 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

- Total number of in-hospital patients surveyed (a) \_\_\_\_\_
- Male patients (b) \_\_\_\_\_ Female patients (c) \_\_\_\_\_
- Average patient age (d) \_\_\_\_\_
- 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) _____
- 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) _____
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**topical dosage forms**

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

**other dosage forms**

nasal spray _____	eye drops _____	suppository _____
-------------------	-----------------	-------------------
- 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) _____
- Do the patients have any suggestions for other future forms of medication? List all suggestions here: \_\_\_\_\_
- 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 <input type="checkbox"/> aerosol     | a A very small amount of liquid that forms a round shape.           |
| 2 <input type="checkbox"/> drops       | b An smooth, thick substance to rub on the skin for healing.        |
| 3 <input type="checkbox"/> inhaler     | c An oily liquid to rub on painful body parts to reduce pain.       |
| 4 <input type="checkbox"/> liniment    | d A medication on material or cloth placed on the skin.             |
| 5 <input type="checkbox"/> ointment    | e A small, round piece of medicine to be swallowed without chewing. |
| 6 <input type="checkbox"/> patch       | f A container with a liquid that is administered in spray form.     |
| 7 <input type="checkbox"/> pill        | g A liquid in which another substance has been dissolved.           |
| 8 <input type="checkbox"/> solution    | h A solid medicine which melts slowly in the rectum or vagina.      |
| 9 <input type="checkbox"/> suppository | i A sweet, liquid medicine taken with a spoon or cup.               |
| 10 <input type="checkbox"/> 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 Files 2.ppt  
 Partner B Files 2.ppt

## OUTPUT

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

## How many drug categories do we need?

**O**n 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. ■

### 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?



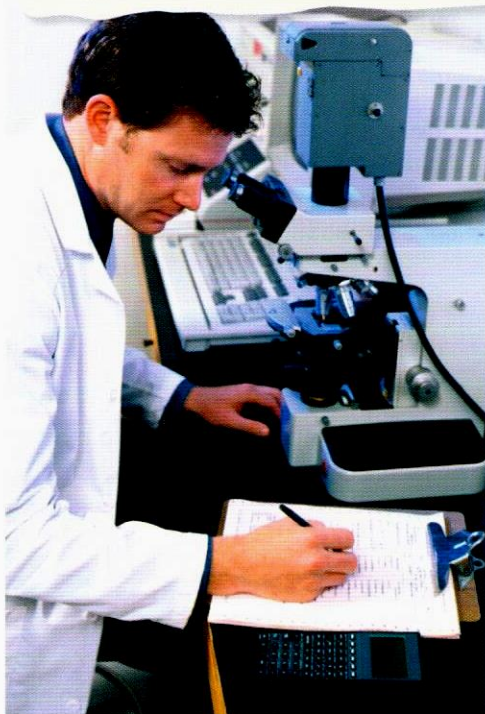
## 3

## 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 not 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 (EMA) 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



– 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 <input type="checkbox"/> You state the reason for a memo.                     | a Please send us ...  |
| 2 <input type="checkbox"/> You state the objective of a course of action.       | b This memo is to advise you that ...                         |
| 3 <input type="checkbox"/> You say the planned schedule.                        | c Our goal is to ...  |
| 4 <input type="checkbox"/> You ask for verification of some information.        | d The laboratory procedures will be reviewed ...              |
| 5 <input type="checkbox"/> You need to have a copy of something.                | e Please confirm ...  |
| 6 <input type="checkbox"/> You say which department in the company is involved. | f Please make sure that ...                                   |
| 7 <input type="checkbox"/> You say what areas will be audited.                  | g The lab management department is scheduled for an audit ... |
| 8 <input type="checkbox"/> 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 \_\_\_\_\_<sup>1</sup> 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 \_\_\_\_\_<sup>2</sup> 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 \_\_\_\_\_<sup>3</sup> 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. \_\_\_\_\_<sup>4</sup> is to identify and correct any quality system defects and to assure compliance with industry standards, especially for laboratory procedures.

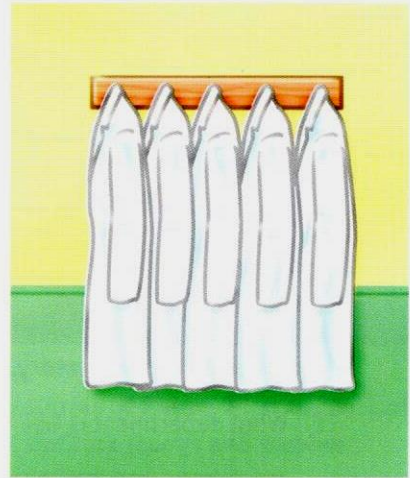
\_\_\_\_\_<sup>5</sup> receipt of this memo and \_\_\_\_\_<sup>6</sup> a copy of all your correspondence with regard to this scheduled audit.





## 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 (X)?

- 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 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**

<b>Purpose and area description:</b>	Annual audit of safety procedures in all laboratories
<b>Major facts:</b>	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.
<b>Observations:</b>	<ul style="list-style-type: none"> <li>a) Six laboratory technicians wore unsuitable clothing and safety equipment.</li> <li>b) One lab assistant did not wash her hands after a procedure involving mice.</li> <li>c) Times of the experiments were not entered on two of the daily lab reports.</li> <li>d) Mice were transported in open cages (in public) to a second lab.</li> <li>e) Improper disposal of toxic waste material was recorded.</li> </ul>
<b>Follow-up:</b>	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**

- 1  improper clothing/safety equipment
- 2  improper hygiene after handling animals
- 3  improper documentation
- 4  improper transportation of lab animals
- 5  improper disposal of toxic waste

**Auditors' observations**

- a chemicals found in normal waste bins
- b lab mice moved outdoors in open cages
- c safety gloves too big, no safety goggles
- d no recording of experiment times
- e hand-washing or sanitizing forgotten

**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.

**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.**



- 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 (EMA), 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.	<input type="checkbox"/>	<input type="checkbox"/>
2 Many people don't realize that animal trials are required by law, before testing in humans can take place.	<input type="checkbox"/>	<input type="checkbox"/>
3 Test animals often have better conditions than farm animals.	<input type="checkbox"/>	<input type="checkbox"/>
4 Participating in clinical trials is a good way to earn some extra money.	<input type="checkbox"/>	<input type="checkbox"/>
5 I wouldn't like to risk my health as a subject in clinical trials.	<input type="checkbox"/>	<input type="checkbox"/>
6 Heavy drinkers are more at risk than subjects in clinical trials.	<input type="checkbox"/>	<input type="checkbox"/>
7 Volunteers make a big contribution to the field of medicine, no matter what their motivation is.	<input type="checkbox"/>	<input type="checkbox"/>
8 If I were seriously ill, I would definitely take part in a clinical study. It could be my last hope!	<input type="checkbox"/>	<input type="checkbox"/>



**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 \_\_\_\_\_<sup>1</sup> 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 \_\_\_\_\_<sup>2</sup> 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 \_\_\_\_\_<sup>3</sup> 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, \_\_\_\_\_<sup>4</sup>, quality, and potency – of the drug's \_\_\_\_\_<sup>5</sup> 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.