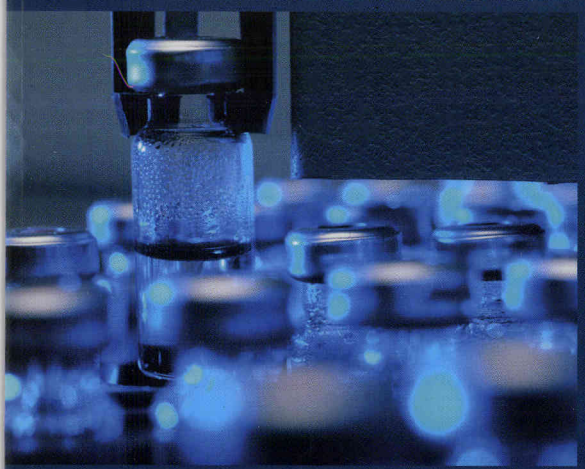
OXFORD Business English

English for the **Pharmaceutical Industry**

Michaela Bücheler, Kathy Jähnig,
Gloria Matzig & Tanya Weindler

EXPRESS SERIES



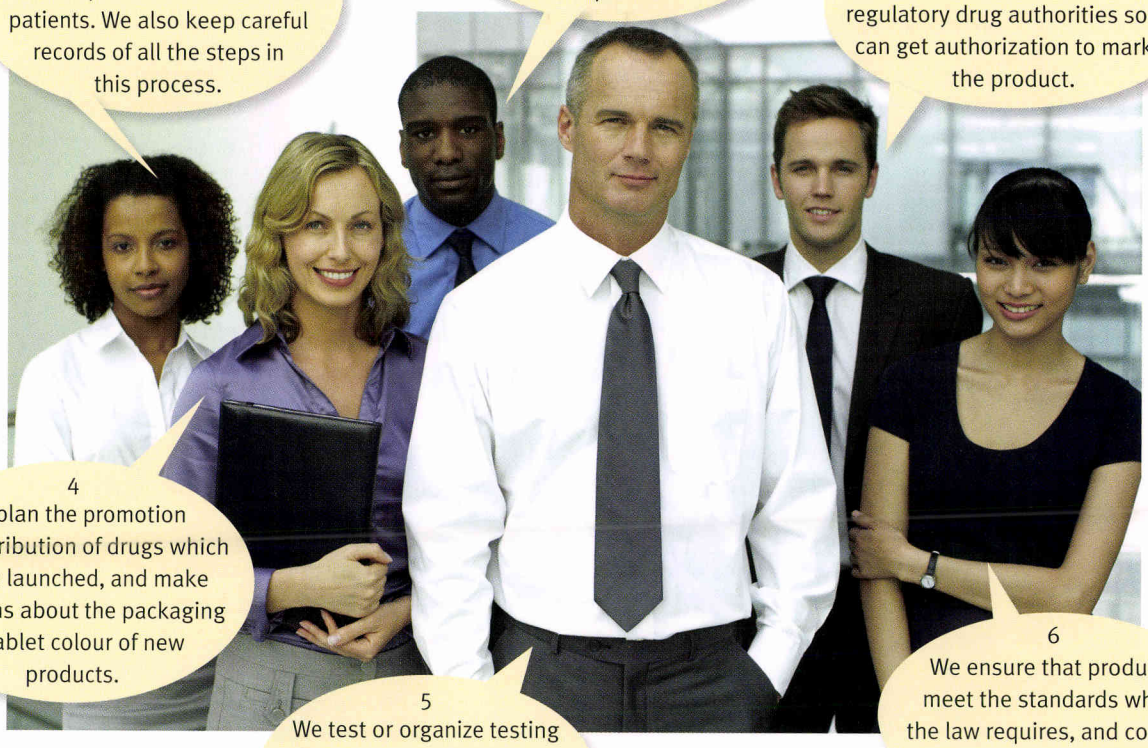
Includes MultiROM

OXFORD

Table of contents

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 (✗)?

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.

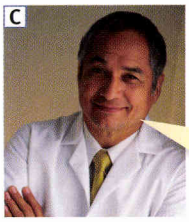
A

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?