

# Pharmaceutical careers for doctors *in the UK*





# 1 Foreword

Medical advances in the last century have helped us all live longer, better lives. The pharmaceutical industry has been at the forefront of innovation throughout that time and is now pioneering new treatments for hard-to-treat diseases. But it isn't just researchers in laboratories that have made that possible; translating those scientific discoveries into tangible improvements for patients is also due to doctors in clinical practice and doctors in the industry.

Our industry is one that relies on the passion and commitment of its people. In return for the expert knowledge that doctors bring to our companies, the pharmaceutical industry offers a wealth of possibilities. From driving technology to make better medicines to using your experience to make sure medicines are safe, there's never been a better time to join and make a difference to real peoples' lives.

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## 2 Introduction

The UK has a vibrant and successful research-based pharmaceutical industry which plays a leading role in a global industry researching, developing and launching new medicines for patients worldwide. Globally, there are more than 7,000 new medicines in the pipeline<sup>1</sup>, with UK-based scientists at the heart of global drug discovery.

However, the success of the pharmaceutical industry does not rest solely on the shoulders of research scientists. There are many opportunities and challenges on offer for doctors who wish to help advance our collective understanding of disease and help develop life-saving medicines for patients.

There is often very little exposure to pharmaceutical medicine – the specialty concerned with the research and development of medicines – during medical undergraduate education or postgraduate training. It is often only after postgraduate clinical training that many doctors even consider a career move into the pharmaceutical industry.

There is surprisingly little information provided about pharmaceutical medicine. Many doctors' understanding may be influenced by limited interactions with the pharmaceutical

industry through medical representatives, by having undertaken an industry placement or through their work on clinical trials.

This booklet aims to highlight some of the roles available to doctors and show the important work that medical practitioners - as pharmaceutical physicians – carry out in the UK's pharmaceutical industry. There are currently about 1,200 doctors in the UK who are members of the Faculty of Pharmaceutical Medicine<sup>2</sup> and there is a plethora of different roles for those interested in working in this future-focused industry.

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<sup>1</sup> 'Pipeline review of innovative therapies – summary deck', EFPIA, March 2017

<sup>2</sup> 'The Faculty of Pharmaceutical Medicine – Foundation, function and future', Boyd A, Cottam B, Obiora K, et al. *Journal of Medicines Development Sciences*, 2017



## 3 The UK pharmaceutical industry

The UK Life Sciences industry is a major contributor to the UK economy; in 2015 alone it contributed £30.4bn in GDP. The pioneering employees within the pharmaceutical (the largest part of the Life Sciences industry) research, develop, manufacture and market life-saving medicines for both people and animals.

Most doctors within the industry – so called ‘pharmaceutical physicians’ – are employed in areas of human medicines and work arm-in-arm with subject-experts to research and develop everything from first-in-kind cancer treatments and game-changing vaccines to over-the-counter pain relief.

Medicines often start life as projects in a research-based pharmaceutical company. The UK has over 660 bio-pharmaceutical companies<sup>3</sup> carrying out medicines research that may change the lives of millions of patients worldwide; it is no wonder the UK is seen as a renowned global hub for research and development (R&D).

The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based bio-pharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. The ABPI represents companies who supply more than 80 per cent of all branded medicines used by the NHS. It is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

The pharmaceutical industry invests huge sums in the research and development of treatments for cancer, heart disease, neurological diseases, arthritis, AIDS and many other conditions for which there are currently no adequate treatments.

The process of finding a new medicine is lengthy, complex and expensive. During the early research phase between 5,000 and 10,000 potential compounds can be screened, only for about 250 to go into the pre-clinical phase<sup>4</sup>. Even fewer go on to become an effective medicine.

Bio-pharmaceuticals is a highly regulated industry: rules and regulations cover every stage of a medicine’s development cycle from early R&D and manufacturing to clinical safety monitoring and marketing. Before a medicine can be marketed in the UK, it must be granted a ‘Marketing Authorisation’ by the European or UK regulatory authority; the European Medicines Agency (EMA) or the Medicines and Healthcare products Regulatory Agency (MHRA) respectively. Marketing Authorisation shows that a medicine has demonstrated appropriate efficacy, safety and quality.

The future relationship between the UK and the European Union in medicines regulation is as yet unknown. For the mutual benefit of patients and industry in the UK and the EU, the UK should seek to negotiate alignment and commonality with the EU for the regulation of medicines.

The approval process for new medicines in the UK is robust. The International Conference on Harmonisation (ICH), made up of Europe, the USA and Japan, works to achieve consistent international standards for various regulatory processes including Marketing Authorisations, clinical development, safety monitoring and manufacturing. ICH standards are recognised globally and applied internationally by many additional countries.

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3 PwC UK, “The Economic contribution of the UK Life Sciences industry”, 2017

4 ‘THE PHARMACEUTICAL INDUSTRY AND GLOBAL HEALTH: Facts and Figures 2017’ IFPMA, 2017

## How medicines are developed and licensed

Initial research on new compounds is carried out in the laboratory, using a wide variety of techniques. It is a legal requirement that all medicines must be studied in animals before they can be used in patient clinical trials. While we know more about the human body than ever before, some medicines behave unpredictably and cannot be studied by computer modelling or in test tube studies. Clinical assessment in humans follows a sequence of phases or uses adaptive design to modify these phases as trials progress.

**Phase I:** a non-therapeutic, exploratory trial in a small number of volunteers who may be healthy or have a specific disease. In contrast to later phase studies, subjects can usually expect no therapeutic benefit from a Phase I trial. These studies determine some aspects of how the medicine works in humans and help establish the dosage of the medicine.

**Phase II:** a small number of patients with the condition are given the medicine to assess both that it works and that it does not produce unacceptable side effects.

**Phase III:** many more patients, perhaps several thousand, take the medicine under supervision for an appropriate period. It is tested in comparison with an established or 'gold standard' treatment and/or placebo. These studies are then used to establish the efficacy and safety of the new medicine. If the results prove satisfactory in terms of quality, safety and efficacy, the data gathered is presented to medicines regulatory agencies. Provided the authorities are satisfied by the evidence, a Marketing Authorisation is issued.

**Phase IV:** the newly licensed medicine is studied in large numbers of patients to characterise how it is used in the real world and to look for rare side effects. In the near future, these studies will be increasingly used to further characterise elements of efficacy in the real world.

Post-Authorisation Safety Studies (PASS) are often initiated after the medicine has been made available for doctors to prescribe to help to identify any unforeseen side effects. These studies may involve many thousands of patients. Post-Authorisation Efficacy Studies (PAES) may also be increasingly used in future.

Medicines are tested continuously even after launch to ensure safety and efficacy. Electronic databases, such as GP databases, are also used to identify safety issues associated with medicines, and data collected can be used to investigate how medicines are used in the real world.

- The pharmaceutical industry invested £4.2 billion in UK R&D in 2015 – more than £11.5 million every day<sup>5</sup>.
- On average, the global industry invests £120 billion into R&D.
- The UK pharmaceutical industry contributes £30.4 billion a year in GDP and £8.6 billion in taxes<sup>6</sup>.
- In the UK, the industry employs around 62,000 people (3), including over 2,000 doctors<sup>7</sup>.
- Pharmaceutical exports generated a trade surplus with the rest of the world of £1.1 billion in 2014<sup>8</sup>.

<sup>5</sup> Office of National Statistics. Statistical bulletin (ed RandD) 42 (ONS, London 2016)

<sup>6</sup> 'Open for Innovation: UK Biopharma R&D Sourcebook 2016', ABPI and Clarivate Analytics 2016

<sup>7</sup> The Pharmaceutical Physician, BMA, September 2016

<sup>8</sup> HM Revenue and Customs, UK Trade Info, February 2014

## 4 The medical work of pharmaceutical physicians

“I joined the pharmaceutical industry because I was interested in a career in clinical research. I have not been disappointed! I enjoy collaborating with statisticians, clinicians, scientists and regulators to design and conduct efficient and feasible clinical trials, helping to bring new medicines to the market that will benefit patients. There is a different challenge every day!”

**Dr Susan Tansey, Vice President & Global Head of Medical Strategy & Science at QuintilesIMS. 2016 – Present**

“After a successful career in general practice I was looking for a different career option where I could challenge myself to build on transferable skills relating to knowledge of medicine, patients and healthcare, as well as working in a truly cross-functional, collaborative, ‘can do’ environment.

“The pharmaceutical industry seemed like an obvious choice and has never disappointed, offering a wide range of career and professional development opportunities, from an academic, people-management, leadership and medical specialty development perspective, whilst all the time allowing me to pursue my drive to work in the best interests of patients.”

**Dr Andrew Webb, Medical Director UK, Ireland and Nordics at Almirall. 2017–Present**

**Medicines development is the process of formulating, testing and evaluating a potential new medicine as it moves from the laboratory to the clinic. Chemists, biologists and pharmacologists with a research science background usually undertake early research.**

Physicians who work in the pharmaceutical industry undertake many roles. Apart from those who go on to careers in general management, it is their competency in medicine that is crucial to their ability to perform their job to the high standards required.

While it is common for doctors to seek a career in industry four to five years after obtaining their medical degree, others join after training in a medical specialty or in general practice to obtain the Certificate of Completion of Training. The increasing complexity of research in the modern pharmaceutical industry has created a demand for physicians with substantial research experience; for example, those with a medical degree and a BSc, MSc, PhD, MD or equivalent.

The following examples illustrate a number of areas with a clinical or medical focus in which physicians are employed within the pharmaceutical industry.

### Working at the frontier of knowledge

The decoding of the human genome has given rise to a once-in-a-lifetime opportunity to devise therapeutic agents with completely novel actions. One of the central problems is establishing a connection between a novel gene and a disease process – research known as target validation. An intimate knowledge of the human disease process and its pathophysiology is essential and a physician scientist with both clinical and research training will have the critical skills necessary for this research

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## First-in-human studies

Before first administration to humans, the relative safety of a new medicine must be assessed. This requires expert knowledge of both the specific medicine and of clinical medicine more broadly. The decision to move a potential medicine into humans is taken by a company Safety Board, on which senior pharmaceutical physicians sit.

The first administration of a new medicine is usually carried out in a clinical pharmacology unit within a pharmaceutical company or, more commonly, by a contract research organisation (CRO) working on behalf of the sponsoring company. These studies are usually conducted on healthy volunteers whose mental and physical health is assessed by pharmaceutical physicians prior to the study. The dose of the medicine is progressively raised, whilst careful assessments of its actions and tolerability are undertaken. This is highly responsible medical work and is carried out by physicians with specific training in this area.

Subsequent clinical work is conducted in patients and this is where the first evidence of clinical efficacy is likely to emerge. Pharmaceutical physicians work with clinical investigators while the study is conducted in an academic medical centre.

## Protocol design and review

The pharmaceutical industry overwhelmingly spends more on health research in the UK than any other sector. At £4.2 billion (or 48% of total expenditure), it edges out higher education (£2.71 billion, 32%) and public sector research institutes (£1.3 billion, 15%)<sup>6</sup>.

Pharmaceutical physicians are responsible for the inclusion or exclusion criteria that apply to patients taking a new medicine, decisions on the measurements to be made, the dose of the medicine and safety monitoring procedures. The design of trial protocols, in collaboration with clinical investigators and regulatory teams, is highly demanding work. It involves a considerable level of skill and clinical knowledge and is all done despite the pharmaceutical physician rarely meeting the patients in the trial.

## Regulatory affairs

The pharmaceutical industry is highly regulated by authorities such as the MHRA, the EMA and the Food and Drug Administration (FDA). Doctors within the pharmaceutical industry play a crucial role in interacting with these agencies during medicine development – for example, in protocol development and regulatory strategy, discussing product labelling prior to approval and formulating advice to prescribing doctors after approval. Pharmaceutical physicians may also work for a regulatory agency. Doctors working for both industry and regulators continue to monitor a medicine while it is being prescribed to patients, and as more is understood about how a medicine is used in the real world, to ensure efficacy and safety.

## Safety assessment

All medicines have a benefit/risk balance. Some adverse effects may be predicted early on in a medicine's development cycle from its pharmacology profile, while others are completely unexpected. Medicines are, therefore, closely monitored during clinical development and throughout the time the medicine is prescribed to patients.

An aspect of a pharmaceutical physician's role is to recognise problems quickly, whether the company, patients or regulators detected them, and determine what course of action is required. This includes following up with a causality assessment of individual cases, analysis of individual or very large numbers of adverse events, designing pharmacoepidemiological studies, and contributing to the design of risk-minimisation measures and other elements of risk management.

These physicians work closely with many other company functions to ensure appropriate safety monitoring and patient protection during medicine development and throughout the time the medicine is prescribed. These decisions also take place within a legal framework. It is a requirement that adverse reactions are reported to the regulatory authorities within strict timelines and that reports – summarising safety and risk management plans – are produced regularly.

### Clinical work in hospital or general practice

Some pharmaceutical physicians in industry have regular, part-time clinical appointments, usually assisting in an outpatient clinic in a specialty in which they have a particular interest or in a General Practitioner's office. A smaller number of physicians have a joint appointment, sometimes at consultant level, between a hospital and a pharmaceutical company or contract research organisation.

### The interface with company senior management

Senior managers in the pharmaceutical industry, some of whom do not have a medical background, rely on having high-quality medical advice from doctors about a whole range of clinical challenges and medical issues. These situations can range from a decision to invest in exploring a new clinical indication for an established medicine, to taking critical decisions, such as withdrawing a major medicine from patients on the grounds of safety.

The clinical judgment of a pharmaceutical doctor is vital to management. Medical registration with the General Medical Council requires doctors to comply with Good Medical Practice, which includes responsibilities for ensuring patient safety.

### Commercial issues

Pharmaceutical doctors play a role in commercial policy and in identifying opportunities as well as overseeing ethical, legal and self-regulatory codes of practice, including the ABPI Code of Practice. As part of this, they must decide whether the company's advertisements and promotion for a medicine conform to the licensed indications.

### Legal responsibilities

A major responsibility of all pharmaceutical physicians is to ensure that activities and procedures relating to the development and marketing of medicines are conducted according to EU laws, which currently regulate pharmaceutical products in the UK. The basic rules contained in European law (including Directives and Regulations) are binding on EU Member States and are implemented into UK law through the Human Medicines Regulations 2012.

An extensive and complex regulatory framework governing the development, manufacturing, sale, supply, promotion, import, export, licensing and safety monitoring of medicinal products exists. As the UK begins negotiating its exit from the European Union, both sides should seek alignment and commonality on the regulation of medicines.

### ABPI Code of Practice responsibilities

The ABPI Code of Practice, company internal policies and standard operating procedures (SOPs) may require that certain duties must be conducted or approved by a registered medical practitioner.

For example, the ABPI Code of Practice, operated and administered by the Prescription Medicines Code of Practice Authority (PMCPA), requires that the final form of any promotional material be certified by either a registered medical practitioner or a pharmacist registered in the UK. This is part of the self-regulatory framework that the industry has in agreement with the Department of Health, MHRA and others.

## Other responsibilities

Regulatory agencies require that companies comply with their standard operating procedures (SOPs) and implement severe penalties if they fail to do so. As an example, one typical company's SOPs require the signature of a registered medical practitioner on the following documents:

- Clinical trial protocols and amendments
- Clinical study report
- Clinical investigators brochure
- Authorisation of 'named patient' supplies of medicines
- 'Dear Healthcare Professional' and 'Dear Investigator' letters
- Case narratives e.g. adverse drug reaction reports
- Case reviews where patients become pregnant during clinical trials
- Major medical decisions about suspension of a clinical trial, withdrawal of a medicine
- Safety board review before first administration of a new medicine in humans
- External documents with medical content, to ensure accuracy and consistency

The signature on a clinical expert report for a regulatory agency must be from a suitably qualified and experienced person.

The day-to-day work of a pharmaceutical physician often involves medical and clinical activity even without bedside contact with patients. As the scientific and medical basis of drug discovery and development has grown more complex so, too, has the level of clinical knowledge required by pharmaceutical physicians. To maintain a high level of expertise, pharmaceutical physicians need to have in place, and to maintain, appropriate scientific exchange between industry, academia and clinical medicine.

As outlined previously, some companies allow their medical staff to hold a clinical assistantship or lecturer's post, usually on the basis of a half-day session per week. The benefit of this to the company comes from continual professional development of the pharmaceutical physician's clinical expertise.





## 5 Roles of doctors in Industry

The pharmaceutical industry typically employs doctors in very distinctive roles which can be related broadly to the medical responsibilities described above. Each role requires appropriate qualifications. Larger companies often employ specialists while, in smaller companies, some or all of the roles may be combined in a smaller number of posts.

### Medical affairs physician/ medical adviser

Once a compound is licensed for marketing, it enters the company's portfolio of medicines available for prescription by clinicians. The new therapeutic product is first adopted for regular use by academic and clinical opinion-leaders, followed by broader acceptance by hospital consultants and, eventually, general practitioners.

Medical advisers are tasked with identifying how the medicine will be used in clinical pathways which will involve discussion with clinical experts. The company will prepare appropriate information packages to support the medical profession as they use the medicine. The company will also organise clinical meetings and symposia, as well as monitor the product's progress in clinical use through a Phase IV clinical research programme.

These studies can involve thousands of patients, often in different locations around the world, and have an emphasis on establishing and monitoring the safety profile of the medicine. Specific post-marketing surveillance observational studies track the product's safety in clinical use amongst patients.

As part of this life-cycle management of the product and the continuing understanding of its scientific profile, the company will consider developing new indications, applications and dosage forms. This is undertaken whilst maintaining a close watch on competitor companies and products.

A medical affairs physician's task is to understand and interpret the scientific and clinical background of a medicine in order to translate it into clinical reality for the benefit of company colleagues, health technology assessors, National Institute for Health and Care Excellence (NICE), NHS

budget-holders, prescribers, dispensers and patients. This includes ensuring all marketing and sales resources are in line with the medicine's licence and the ABPI's Code of Practice.

Medical affairs physicians have a diverse role which requires an appetite for commercial involvement, a strong sense of ethics and the ability to work in a team. Their career will vary according to a company and its product portfolio. A company with specialist hospital products, for example in oncology, is likely to be looking for doctors with a specialist background whilst a company with a broad portfolio of GP products is likely to be looking for generalists.

### The medical strategist

This role is one which suits a senior consultant or specialist with a wide range of experience in clinical and pharmaceutical medicine. The individual will probably have 10 or more years of experience in the clinic followed by a further 10 years or so in a range of positions in industry. The doctor will almost certainly work at the company's worldwide headquarters.

A medical strategist works either single-handed or, more likely, as a member of a multi-disciplinary, long-term planning group. The strategist's role is to have a vision of the future of clinical medicine and to help convert this into a practical strategy for execution by the research and development division.

Increasingly, technology enables the industry to design – as well as discover – therapeutically useful compounds. The medical strategist's role is to lead the company into more promising fields; areas of unmet medical need with a view to success **over a period of between five and 20 years.**

### The clinical pharmacologist

In this type of role, the clinical pharmacologist will often have a background as a research registrar or senior lecturer who wishes to move from clinical or academic medicine.

The clinical pharmacologist's role is to characterise the activity of a new medicine using all physiological or psychological measures to understand its mechanism of action in humans, characterise its metabolism and kinetics, and ensure and monitor its safety at a given dose. There will be continuing close co-operation with the research division's pharmacologists and toxicologists throughout.

The most challenging ethical decision that the medical, research and development teams must take is to decide whether to progress testing into humans for the first time (Phase I). In Phase I development, this work is usually done with non-patient volunteers: healthy people who do not anticipate any therapeutic benefit from taking the medicine. Clinical pharmacologists in industry often have a clinical track record in specific therapeutic areas which would otherwise qualify them for a consultant post or professorial chair.

Once a compound is in Phase II development, the work shifts from company, CRO or hospital laboratories to the clinic where the medicine will be administered for the first time to patients anticipating therapeutic benefit. To undertake this work in the UK, a company needs external co-operation and consent from the:

- Regulatory Authority that licenses the clinical trials
- Research Ethics Committee
- NHS
- consultant or other physician caring for the patients concerned and their team
- patients; usually few in number and who will be subject to intensive monitoring of many clinical and physiological variables

In Phase II, the pharmaceutical physician is unlikely to be involved in the clinical work. This is delegated to the staff of the investigating centres. The Phase II work effectively repeats and expands Phase I but it also seeks to confirm that the compound works as anticipated from pre-clinical and Phase I studies, and has (or does not have) the potential to provide clinical benefit.

The pharmaceutical physicians concerned are still involved

in research, working largely with academic colleagues and support staff. Their experience and interests should be equal to those of the Phase I physician but with the added experience of management and diplomatic skills enabling them to manage multi-disciplinary projects through other people.

### The clinical research physician

Following pre-clinical Phase I and early Phase II research, a decision will be taken as to whether to extend the Phase II work into Phase III clinical trials. The aim then is to satisfy the company, the regulatory authorities – and, later, the Health Technology Assessment agencies, the medical profession and patients – that the new medicine is effective and appropriately safe in the chosen indications and formulations.

In almost all therapeutic fields this means conducting studies in large numbers of patients (between 2,000 and 5,000 people) over a longer period of time so that the therapeutic hypotheses may be better investigated. Phase III clinical trials are usually conducted at an international level where company-headquartered physicians delegate the work to local subsidiary companies; their medical teams have the best understanding of national clinical needs and what is feasible.

Generally, there will be a 'core programme' of clinical studies, the results of which can be used to achieve product registration in many countries around the world. These results might be coupled with local programmes conducted to satisfy specific national regulatory requirements, or to test specific formulations or routes of administration relevant to the clinical preferences of the medical culture concerned.

Effects may be seen for the first time in Phase III trials when large, long-term statistical data become available. As registration approaches, important financial decisions are made in other parts of the organisation such as considerations for building new manufacturing factories, the preparation of marketing plans (including reimbursement discussions/planning), the production of medical literature and the training of personnel.

For Phase III trials, the pharmaceutical industry needs clinical research physicians whose skills with people (negotiating, distance-management and diplomacy), practical clinical experience and ability to bring in results on time, complement their academic achievements and research skills bring life-changing medicines to patients.

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## Pharmacovigilance and post-marketing surveillance

Many pharmaceutical physicians work in medicines safety in pharmacovigilance departments within companies or regulatory authorities. The work includes assessment of individual cases through to monitoring of, and alertness to, safety issues which could affect the assessment of a medicine's risks and benefits.

## Physicians in Contract Research Organisations

In the past 10 to 20 years, pharmaceutical companies have increasingly started to contract out their clinical trials to contract research organisations (CROs). This has led to more roles for pharmaceutical physicians in these organisations, in jobs which encompass most of those described above – medical strategists, clinical pharmacologists and clinical research physicians.

The diversity of roles is because all phases of clinical trials' work can be contracted out plus the size of the sponsor company can vary from a small, emerging biopharma company, without their own physicians, to a major pharmaceutical company with many internal physicians.

Where companies have their own physicians but have outsourced studies, CRO physicians liaise with the sponsor physician. For some smaller companies, the CRO physician might take on the role of Chief Medical Officer and/or be required to advise on strategy, such as organising clinical development plans and participating in discussions with regulators.

CROs vary in size with the larger ones assisting in the conduct of Phase I trials as they have their own clinical pharmacologists. These CROs will also have their own pharmacovigilance departments with roles for physicians similar to those in pharmaceutical companies. The main difference is that the CRO physician is likely to work on several products in a specific therapeutic area rather than on one product through its entire clinical development, as is more usual in pharmaceutical companies.

CROs usually expect a physician to be a specialist in a particular therapeutic area – for example, infectious disease – and hold a CCT (Certificate of Completion of Training) or equivalent. Smaller CROs or consultancies may recruit

physicians who have not necessarily completed specialist training and their physicians may be expected to work on studies in various therapeutic areas.

CRO physicians can also get involved in business development activities, particularly if working in a more strategic role. These activities include bidding for clinical work which could involve reviewing clinical trial proposals that are received and advising on the medical strategy needed to successfully plan and conduct those clinical trials. The input required will vary considerably depending on the sponsor company and their internal expertise. These strategic roles ensure that medicines get to patients in ever more effective ways.

## Other medical roles

In larger pharmaceutical companies there are also opportunities for doctors to specialise in specific areas.

**Pathology:** Work is usually in the biological sciences sector of the research division and typically as part of the toxicology department.

**Vaccines:** The development and testing of this specialised group of medicines which make such an impact on public health.

**Paediatrics:** Many sponsor companies and CROs have paediatric committees or councils headed up by a paediatrician. In addition, due to the amount of paediatric legislation in both Europe and the US, there is a demand for paediatric-trained physicians in many clinical development roles.

**Rare diseases:** As with paediatrics, due to the legislation related to orphan drug development and the increased focus on drug development for rare diseases, there are many physician roles in this area of clinical development.

**Medico-legal affairs:** There are potential roles in companies operating in areas that make them sensitive to political, consumer or media influence such as contraceptive medicine, infant nutrition and anti-inflammatory medicines.

**Health economics:** In today's economic climate, both in the UK and elsewhere, there is an emphasis on cost-effectiveness of medicines and value for money by healthcare systems as well as considerations of clinical effectiveness and safety. Doctors can work in specialist teams to help create health economic models and health technology appraisal submissions.

**Medical communications:** Doctors may be required to present aspects of products, pharmaceutical companies or the industry through a variety of channels including the media.

### Entry qualifications and training

The majority of companies require physicians to be licensed with the General Medical Council (GMC) for entry into the industry, particularly in medical affairs roles.

A GMC licence is also a requirement for gaining a certificate of completion of training (CCT) through the pharmaceutical medicine specialty training programme (PMST). Doctors considering a career move to the pharmaceutical industry in the UK should be registered with the GMC as this offers the best chance of gaining a medical role.

To qualify for a CCT through the PMST, it is also essential to have completed a period of clinical training since qualifying in medicine. In the UK, this is a minimum of four years for doctors qualifying from 2005 onwards or three years for doctors qualifying prior to 2005.

Scientific degrees (e.g. BSc, MSc, PhD) are desirable, but not essential, additional qualifications. Postgraduate clinical diplomas and degrees (e.g. MRCP, MRCGP, MD, and MRCS) are also desirable but not essential, unless specifically sought by an employer.

### Education and training in pharmaceutical medicine

Pharmaceutical Medicine has developed as a medical scientific discipline over the last 40 years and, in 1989, the Faculty of Pharmaceutical Medicine (FPM) was established by the Royal Colleges of Physicians. In 2002, pharmaceutical medicine was recognised by the Department of Health and listed as a medical specialty in the UK.

Doctors joining the pharmaceutical industry are encouraged to undertake education and training in pharmaceutical medicine with a view to becoming certified in the specialty. This includes obtaining the FPM's Diploma in Pharmaceutical Medicine (DPM) which recognises a level of knowledge in the discipline.

The full PMST programme is a workplace-centred competency-based programme supported by the Joint Royal Colleges of Physicians Training Board (JRCPTB) and the FPM to standards set down by the GMC. Physicians who gain their CCT in Pharmaceutical Medicine, through the PMST programme, are able to apply for a place on the GMC's specialist register.

The four-year PMST programme is undertaken by doctors employed as pharmaceutical physicians and includes the specialty knowledge base and the Diploma in Pharmaceutical Medicine (DPM). The programme also includes seven modules of training in practical aspects of the specialty in order to demonstrate competency to practise as a specialist. Six of the modules – at least two of which must be undertaken in the workplace – cover medicines regulation, clinical pharmacology, clinical development, statistics and data management, the healthcare marketplace and medicine safety surveillance.

The seventh module covers aspects of interpersonal, management and leadership skills relevant to the practice of pharmaceutical medicine which must also be undertaken in the workplace. PMST is operated within a quality framework and adheres to the standards of Good Medical Practice laid down by the GMC.

For pharmaceutical physicians who wish to specialise in clinical pharmacology as Principal Investigators in Phase I units, the FPM offers a two-year Diploma in Human Pharmacology.

## Professional support

Doctors in the industry have their own professional association, the British Association of Pharmaceutical Physicians (BrAPP) which was founded in 1957 to encourage professional development and organise training for doctors in the industry. BrAPP was instrumental in negotiating the DPM of the Royal Colleges of Physicians in 1976. A committee with the ABPI established a post-graduate training course in pharmaceutical medicine which was transferred to Cardiff University. This two-year course, with five residential sessions each year, covers the FPM's syllabus for Pharmaceutical Medicine in preparation for the DPM examination.

Today there are a number of courses available which cover the syllabus for doctors wishing to take the DPM.

However, no post-graduate course is all-inclusive and participants are encouraged to extend their knowledge by personal study and attendance at relevant courses. The latter, run by bodies such as universities, often offer Masters-level diploma and degree programmes in areas of pharmaceutical medicine plus a number of specialist training programmes for the pharmaceutical and technical industries.

Industry encourages its doctors to attend and participate in the therapeutic area symposia and congresses which enable them to be at the forefront of knowledge in their particular area.

The development of management and communication skills may also be covered in this way, or more formally by in-house or external courses.

Another important aspect of training is practical learning on the job. Instruction from senior medical and technical staff within an organisation is the basis of this, each covering their area of expertise by personal instruction or small group activities.

This includes training and experience in the application of the ABPI's Code of Practice, which is additional to training courses from the PMCPA. Such training and acquired competence in ABPI Code of Practice matters can lead to the recommendation to be the company signatory for certification of promotional and other material falling under the Code and being registered as such with the PMCPA and the MHRA.

## Revalidation

A doctor will be required to engage with the revalidation process if they are undertaking any form of medical practice. UK law currently requires the practitioner to hold a Licence to Practise and/or if the terms and conditions of a doctor's employment require them to hold a Licence to Practise.

Many employers require pharmaceutical physicians to hold a Licence to Practise.

Revalidation for pharmaceutical physicians is supported by the industry and the Faculty of Pharmaceutical Medicine (FPM) recommends that pharmaceutical physicians practising in the UK retain their Licence to Practise. The Faculty has worked with the Academy of Medical Royal Colleges (AMRC), the GMC and the Department of Health to develop the core and specialty-specific standards for revalidation.

The FPM was named as a designated body for revalidation under the Medical Profession (Responsible Officers) Regulations 2010; subsequently, a number of pharmaceutical companies have been named as designated bodies.

Pharmaceutical doctors employed by a company with designated body status would have a prescribed connection with that company for the purposes of revalidation.

Where a doctor in pharmaceutical medicine practice has a prescribed connection with the Faculty-designated body, they may register with the Faculty appraisal and revalidation programme. Once registered with the programme, doctors will have access to the Faculty annual appraisal system, an interactive e-system onto which supporting information can be uploaded and the Responsible Officer service.

The requirements for revalidation of pharmaceutical physicians are broadly the same as for doctors who are in clinical practice in terms of the supporting information that must be produced at the annual appraisal. The exceptions are the requirement to produce evidence of patient feedback (unless the doctor undertakes occasional clinical sessions), and the option to substitute two case studies per annum instead of a full audit.

### Career development

The majority of doctors enter the industry at the basic level of clinical research physician or medical adviser, from which they progress, after two or three years, to a more senior level with varying degrees of project, product and management responsibility. They may progress further to lead a therapeutic area team or to take on more medical management responsibility in the clinical research or medical services area. At this time, they can expect to have been in the industry between four to six years.

However, the point of entry also depends on the experience and expertise of the candidate in question. Physicians have entered into senior roles in industry, for example, having already become respected leaders in their scientific fields.

Career development depends on various factors including opportunities within the company or related part of the industry, the individual's performance and track record, as well as interest, ability and aspirations – not forgetting the competitive element in career progression.

Many doctors move into medical affairs roles where there are many paths to pursue, both locally and internationally. Some remain in clinical development, either as a therapy area or product specialist, or in medical management.

Career development in medical affairs, in clinical development or R&D management, may lead to the post of Medical Director. Routes may involve remaining in the local subsidiary or taking on a more international role.

While many doctors move into commercial positions, some decide to move into regulatory agencies– for example, as medical assessors within the MHRA. This is demanding work in the public sector: scrutinising the dossiers submitted by industry for Marketing Authorisations and ensuring their compliance with national and international legislation, and guidance; and advising the UK Commission on Human Medicines (CHM) or the EU Committee for Medicinal Products for Human Use (CHMP) and other regulatory groups.

This medical assessment work, together with the monitoring of adverse reactions to marketed products as reported by patients or doctors – for example, through the UK Yellow Card Scheme or to the EU level EudraVigilance database or through journal reports – in turn helps to ensure the quality, safety and efficacy of medicines.

A number of doctors in their mid-to-late career in the industry leave companies in order to become consultants in a growing number of fields. Here they can offer scientific, medical and regulatory expertise to areas such as drug development and medico-marketing advice as well as to broader strategic, business, financial and general management aspects of a company or the wider pharmaceutical industry.

Within the industry there are also opportunities to work abroad, either by holding a regional or global role or by relocating to live and work abroad. This can be beneficial in terms of developing a deeper understanding of how a global industry works.



## 6 The doctor as a manager

Just about every medical job in a pharmaceutical company involves its holder in non-medical and managerial responsibilities. The salary and status of doctors in the company reinforce the need for professional, managerial behaviour.

In clinical practice, 'management' used to mean telling patients, nurses and ancillary staff what to do. Now this paternalistic approach has been replaced by an integration of the doctor within the team of healthcare and other professionals. The practice of pharmaceutical medicine invariably involves getting results through working with other people and so matrix management, project management and team participation is crucial.

Doctors in industry should:

- Maintain commitment to company goals by planning, establishing and reviewing objectives, tasks and organisation structures, which will help to meet the company's overall objectives as well as his/her own.
  - Make sure that any activity or act is designed to enhance and maintain the company's image in the marketplace and community, while ensuring patients' interests are protected.
  - Accept responsibility for his/her own work and that of employees and outside appointees such as consultants and clinical trial investigators.
  - Manage all activities in ways which are consistent with the company's employee relations philosophy and policy.
  - Perform regular appraisals/reviews with all subordinates and outside appointees to identify training needs that will improve performance and further individual development.
  - Work in positive and constructive ways with managers and professionals in other departments while maintaining individual ethics, integrity and commitment.
  - Develop high-quality problem-solving skills and make use of the specialist resources both within the company and outside.
  - Ensure their own continued training and development and training so as to maximise their talents in meeting organisation objectives.
- Ensure that the company operates within the spirit and letter of the law on those matters and in those territories for which responsibility is held and accept that those responsibilities can have direct legal implications for themselves.
  - Comply with company rules and procedures as well as operating within codes of practice concerning medical, technical, operational or personnel matters.
  - Recognise that the company has obligations to its employees, suppliers, prescribers, patients, the general public and shareholders. Respect the interests of these groups in the conduct of their work.
  - Manage each area or project under his/her responsibility to ensure: objectives are defined, planned and communicated; that progress is monitored; and the end results are evaluated.

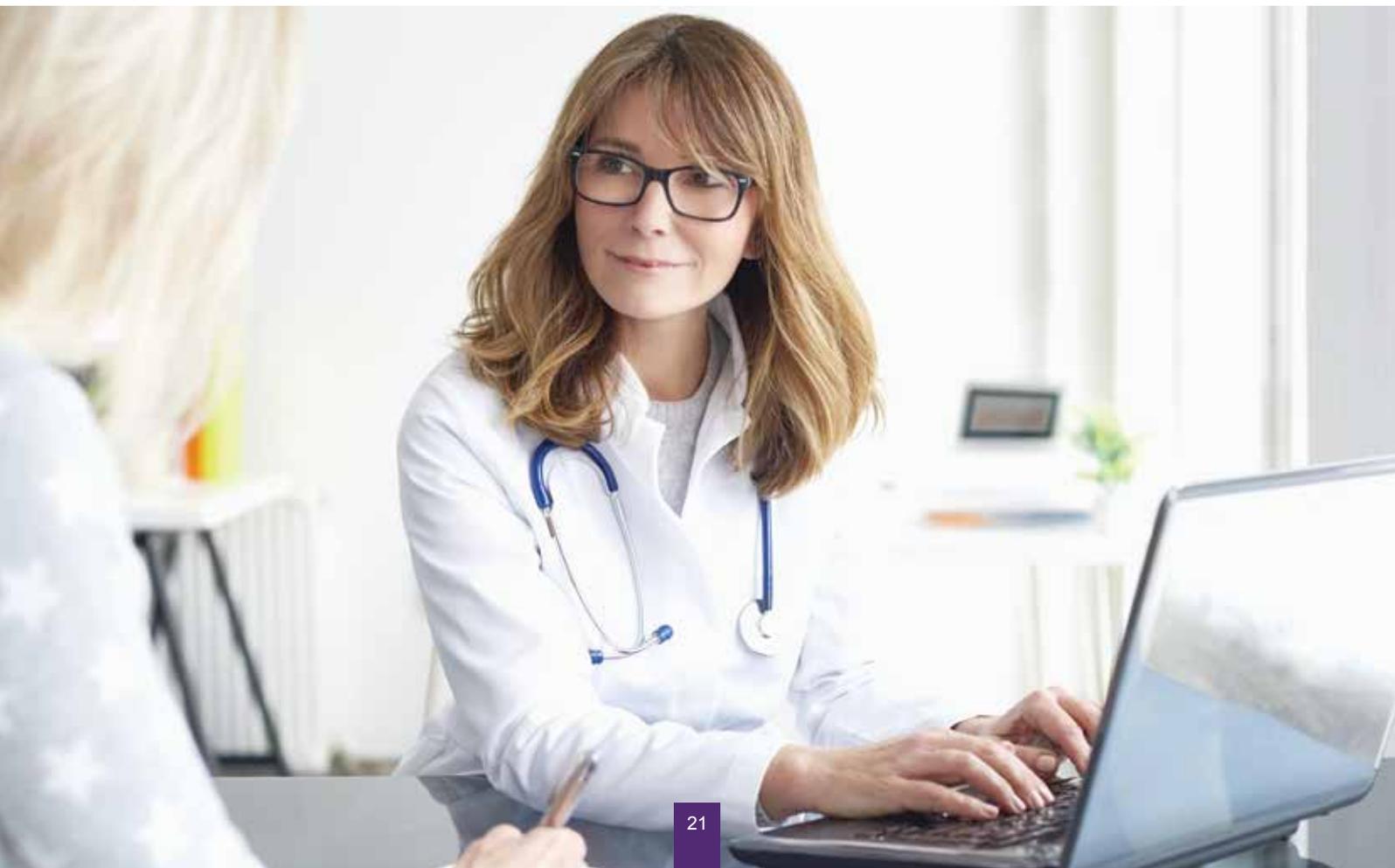
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## 7 Changing direction

Should pharmaceutical physicians wish to change career course in the industry, there are various opportunities to explore. This is where experience of different areas (e.g. pharmacovigilance and medical affairs) can be beneficial.

One possibility is to return to clinical practice or academic medicine. Some doctors reach senior positions in the pharmaceutical industry before deciding to return to clinical practice. This move is not without its challenges; a year or two away from full-time practice gives former peers opportunities to move ahead on short lists for NHS and other clinical jobs. Nevertheless, this move is more than possible, particularly if medical practitioners have kept up associations with medical practice. The holding of a clinical assistant or lecturer's post helps in such instances. Some pharmaceutical physicians decide, after some years of working for a company, that they would prefer to be independent, and set up a consultancy or contract company on their own, or with colleagues.

Other physicians move within companies or in the wider pharmaceutical and biotechnology sector to take up non-medical roles in marketing or general management. To move to these non-medical roles, some physicians acquire a business qualification such as an MBA, although this is not necessary. The most senior posts in companies and corporations are available to them through this route.



## 8 Summary

There is an exciting, stimulating and rewarding career for a doctor who wishes to develop a career as a pharmaceutical physician. Within pharmaceutical companies, most will be employed in medical affairs where they will translate scientific information to clinical reality, providing post-marketing support and monitoring of new medicines. Within a company, physicians may also be involved in the clinical research and development of these new medicines.

Alternatively, doctors can be employed in contract research organisations or, outside the pharmaceutical industry, as medical assessors in the medicines regulatory agencies. However, there are many other fields available to doctors in industry and in allied organisations, from basic research to marketing. The most successful individuals can rise to manage national and international organisations or become CEOs of global companies.



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# 9 Industry careers and finding a job

## Careers information

### Additional resources on careers in the pharmaceutical industry:

#### **The Association of the British Pharmaceutical Industry (ABPI)**

7th Floor Southside  
105 Victoria Street  
London SW1E 6QT  
Telephone: +44 (0) 20 7930 3477  
Fax: +44 (0) 20 7691 7355  
Website: [www.abpi.org.uk](http://www.abpi.org.uk)  
Careers website: <http://careers.abpi.org.uk>

#### **British Association of Pharmaceutical Physicians (BrAPP)**

Royal Station Court  
Station Road  
Twyford, Reading  
Berk RG10 9NF  
Telephone: +44 (0) 118 934 1934  
Fax: +44 (0) 118 932 0981  
Website: [www.brapp.org.uk](http://www.brapp.org.uk)

#### **The Faculty of Pharmaceutical Medicine**

19 Angel Gate  
326a City Road  
London EC1V 2PT  
Telephone: +44 (0) 20 3696 9040  
Website: <http://www.fpm.org.uk>

#### **British Medical Association**

BMA House  
Tavistock Square  
London WC1H 9JP  
Telephone: +44 (0) 0300 123 123  
Website: [www.bma.org.uk](http://www.bma.org.uk)

## Finding a job

The simplest way to find a job in the industry is to search the jobs postings on BMJ Careers and through other relevant journals where companies and specialised firms often advertise vacant posts.

Direct approaches to companies are sometimes fruitful, even if they are not currently recruiting. Specialist pharmaceutical recruitment firms handle a large proportion of the industry's vacancies and are in a good position to offer advice. Details of recruitment companies can be found on the internet.

Networking is also a useful way to hear of vacancies and gain careers advice. LinkedIn is an invaluable tool for this, as is attending careers events such as the BMJ Careers Fair.

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