

An insight into careers for doctors

with the UK pharmaceutical industry



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This booklet outlines the part that medical practitioners play in the pharmaceutical industry, particularly in the UK. It aims to provide background information to help you consider whether a career as a pharmaceutical physician, working in a pharmaceutical company or in a related organisation involved in pharmaceutical research and development, would be a suitable choice for you.

You probably recognise that the development of a new medicine takes place within research-based pharmaceutical companies, which operate as part of a large international industry. You may have learnt something of the industry by contact with medical representatives, or even through experience in clinical trials.

Yet, the role of doctors in the pharmaceutical industry is not generally well understood by most of those who work outside the industry. It may even come as a surprise to you to learn that there are over 2,000

pharmaceutical physicians in the UK, working as clinical research physicians, clinical pharmacologists, medical advisers and consultants.

There is little exposure in medical undergraduate education or postgraduate training to the medical specialty concerned with research and development of medicines, namely pharmaceutical medicine, and little information about potential careers in the industry is provided in medical schools. Indeed most medical students do not have contact with industry doctors.

It is hoped that this booklet enables you to consider the options for a career in the area of medicines' research and development, and to seek further advice for an informed career choice to suit your experience, skills and aspirations.



The UK pharmaceutical industry

The pharmaceutical industry researches, develops, manufactures and markets medicines for use in human and animal healthcare. This booklet concentrates on human medicines, because that is where most pharmaceutical physicians are employed.

Whilst there are two methods of access to medicines, namely those available on prescription and those that can be bought over the counter, most of the products have started life in the same way – as a project in a research-based pharmaceutical company.

In the UK, pharmaceutical companies providing medicines for human use comprise large, medium and small organisations in terms of turnover, and may be based significantly on research and development (R&D) activity or directed principally to marketing and sales. For example, they may be UK-owned companies, or subsidiaries of European, American or Japanese parent companies.

The UK-based industry is represented by the Association of the British Pharmaceutical industry (ABPI), which brings together companies producing prescription medicines, other organisations involved in pharmaceutical R&D and those with an interest in the pharmaceutical industry operating in the UK. ABPI member companies manufacture and supply 90% of the medicines prescribed through the National Health Service and are major exporters to countries all over the world.

Despite considerable global consolidation of the pharmaceutical industry in recent years, there are very few large firms within it, and none approaches commercial dominance over the others. For example, the company with the largest sales to general practitioners in the UK still has less than 13.5% of the primary care market, and under 12% of the total UK market¹. However, within different areas of medicine, some companies may have a considerable percentage share of the market for a particular therapeutic area.

The term 'Research' means the discovery or design of biologically active molecules which have not previously existed in a therapeutically useful form. 'Development' means the process of formulation, testing and evaluation which takes place as the potential new medicine moves from the laboratory towards and into the clinic. Research is usually undertaken by chemists, biologists, pharmacologists and others with a research science background, whilst most pharmaceutical physicians work in one or more areas of development.

Pharmaceutical R&D is complex, lengthy and expensive; only one compound in many thousands screened eventually reaches the market as a medicine, and of these only one in seven goes on to become a commercial success:

- The industry invested £4.85 billion in UK R&D in 2011 – more than £13 million every day².
- On average, it takes around 12 years and \$1.5 billion (approximately £1.15 billion) to develop a new medicine³.
- The pharmaceutical industry invests huge sums in research into treatments for cancer, heart disease, neurological diseases, arthritis and AIDS, as well as many other conditions for which there are currently no adequate treatments.
- Pharmaceutical companies carry out over a quarter of all industrial R&D conducted in the UK, more than any other sector⁴.
- One in six of the world's most popular prescription medicines were discovered and developed in the UK⁵.
- The UK industry employs around 68,000 people⁶, more than a quarter of whom are graduates, including over 2,000 doctors. Thousands more jobs are generated in related industries.
- Pharmaceutical exports generated a trade surplus with the rest of the world of £5 billion in 2012⁷.



¹ IMS Health British Pharmaceutical Index, IMS Health Hospital Pharmacy Audit 2011

² Office of National Statistics (ONS) Business Enterprise Research and Development 2011

³ Paul S et al How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nature Reviews Drug Discovery, Volume 9 March 2010

⁴ ONS Business Enterprise Research and Development 2011

⁵ OHE calculations based on IMS Health World Review Analyst 2011

⁶ Office of Health Economics (OHE) calculations based on ONS Business Enterprise Research and Development 2011

⁷ HM Revenue and Customs UK Trade Info 2012

Despite the high percentage of sales reinvested in R&D, even the large companies find it increasingly difficult to support the necessary investment across their whole portfolio from prescription pharmaceutical sales alone. Furthermore, with the possible exception of the USA, no single country's pharmaceutical market enables a company to recoup the cost of developing a new medicine. Therapies must therefore be introduced internationally with a view to global marketing in the longer term.

The pharmaceutical industry is highly regulated and this particularly includes the development, manufacture, safety monitoring and marketing of its medicines. 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. The marketing authorisation shows the medicine has demonstrated appropriate efficacy, safety and quality. The approval of medicines marketed in the UK is performed to a robust standard

and the International Conference on Harmonisation (ICH), which is made up of Europe, the USA and Japan, works to achieve consistent international standards in a range of regulatory processes including marketing authorisations, clinical development, safety monitoring and manufacturing. ICH standards are recognised globally and applied internationally by many additional countries.



How medicines are developed and licensed

Initial research on new compounds is carried out in the laboratory, using a wide variety of techniques. Promising compounds are then studied in animals, to investigate effects that cannot currently be predicted from the computer and test tube studies. A sequence of phases of clinical assessment in humans follows strict guidelines:

Phase I: a non-therapeutic, exploratory trial in a small number of human subjects 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 1 trial. These studies will determine some aspects of how the drug works in humans and help to establish the dose.

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 are presented to the medicines regulatory agencies. If 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 will be increasingly used to also 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 and to help 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.

Electronic databases such as GP databases are also used to identify safety issues associated with medicines and to explore how they are used in the real world.

The medical work of pharmaceutical physicians

Medical practitioners who work in the pharmaceutical industry undertake many roles, but, apart from those who go on to careers in general management, it is their competence in medicine that is crucial to their ability to perform their job to the high standards required. In this respect, it is of paramount importance that, in an industry which aims to perform profitable research in the interest both of patients and shareholders, physicians employed by the companies are able to ensure appropriate ethical standards in company research projects and marketing campaigns. Although they are employed by the companies, they remain doctors first and foremost, and as such their primary interest is the welfare of patients.

While some physicians decide 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 clinical and medical roles of physicians in the pharmaceutical industry.

Working at the frontier of knowledge

The decoding of the human genome has given rise to a once in a life-time 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 – a process known as target validation. An intimate knowledge of the human disease process and its pathophysiology is essential and the physician scientist with both clinical and research training has the critical skills.

Early studies of new drugs in man

Before first administration to man, the relative safety of a new drug must be assessed. This involves expert knowledge of both the drug and of clinical medicine. The decision to move into man is taken by a company Safety Board of which senior pharmaceutical physicians are members.

The first administration of a new drug is usually carried out in a clinical pharmacology unit within a pharmaceutical company, or very commonly today, by a contract research organisation (CRO) working on behalf of the sponsoring company. The



study is normally conducted on volunteer subjects whose mental and physical health is assessed by the investigators, who are often pharmaceutical physicians. This is highly responsible medical work as the dose of the drug is progressively raised with careful assessment of its actions and its tolerability.

Subsequent clinical work is conducted in patients when the first evidence is likely to emerge as to whether the drug shows promising therapeutic activity. Pharmaceutical physicians work with clinical investigators, with the study conducted in an academic medical centre with which they are closely associated.

Protocol design and review

The largest sponsor of clinical research in the UK is the pharmaceutical industry. The pharmaceutical physician is responsible for the inclusion and exclusion criteria that apply to patients, and decisions on the measurements to be made, the dose of the drug and safety monitoring procedures. The design of trial protocols, conducted in collaboration with clinical investigators, is highly demanding work involving a considerable level of skill and clinical knowledge, even though the pharmaceutical physician very rarely meets the patients in the trial.

Regulatory affairs

As mentioned previously, the pharmaceutical industry is highly regulated by regulatory authorities such as the MHRA, the EMA and the Food and Drug Administration (FDA). Physicians in 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, formulating advice to prescribing doctors after approval. Physicians working for both industry and regulators continue to monitor a medicine while it is on the market as more is known about its use in the real world to ensure a positive risk benefit balance for patients.

It is no exaggeration to say that the physician in industry who is responsible for these matters has usually more influence over the way the medicine will be used than the individual prescribing doctor.

Safety assessment

No medicine is 100% safe, some adverse effects may be predictable early on from its pharmacology, but others are completely unexpected. Medicine safety is therefore closely monitored during clinical development and throughout the time the medicine is given to patients. A high moral and legal responsibility rests upon pharmaceutical physicians responsible for safety to recognise problems quickly, whether detected by the company, patients or regulators and determine whether further action is needed. This includes following up/causality assessment of individual cases, analysis of individual and/or very large numbers of adverse events, performing pharmacoepidemiological studies or 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 medicines time on the market. These decisions also take place within a legal framework and it is a requirement that adverse reactions are reported to the regulatory authorities within strict timelines as well as periodic reports summarising safety and risk management plans.

The interface with key clinicians

The pharmaceutical industry uses external clinical experts extensively in deciding research policy, evaluating problems and arriving at solutions. However, experience shows that unless the pharmaceutical physicians who interact with these external experts are of similar calibre, both intellectually and clinically, the relationship does not function well. This is as much medical work as a case conference in a hospital.

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 special interest. In this capacity they are responsible to the consultant in charge. 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, most of whom do not have a medical background, rely upon having high-quality medical advice from their staff physicians about a whole range of clinical problems and medical issues. These situations can range from a decision to invest a moderate sum to explore a new clinical indication for an established product up to the critical and difficult decision to withdraw a major product from the market on the grounds of safety. The clinical judgment that the pharmaceutical physician contributes is vital to management, and the independence that medical registration with the General Medical Council (GMC) offers can be important to the pharmaceutical physician on those rare occasions when the advice is unwelcome.



Commercial issues

Pharmaceutical companies live and prosper by selling their medicines. Pharmaceutical physicians play a proper part in helping to evolve commercial policy and identify opportunities. However, they also play a restraining role as it is they who 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 the laws within the EU which regulate pharmaceutical products. The basic rules are contained in European law (including Directives and Regulations), which are binding on EU Member States and implemented into UK law through the Human Medicines Regulations 2012 (which consolidated and replaced most of the Medicines Act 1968, and its extensive legislation (statutory instruments), and by administrative requirements on particular topics, issued as guidance by the applicable regulatory authorities (including the EMA and MHRA). This forms an extensive and complex regulatory framework governing the development, manufacture, sale, supply, promotion, import, export, licensing and safety monitoring of medicinal products.

In the pharmaceutical industry very few activities require a registered medical practitioner in order to be carried out legally. However, many companies have internal policies and standard operating procedures (SOPs) that require that certain duties must be conducted or approved by a registered medical practitioner.

These activities and duties include:

- Approval of advertising copy for promotion in the UK under the ABPI Code of Practice; operated by the Prescription Medicines Code of Practice Authority (PMCPA). This is part of the self-regulatory framework that the industry has in agreement with the Department of Health. Suitable trained pharmacists can now also sign-off such material.
- The EU requires that there is a resident registered medical practitioner when a company markets a medicine in the EU.

- The signature on a clinical expert report for a regulatory agency must be from a medically qualified person, although in this case not necessarily a company employee.
- Regulatory agencies require that companies comply with their standard operating procedures (SOPs) and they can be subjected to severe penalties if they fail to do so. As an example, one typical company's SOPs require the signature or participation of a registered medical practitioner with 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 became pregnant during clinical trials
 - Major medical decisions about suspension of a clinical trial, withdrawal of a medicine etc
 - Safety board review before first administration of a new drug to man
 - Review of text of company external documents with a medical content to ensure accuracy and consistency.

Thus, the day-to-day work of the pharmaceutical physician has a high medical and clinical content even if it does not involve bedside contact with patients. As the scientific and medical basis of drug discovery and development has grown more complex so the level of clinical knowledge required of pharmaceutical physicians has grown. To maintain a high level of expertise, a free interchange between industry, academia and clinical medicine is essential and to be encouraged.

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 to the company coming from the continuing medical experience for the pharmaceutical physician and the investigator contacts that are made.

The pharmaceutical industry typically employs doctors in very distinctive roles, which can be related broadly to the medical responsibilities described above in the work of the pharmaceutical physician. Each role requires appropriate qualifications. The larger the company concerned, the more likely it is to employ specialists. In smaller companies some or all of the roles will be combined in a few posts, or in extreme cases even a single post.

The major roles are:

The medical strategist

A senior consultant or specialist with wide experience of 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 the industry. The doctor will almost certainly work at the company's worldwide headquarters. This role, either single-handed or, more likely, as a member of a multi-disciplinary long-term planning group, 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 these days, technology enables the industry to design (as opposed to discover) therapeutically useful compounds. However, there is very little point in embarking today on a programme to develop, say, another beta-blocker for use in hypertension or another benzodiazepine tranquilliser for sleep disorders. So today, the medical strategist's role is to lead the company into more promising fields, especially areas of unmet medical need, with a view to success in the strategic plan period – between five to 20 years hence.



The clinical pharmacologist

This doctor was probably a research registrar or senior lecturer before leaving clinical or academic medicine to join the industry.

The clinical pharmacologist's role is to characterise the activity of each potential new drug by reference to all relevant physiological or psychological measures; to understand its mechanism of action in man; to characterise its metabolism and kinetics; and to 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 decision to progress testing into humans for the first time (Phase I) is the most challenging ethical decision that the medical, research and development staff have to take. Whilst this decision is essentially a company matter, there are external constraints as regulatory approval is required as for all clinical trial work. If the compound is in Phase I development, this work is usually done with non-patient volunteers, who are normally healthy people, who volunteer freely, and who do not anticipate any therapeutic benefit from taking the potential drug under test.

The work suits 'hands-on' doctors with good research minds and the industry usually employs people who have the same kind of academic and clinical track records in specific therapeutic areas which would otherwise qualify them in due course for a consultant post or professorial chair.

Once a compound is in Phase II development, the work shifts from the company, contract research organisation (CRO) or hospital laboratories into the clinic, where the potential drug 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, which licenses the clinical trials
- the consultant or other physician who is caring for the patients concerned
- the Research Ethics Committee relevant to the hospital trust
- the patients themselves; usually few in number who will be subject to intensive monitoring of many clinical and physiological variables.

Roles of doctors in industry



There is a fundamental difference from Phase I, in that 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 in addition it seeks to confirm that the compound works in the ways anticipated from pre-clinical and Phase I studies, and has (or has not) the potential to relieve or remove the target disease state.

The pharmaceutical physicians concerned are still essentially involved in research, still working largely with academic colleagues and support staff who are like-minded. The industry usually prefers to employ doctors whose experience, interests and achievements are similar to those of the Phase I physician, but with the added requirements of management and diplomatic skills enabling them to manage multi-disciplinary projects through other people.

The clinical research physician

Assuming that all has gone well, and that the pre-clinical, Phase I and early Phase II work has confirmed that the company has a good potential therapy on its hands, the next major decision is to extend that Phase II work and move into Phase III clinical trials. The aim then is to satisfy the company, the regulatory authorities, and later, the Health Technology Assessment agencies such as NICE, 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 mounting studies in large numbers of patients (in the order of

2,000 - 5,000) over long periods of time, so that the therapeutic hypotheses may be explored with more statistical power. Due to the economic considerations set out above, the Phase III clinical trials programme is usually set up as an international project, in which the company Headquarters delegates responsibility for the work to its local subsidiary companies – since their medical staff are usually the people with the best understanding of national clinical needs. Generally speaking, there will be a ‘core programme’ of clinical studies, the results of which can be used to achieve product registration in many countries of the world. This might be coupled with local programmes conducted to satisfy particular national regulatory requirements, or to test particular formulations or routes of administration which are relevant to the clinical preferences of the medical culture concerned.

There should not be too much new science emerging in Phase III, apart, of course, from effects that only come to light when large and long-term statistical samples are available for the first time.

Also, as the date for registration approaches, decisions of great financial importance are being made in other parts of the organisation, perhaps involving the building of new factories or the installation of a new plant, the preparation of marketing plans, including reimbursement discussions/planning, the production of medical literature and the training of personnel.

It follows that in looking for clinical research physicians to work in Phase III trials, the industry tends to be more interested in employing those whose skills with people (negotiating, distance-management,

diplomacy), practical experience of day-by-day clinical medicine, and ability to bring in results on time, complement their academic achievement and research-mindedness. Of course, the ideal candidate would combine all these features.

The medical adviser/medical affairs physician

Once a compound has been licensed for marketing, it enters the company's portfolio of medicines that are available for prescription by clinicians for their patients. The typical sequence for an entirely new therapeutic product involves its adoption for regular use by academic and clinical opinion leaders, followed by broader acceptance by hospital consultants and its eventual acceptance by general practitioners. This process is rarely accidental, since it depends upon carefully-planned strategies which are put into action in the medical, marketing and sales departments of the companies concerned.

The steps include identifying the position that the therapy will occupy in various clinical environments, and promoting its acceptance in relevant sectors of practice. Medical representatives and other staff will be trained in physiology, pharmacology and clinical practice in the therapeutic area concerned. The company will prepare appropriate information packages to support the profession as they use the product. It will also organise clinical meetings and symposia. The company will also monitor the product's progress in clinical use and will continue to develop its scientific profile through mounting a Phase IV clinical research programme, usually on an international basis. These studies can involve between 50 and 10,000 patients, and have an emphasis also on establishing and monitoring the safety profile of the product. Specific post-marketing surveillance observational studies track the product's safety in clinical use.

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. All the time it will maintain a close watch on competitor companies and products.

The medical affairs physician's task is to understand and interpret the scientific and clinical background and to translate it into clinical reality for the benefit of company colleagues, health technology assessors such as NICE, NHS budget holders, prescribers, dispensers and patients. This physician will normally work with a very wide spectrum of people both inside and outside the company.

The precise requirements of a company recruiting these physicians will vary, mainly according to its product portfolio of specialist hospital products. For example in oncology it 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. Whatever the individual's clinical expertise and interests, an appetite for commercial involvement balanced by a sense of ethics, and willingness to work in a team are likely to be pre-requisites for success.

Other medical roles

Particularly in the larger companies, there are also opportunities for doctors who wish to specialise in:

Pathology – usually in the biological sciences sector of the research division, and typically as part of the toxicology department.

Vaccines – to be involved in the development and testing of this specialised group of medicines, which make such an impact on public health.

Medico-legal affairs – especially where the company is operating in areas that render it more-than-usually sensitive to political, consumerist or media influence e.g. contraceptive medicine, infant nutrition, anti-inflammatory drugs.

Pharmacovigilance and post-marketing surveillance – a growing discipline of particular interest to epidemiologists and others with statistical and analytical interests. This is related to the widespread monitoring of and alertness for safety problems and issues, which have a bearing on the assessment of risk and benefit of medicines as used in the community.

Health economics – especially in today's climate both in the UK and elsewhere, where there is an emphasis on cost-effectiveness of medicines, and value for money by the healthcare system, as well as on clinical effectiveness.

Medical communications – has a need for experienced doctors to be involved in presenting aspects of product, company and industry through a number of media to a variety of audiences which includes the medical and healthcare professions, other professions such as financial and legal, as well as to patients and public.

Entry qualifications and training

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

GMC registration is also a requirement for specialty training through the pharmaceutical medicine specialty training (PMST) for a certificate of completion of training (CCT).

Thus, doctors considering a career move to the pharmaceutical industry in the UK should be registered with the GMC, and this offers the best chance of gaining a medical role in the pharmaceutical industry.

For qualifying for a CCT through PMST, it is also essential that they should have completed a period of clinical training since qualifying in medicine. In the UK this is a minimum of four years for doctors

qualifying in 2005 or since, and three years for doctors qualifying prior to 2005.

Scientific degrees (eg BSc, MSc, PhD) are desirable, but not essential, additional qualifications.

Postgraduate clinical diplomas and degrees (eg MRCP, MRCGP, MD, 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 was established by the Royal Colleges of Physicians of the UK. 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 Faculty's Diploma in Pharmaceutical Medicine (DPM), which has been offered since 1976 and recognises a period of training and a level of knowledge in the discipline.

The full PMST programme is a workplace-centred competency-based programme under the auspices of the Joint Royal Colleges of Physicians Training Board (JRCPTB) and the Faculty of Pharmaceutical Medicine (FPM), to standards set down by the GMC. Completion of PMST leads to a Certificate of Completion of Training (CCT-UK) in Pharmaceutical Medicine and the eligibility to apply for a place on the GMC's specialist register.

PMST is a four-year programme undertaken by doctors employed as pharmaceutical physicians and includes the specialty knowledge base, the DPM, which covers the Syllabus for Pharmaceutical Medicine. It 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 on-the-job in the workplace, cover medicines regulation, clinical pharmacology, clinical development, statistics and data management, the healthcare marketplace and drug safety surveillance. A 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 regulatory body, the GMC.

For pharmaceutical physicians who wish to specialise in clinical pharmacology as Principal Investigators in Phase I units, the Faculty of Pharmaceutical Medicine 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 Diploma in Pharmaceutical Medicine (DPM) of the Royal Colleges of Physicians in 1976, and in a Joint Advisory



Committee with the ABPI established a post-graduate training course in pharmaceutical medicine which was transferred to Cardiff University. This is a two-year course with five residential sessions each year, which covers the Faculty'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, any post-graduate course is not all-inclusive and participants are encouraged to extend their knowledge by personal study and attendance at other relevant courses, which are organised and run by a number of bodies such as universities, which offer Master-level diploma and degree programmes in areas of pharmaceutical medicine, and a considerable number of specialist training organisations for the pharmaceutical and technical industries. In addition, industry encourages its doctors to attend and participate in the therapeutic area symposia and congresses, which enable them to be at the forefront of the advancing knowledge in their particular area.

Entry qualifications and training

The development of management and communication skills may also be covered in this way, or more formally by in-house or external courses. Another most important aspect of training is that which is done 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 application of the industry's Code of Practice, which is additional to training courses from the PMCPA. Such training and acquired competence in 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 s/he is undertaking any form of medical practice which, under 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 him/her to hold a Licence to Practise.

It is anticipated that many employers for whom pharmaceutical physicians work will require them to hold a Licence to Practise; therefore, maintaining a Licence to Practise may be important to individuals in the future.

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

The Faculty of Pharmaceutical Medicine 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 physicians 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, s/he 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 the same as those doctors who are in clinical practice in terms of the supporting information that must be produced at the annual appraisal, with the exception of 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.

Doctors enter the industry usually at the basic level of clinical research physician or medical adviser, from which they progress after two to three years to a more senior level, involving 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 from four to six years.

Thereafter career development depends on a number of factors concerning opportunities in 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.

Career development in medical or R&D management may lead to the post of medical director or therapy area director within the R&D arena.

Some doctors move into the commercial area of the company and there are many routes for them to pursue both locally and internationally.

Thus a doctor may remain in the medical area, either as a therapy area or product specialist, or in medical management. He or she may move more into marketing and the commercial side of the company. Both of these routes may involve remaining in the local subsidiary or taking on a more international role, and even responsibilities in headquarters.

Having gained experience in a pharmaceutical company, some doctors move across to the contract research sector and take up senior operational or strategic roles in contract research organisations (CROs), again locally or internationally.

Some doctors decide to move into the regulatory agencies as for example, medical assessors within the MHRA/EMA, both based in London. This is demanding work in the public sector scrutinising the dossiers submitted by industry for Marketing Authorisations, 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 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 the nation's medicines.

An increasing number of doctors in mid-to-late career in the industry leave companies in order to become consultants in a growing number of fields – offering scientific, medical and regulatory expertise as they apply to drug development, to medico-marketing advice and to involvement in the strategic, business, financial and general management aspects of the company or the wider pharmaceutical industry.



Why you might consider a move into the industry



There are now many more pharmaceutical physicians than there are, for example, full-time certified cardiologists in the UK. Each had his or her own reasons for moving into the industry.

Typical among their objectives have been:

- Maintaining and expanding their personal commitment to the well-being of the largest possible number of patients.
- Getting to be part of a purposeful and forward-looking enterprise.
- Being at the leading edge of therapeutic discovery and progress.
- Putting themselves in a position where there is better feed-back about their progress and performance.
- Renewing the element of intellectual challenge in their daily lives.
- Keeping professionally alive and up to date.
- Having opportunities to build positive relationships in a broad clinical and business community.
- Having opportunities to travel, in the UK or internationally.
- Freeing their personal and financial advancement from 'systems' constraints.
- Being able to influence the direction taken by important enterprises.

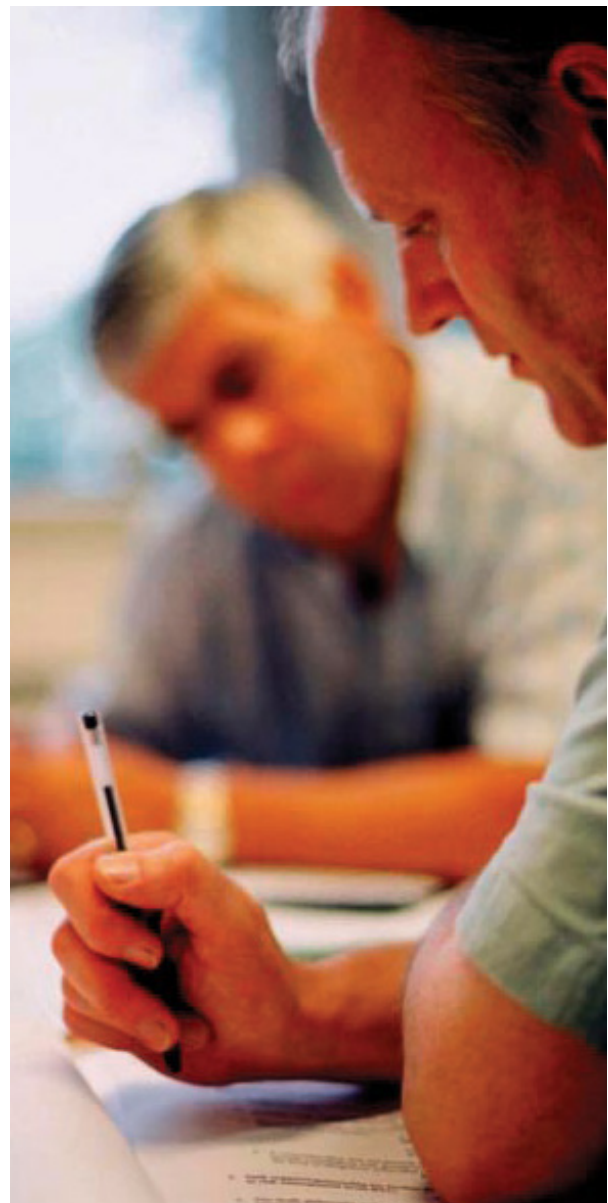
The list is not exhaustive but includes the reasons most frequently cited by successful doctors in the industry.

Just about every medical job in a pharmaceutical company involves its holder in non-medical and managerial responsibilities of kinds they may never have met before. Furthermore, pay and status of doctors in the company reinforce the demand for managerial behaviour. Previously, managing in clinical practice meant 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 professionals or various disciplines. The practice of pharmaceutical medicine invariably involves getting results through other people, and so matrix management and project or management team participation is of the essence.

Here are some of the things most doctors in industry need to take to heart, and may need to learn to recognise:

- 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.
- Accept responsibility for his/her own work and that of subordinates and outside appointees: consultants, clinical trial investigators and so on.
- Manage all activities in ways which are consistent with the company's employee relations philosophy and policy.
- Perform regular appraisal/review with all subordinates and outside appointees so as to identify and be able to initiate actions to improve performance – to further individual development and identify training needs.
- 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 within the company and outside.
- Ensure the continued development and training of oneself and all subordinates so as to maximise their talents in meeting organisation objectives.
- Comply with company rules and procedures as well as operating within codes of practice concerning medical, technical, operational or personnel matters.

- 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.
- Recognise that the company has obligations not only to its shareholders, but to its employees, suppliers, prescribers, patients and the general public and respect the interests of these groups in the conduct of their work.
- Manage each area or project under his/her responsibility in such a way that objectives are defined, planned and communicated, that progress is monitored and the end results are evaluated.



Is there an exit?

If you enter the pharmaceutical industry and find it does not suit you, it is possible to return to clinical practice or to academic medicine, especially if you have a higher qualification.

Some have reached senior positions in the pharmaceutical industry before deciding on a change and returning to clinical practice. This can be extremely difficult because a year or two away from full-time practice will give your former peers every opportunity to move ahead on short lists for NHS and other clinical jobs. Nevertheless, it can be done, particularly if one has kept up associations with medical practice. The holding of a clinical assistant or lecturer's post helps in such instances.

Others have decided after some years working for a company that they would prefer to be independent, and have set up a consultancy or contract company on their own, or with colleagues, and have run clinical trials for pharmaceutical companies which have insufficient staff, too many products, or both. Some are highly successful, but it can be very difficult to get started.

Still other physicians move in their companies or in the wider pharmaceutical and biotechnology industries to take up non-medical roles in marketing or general management, in some cases, but not necessarily, after acquiring a business qualification such as an MBA. The most senior posts in companies and corporations are available to them through this route.

Summary

There is an exciting, stimulating and rewarding career for a doctor wishing to start and develop a career as a pharmaceutical physician. Most will be employed in pharmaceutical companies primarily responsible for the clinical research and development, registration and post-marketing monitoring of new medicines. They may also be employed in contract research organisations or outside the pharmaceutical industry as medical assessors in the medicines regulatory agencies. However, other fields are available to doctors in industry, and in organisations allied to it, from basic research to marketing and the most successful can rise to manage national and international organisations.



The simplest way to find a job in the industry is to watch the advertisement pages in the weekly BMJ Careers section (and occasionally other relevant journals) where the companies and specialised firms often advertise vacant posts.

Direct approaches to companies are sometimes fruitful, even if they are not currently advertising – but this can be something of a lottery.

Recruitment firms handle a very large proportion of the industry's vacancies year-to-year and are in a good position to offer independent advice.

Further information can be obtained from:

The Association of the British Pharmaceutical Industry (ABPI)

7th Floor, Southside, 105 Victoria Street
London SW1E 6QT

Telephone: +44 (0) 870 890 4333

Website: www.abpi.org.uk

Careers information 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 1943

Fax: +44 (0) 118 932 0981

Website: www.brapp.org.uk

The Faculty of Pharmaceutical Medicine 3rd Floor, 30 Furnival Street

London EC4A 1JQ

Telephone: +44 (0) 20 7831 7662

Fax: +44 (0) 20 7831 3513

Website: www.fpm.org.uk

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