

Why Postgraduate Training in Pharmaceutical Medicine is important

This edition of the Faculty Newsletter is themed on Postgraduate Training in Pharmaceutical Medicine. It is now eight years since pharmaceutical medicine was recognised as a medical speciality. During this time the programme of training has evolved and therefore we are providing an update to the membership on the current programme and on future developments.

There are also practical articles and guidance on approaching the modular training elements of specialty training as well as an article on how to ensure our continuing professional development.

Finally, we will look at international developments in this area with a focus on training in Italy and South Africa, again reminding the membership of the global nature of our specialty and the fact that one third of the membership is based outside of the UK.

We hope you find this newsletter informative!

Dr Jit Solanki FFPM

Advocacy Committee

Postgraduate Education & Training of Pharmaceutical Physicians Leading to a Certificate of Completion of Training (CCT)

Prof Peter Stonier FFPM

Director of Education & Training

Since 2005, when the first pharmaceutical physicians completed their specialist training in the newly-listed medical specialty of pharmaceutical medicine, over 120 Certificates of Completion of Training (CCTs) have been issued to them; physicians working in pharmaceutical companies, in contract clinical research organisations and in the Medicines and Healthcare products Regulatory Agency. Today over 220 pharmaceutical and regulatory physicians are engaged in the specialty training programme leading to a CCT and eligibility for a place on the specialist medical register of the General Medical Council (GMC).

It is now eight years since pharmaceutical medicine became a recognised, medical specialty in the UK, one of 28 specialties of the Royal Colleges of Physicians, and this has been an eventful period for pharmaceutical physician education and training. Following the introduction of Higher Medical Training (HMT) in 2002, its successor programme, Pharmaceutical Medicine Specialty Training (PMST) has become established as the approved and fully accredited education & training programme for doctors working with the pharmaceutical industry in the field of pharmaceutical medicine.

The aim of PMST is for pharmaceutical physicians to acquire the necessary knowledge, skills and attitudes to practise pharmaceutical medicine to the highest technical, ethical and professional standards for the benefit of the employing organisation, the development of medicines, and the wellbeing & safety of patients.

Continued overleaf



Advancing the science and practice of pharmaceutical medicine for the benefit of the public

The Faculty of Pharmaceutical Medicine

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continued Postgraduate Education & Training of Pharmaceutical Physicians Leading to a Certificate of Completion of Training (CCT)

PMST is a 4-year workplace-centred competency-based programme, with a specialty knowledge base and a 7-module programme of practical competencies across the breadth of pharmaceutical medicine, which are completed in the workplace, through interactive whole module courses, or through a combination of workplace training and course supplementation. Specialty knowledge is assessed through the Diploma in Pharmaceutical Medicine examination, whilst acquisition of competencies are measured through continuing assessment and appraisal, with independent evaluation of progress and achievement through the Annual Review of Competence Progression (ARCP). The PMST programme must deliver flexible, practical, supervised training for pharmaceutical physicians to standards laid down by the GMC, the competent authority.

Pharmaceutical physicians come from a variety of backgrounds and clinical specialties with or without additional scientific training and research experience. A UK pharmaceutical physician will be a registered doctor with a minimum of four years postgraduate clinical training and will undertake a wide range of activities and roles in early- and late-phase development of medicines, in safety monitoring & assessment of benefit-risk balance, and in medical affairs, incorporating the commercialisation & life-cycle management of medicines. These activities make up the broad medical discipline of pharmaceutical medicine, requiring an understanding of basic research, drug development & evaluation, clinical trials & registration, drug safety & the benefit-risk balance of medicines, medical marketing & business administration, pharmacoeconomics and the social impact of healthcare interventions.

On joining the industry, physicians require education and training in pharmaceutical medicine in order to integrate their clinical, and, in some cases, scientific skills with the requirements for practising pharmaceutical medicine within the industry in the development and maintenance of medicines.

Practical PMST is a workplace-centred developmental programme in which the accrual of knowledge, skills and behaviours leads to the

acquisition of performance and competency across the breadth of pharmaceutical medicine. In contrast to most medical specialties pharmaceutical physicians devise an individual programme of training depending on their experience, job description, skills and career direction. Whilst this covers the breadth of the curriculum, there remains considerable flexibility in the content and emphasis within each programme. This is determined to some extent by the organisation in which the physician works and the projects and training opportunities that present themselves over a period of time. Many if not all of the processes involved in PMST are the responsibility of the trainees themselves, from preparing a training plan, to maintaining the training record, to ensuring with their educational supervisors timely and appropriate assessments and appraisals and preparation for the annual review.

Having a dedicated educational supervisor, usually a senior pharmaceutical physician based in the workplace who is trained and approved for the role, has been demonstrated already to be a vital ingredient to achieving the milestones and outcomes of PMST. The supervisor has a facilitatory role in ensuring that training opportunities are available, and is also involved in assessments and appraisals as well as preparation for annual reviews.

PMST is a regulated programme for certification and accreditation of physicians through the CCT. Accountability for standards of postgraduate medical training lie with the GMC, responsibility for delivery of training and maintenance of standards being devolved to the regional Deaneries. In pharmaceutical medicine the one national (or virtual) deanery comprises the Lead Postgraduate Dean, the Faculty of Pharmaceutical Medicine, and the JRCPTB, through its committee, the Specialty Advisory Committee for Pharmaceutical Medicine (SAC-PM). PMST is embraced by the quality framework laid down by the GMC for quality control, management and assurance of its systems and processes to ensure compliance with standards for training and assessment.

At the end of 2009, the Deanery had its first inspection by the competent authority, and this intensive 4-day exercise resulted in a number of actions affecting trainee care and representation, educational supervision, training of trainers, as well as pointers to good practices, demonstrated by several of the companies visited.

Going forward

Whilst PMST may have become established as the approved professional training programme for pharmaceutical physician accreditation, the programme itself has not stood still. It is development of the curriculum which drives PMST forward, keeping it up date, in terms both of relevant specialty content and of appropriate educational principles and processes for workplace-based learning. First as HMT (2002-2005), then as PMST (2005-) with further revision of the curriculum to PMST2 in 2010, in order to meet the 17 standards of training and assessment laid down by the GMC, specialty training has been adaptive to the needs of pharmaceutical physicians, of employers and of developments in pharmaceutical medicine and drug development science.

With the introduction of PMST2 in August 2010 come a number of further changes. Firstly, the introduction of workplace-based assessments of competency (WPBA) across the programme will aim to introduce over time the standardisation of assessment of competency. Secondly the introduction of an e-portfolio, with electronic record-keeping, will enable the replacement of paper-based records, facilitate assessments and evaluation of individual programmes through the ARCP. The e-portfolio, familiar to medical graduates since 2007, will also simplify the current practice of hard copy evidence collection and filing. Thirdly, the introduction within the curriculum of more general competencies, relating to medical leadership, training and teaching others, and interpersonal and management skills amongst other core competencies, many of which will already be familiar to pharmaceutical physicians.



In summary

Pharmaceutical medicine can provide dynamic and challenging careers for pharmaceutical physicians, who feel that their medical skills extend beyond individual patient encounters. Commercial acumen, management & leadership skills and an ability to communicate effectively are all hallmarks of successful doctors in the industry.

The work of pharmaceutical physicians influences many aspects of the medical profession and of the well-being and safety of patients consuming the industry's products. Arguably, this work also represents one of society's best hopes for the development of innovations and of new medicines for future healthcare.

To have appropriately trained, accredited and publicly accountable physicians in their roles undertaking this work seems a logical step and indeed an essential requirement.

PMST, leading to a CCT, provides a workplace-centred programme for accreditation of competent pharmaceutical physicians, and at the same time a varied and relevant programme of education and training, aimed at enhancing the knowledge and skills of physicians in the processes and methodologies of discovery and development of medicines.

The PMST programme continues to develop, to meet standards of training and assessment laid down by the GMC, to remain up to date and relevant with respect to pharmaceutical medicine content, and to emphasise a learner-centred professional postgraduate education and training programme.

The practical competencies in PMST

Dr Sharon McCullough FFPM, Senior Specialty Advisor

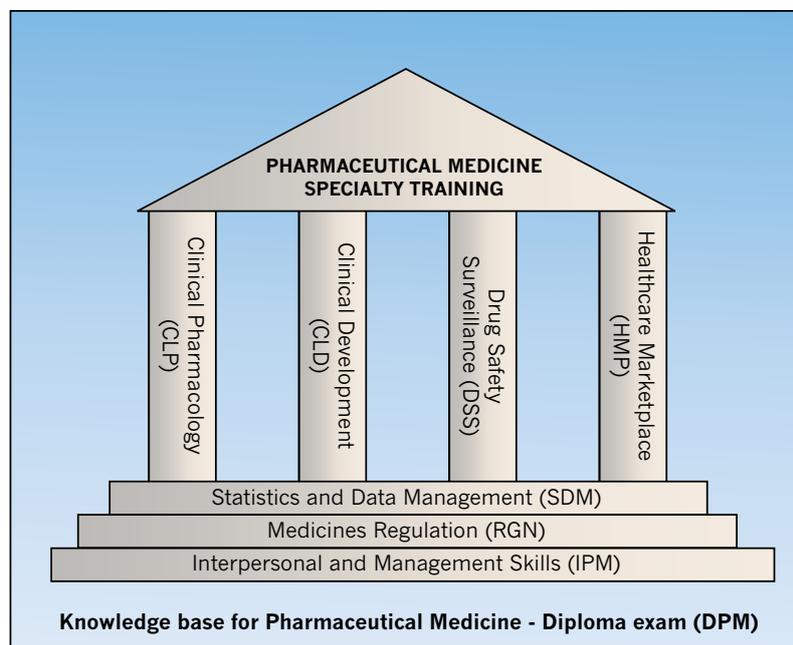
By the end of Pharmaceutical Medicine Specialty Training (PMST), a trainee needs to have demonstrated competence in the seven practical modules of the curriculum (Figure 1). These workplace based modules accompany and build on the knowledge base that is assessed in the Diploma exam, and require the trainee to demonstrate that they possess the applied knowledge, skills and attitudes of a competent pharmaceutical physician.

The modules cover the entire scope of physicians' roles in industry. Three of the modules: interpersonal and management skills (IPM), statistics and data management (SDM) and medicines regulation (RGN) deal with the fundamental tools and principles that are used in many industry roles; in fact the IPM module is known as the 'generic' module, since all of its requirements can be demonstrated within any area of practice. The other four modules – clinical pharmacology (CLP), clinical development (CLD), drug safety surveillance (DSS) and healthcare marketplace (HMP) - represent more discrete areas of practice. Many physicians will have a role that is based firmly within one of these four areas, but it is likely to cover aspects of at least one or two of the others.

The curriculum has been designed so that a medic in virtually any role in industry could undertake the practical training. Some trainees

may have jobs that make it difficult for them to demonstrate competence in all or part of a module – for example someone working in a CRO or regulatory authority might find it hard to gain experience in aspects of healthcare marketplace. In these situations trainees may be able to demonstrate competence by satisfactory completion of a course covering all or part of a module. There are Faculty accredited courses covering all of the modules - apart from interpersonal and management skills which must be completed in the workplace. It is possible to do up to four modules by taught courses, although most trainees only do one or two. A substantial number of trainees complete all of their practical training in the workplace, either by moving to a different role within a company or with another company, or by creative use of secondments, projects and attachments. Interestingly it appears to be medium-sized companies that currently provide the greatest scope for trainees to complete all of their training 'on the job'; small companies may not have sufficient resources to do this while trainees in large organisations can find it difficult to gain experience across internal divisions or departments.

Full details of the practical modules can be found in the curriculum for PMST on the Faculty website.



*The temple of PMST:
built on the knowledge
base and supported by
the practical modules*

Continuing Professional Development – A Practical Guide

Dr David Blowers FPM, FPM Director of CPD

Some pharmaceutical physicians comment that they don't have time for CPD; this is rather surprising as most of us learn something every day.

CPD is a means to a very important end and will be a key component of medical revalidation when it is implemented.

The very important end is proving to our employers, clients or third parties and the public that we really can do "what it says on the packet". Whatever one's area of specialisation, the need to remain up to date is also crucial to the competitive edge that is required of all of us.

CPD is achieved by recording what has been learnt and providing some reflection on how the new learning has changed our practice; it is important as part of appraisal and should not be regarded as burdensome.

An example might be; you attend a meeting at the MHRA and hear an explanation of the new requirements for notifying changes to the Detailed Description of Pharmacovigilance Systems (DDPS). On return to the company you discuss what you learnt with a colleague from regulatory affairs. Your colleague realises that your present process of saving "administrative" changes for an annual update now breaches the revised regulations; several such changes are thus sent to the regulatory authority as type 1A variations. Your DDPS is thus updated in a timely manner, you have passed on knowledge that has helped colleagues to improve internal processes and your company has avoided major findings at the next MHRA Pharmacovigilance inspection.

Another example could be competitive intelligence that you gained at an international meeting; which can be used during a review of a study against "reference therapy"; choosing an appropriate competitor might give your company a commercial edge and facilitate positive reviews from NICE and the Scottish Medicines Consortium.

These are just a couple of examples of how knowledge gained can be used to enhance your contribution to your company.

Those who have completed specialty training in pharmaceutical medicine have already learnt the value of keeping good records and so CPD is merely an extension of what was undertaken during training.

With a busy job, making time to keep detailed records might appear difficult, but Faculty has a simple on-line system accessible to all the membership whether UK or overseas based. Our system will provide the validation that will be required to satisfy the proposed revalidation process required by the GMC.

It is to be hoped that we all enjoy life-long learning and CPD provides a framework to codify the learning that is part of our day-to-day activities.

Visit the Faculty website for detailed information on the CPD system and how you can participate.

Get involved now and be ready for one component of revalidation when it is implemented. If you have questions, contact the Faculty office and we will respond to you with specific guidance.

Consultations: Members' contributions invited

Details of consultation responses currently under review by the Faculty are now listed on the Faculty website. Members are invited to help contribute to Faculty responses on these by sending any comments or recommendations to fpm@fpm.org.uk. Members are also invited to notify the Faculty of any consultations that may be relevant to the Faculty.

International Developments in Postgraduate Education in Pharmaceutical Medicine

Dr Ibrahim Farr FFPM, Dr Bernd Rosenkranz FFPM, Dr Domenico Criscuolo FFPM

The International Committee of the Faculty of Pharmaceutical Medicine is one of the main Faculty's Committees and represents the international membership of our Faculty which totals around a third of the membership. One of its main objectives is to provide support towards local recognition of pharmaceutical medicine and subsequently towards the development of training programmes which lead to this. The Committee meets by teleconferences at least once every quarter and holds a face-to-face meeting in November in London, prior to the Annual General Meeting. The 16 members of the Committee come from various countries (Belgium, France, Ireland, Spain, Germany, Italy, South Africa, USA, Singapore, India, Australia and Japan) but thrive to represent the full international membership in all countries outside the UK. In this article, two of the International Committee's members (Dr. Domenico Criscuolo from Italy and Prof. Bernd Rosenkranz from South Africa) brief us on the latest developments in these two countries regarding postgraduate education in pharmaceutical medicine.

Postgraduate Education in Pharmaceutical Medicine in Italy

Italy has a long tradition of active and successful pharmaceutical companies: two widely used drugs, rifampicin and adriamycin, were discovered and developed by Italian pharmaceutical companies. In 1964 a scientific association was founded and named SSFA (Società di Scienze Farmacologiche Applicate, Society for Applied Pharmacological Sciences): its members were all the professionals involved in research and development of drugs. In those days, the majority of members were pharmacologists and toxicologists, while medical doctors represented a small minority.

As we all know, pharmaceutical companies underwent dramatic changes from the 80s until nowadays: most Italian pharmaceutical companies were merged into large multinational corporations, and most of the research centres were closed.

SSFA is still a very active association, with about 800 members: their professional roles are however completely different. We do have

in fact several working groups, the largest of them are Pharmaceutical Medicine (about 300), Quality Assurance in Research (about 250), Pharmacovigilance (about 200) and Observational Studies (about 150).

SSFA was instrumental in the foundation of two master courses in Research and Development of Drugs. The first one was established in Rome in 2008, it is running now in its third year, and has a growing number of students, from 30 to 45 to 55 in the third edition. A similar course was also established in Milano in 2009: in the first year there were 16 students, which became 39 in the second year.

Both masters follow the syllabus developed by IFAPP and by FPM: they have a number of hours devoted to frontal lessons varying from 200 to 220. Both of them offer the opportunity of a 3 months stage in either pharma companies, CROs, Ethics Committees or at the Italian Drug Agency. This period is highly appreciated, as frequently it represents the first step for a job opportunity.

At the end of the master course, students select a topic and prepare a dissertation thesis, which is discussed and commented in front of a committee, formed by both University teachers and Pharma executives.

Pharmaceutical Medicine is not considered a medical specialty, and no effort is in place to get this recognition: it should also be noted that most professionals involved in matters related to Pharmaceutical Medicine are not medical doctors. Indeed there are MDs in the job, but they are a minority as compared to other professionals like biologists, pharmacists and biotechnologists.

Postgraduate Education in Pharmaceutical Medicine in South Africa

In South Africa, physicians working in the pharmaceutical industry are organised in the South African Association of Pharmaceutical Physicians (SAPP, <http://www.saapp.org.za/about/>) which has 83 members (as of 2005). No efforts have been made to recognize pharmaceutical medicine as medical specialty in this country. Instead, Clinical pharmacology

The Voice of Trainees (and Potential Trainees): the Trainees Subcommittee

Dr Colin Hayward MFPM

Chairperson, FPM Trainees

Subcommittee

Hands-up if you knew there is a dedicated page on the Faculty website for trainees? OK – I had to look it up too - but it is there and it does tell you who the Trainees Subcommittee members are and will give you updates of our regular meetings (<http://www.fpm.org.uk/committees/trainees/>). You may not have known it before but the Trainees Subcommittee exists to represent you and your thoughts to the Faculty as well as to facilitate communication between trainees and between the Faculty and trainees.

The subcommittee members come from many different backgrounds such as small and large Pharma and regulatory agencies. Dan O'Connor, a subcommittee member who works for the MHRA says "The role of the committee is to engage and represent trainees and I hope the committee provides trainees with an approachable forum in which to voice concerns and share best practice".

Over the coming months we will be looking at how we can engage and interact more with fellow trainees. Many of you attended our Annual Trainees' Meeting in May and, following the positive feedback we have received, we will certainly be running this event again in May 2011.

This represents just one single day however, where we can all exchange ideas and share issues together. We will continue to look at other ways we can keep our collective ears to the ground on an ongoing basis. Some ideas suggested already include a chatroom style forum on the internet and informal "surgery" type meetings at various locations around the UK. We would welcome your further suggestions to increase interactions amongst trainees.

Continued overleaf

has been recognized as its own full specialty in 2009, comprising one of the Colleges of Medicine in South Africa (CMSA, the equivalent of the UK RCP).

A full 2 year course for pharmaceutical medicine has been established at the Division of Pharmacology, University of Stellenbosch in this year. The postgraduate diploma course (Pharmaceutical Medicine) has been approved by the University and the South African Department of Education. Final approval of the programme by the South African Qualifications Authority (SAQA) is pending. As of April 2010, the University offers the individual modules of the programme as four separate short courses. Successful participants will be awarded CPD points and a certificate of competence.

The full diploma programme consists of four modules, introduction to pharmaceutical medicine, non-clinical development of medicines, clinical development and pharmacovigilance and marketing, a research project and regular assessments including the final examination. The syllabus of the programme is based on that proposed by the Faculty and by IFAPP to ensure harmony with other existing programmes. Applicants with a medical, dental or pharmacist degree can be admitted to the programme on the basis of the degree, whilst those with a nursing, biomedical or other relevant science degree need to have had two years of experience in pharmaceutical medicine.

In order to assess the situation regarding courses on pharmaceutical medicine currently planned internationally, the International Committee of the Faculty has asked a working group during this year to look at standardized materials used for teaching and/or exams, e-learning, budgets, sponsoring opportunities, and recommendations for potential synergies. Members are Bernd Rosenkranz (South Africa, chair), Ibrahim Farr (Spain), Raymond Chua (Singapore), Domenico Criscuolo (Italy), Pankaj Goyal (India), and Pipasha Biswas (UK/India); the group is actively supported by Barry Muzzeroll (Faculty administration).

continued The Voice of Trainees (and Potential Trainees): the Trainees Subcommittee

The Diploma Examination is always a hot topic that is often brought to our attention, particularly with reference to increasing the number of exam sittings a year from the current one per year. The preparation and resource in running the exam once per year is phenomenal. The best way we, as trainees can create a need for a second sitting is to have as many people sitting the October exam as possible.

A further role of the Trainees Subcommittee is to interact with trainees of other specialties and promote pharmaceutical medicine. Subcommittee member Monica Shaw who works on the International ADHD portfolio at Shire feels that “training through HMT / PMST provides pharmaceutical physicians with a broad understanding across key areas in industry. In addition, by being GMC approved, this training establishes pharmaceutical medicine as a

validated specialty. The Trainees Subcommittee is there to support physicians throughout this training and helps people to forge strong links with both the Faculty and other trainees”.

Thanks to you, pharmaceutical medicine continues to be at the forefront of specialist training for physicians. So now you know a little more about who we are and what we do please make sure you keep in touch. We'll let you know in advance of every meeting and we'll give you a brief summary of the discussions afterwards. If you would like to raise any points then please contact us in confidence at traineesubcommittee@fpm.org.uk so we can truly reflect your needs and guide the Faculty as appropriate. As Dan says “I would encourage all trainees to get involved as much as they can, to ensure our specialty goes from strength to strength.

**The 2010 Annual Meeting
will take place on
Friday, 19 November,
at the Royal College of Physicians London**

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