

Accredited Professional Development For the Medical and Healthcare Industries

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A conference organised by the Pharmaceutical Industry Advanced Training (PIAT) in the School of Pharmacy & Pharmaceutical Sciences, University of Manchester, was held on 13 September 2007 to launch four new programmes in Clinical Trials, Toxicology, Pharmaceutical Microbiology, Pharmaceutical Business and Licensing. Presentations on the unique new distance learning PIAT programmes for the pharmaceutical industry were delivered.

Brian Lockwood started with an overview of the original PIAT programme. He outlined the history of the original programme, which was proposed in 1989 in collaboration with the UK Pharmaceutical Industry. Modules were written by experts based in major Pharma Companies from the UK, Japan, Switzerland, Thailand and academia. Originally there were eight modules, now there is a choice of 17 modules available. The modules have EU and US relevance, and are applicable worldwide due to the overriding importance of FDA and EMEA regulations. The aims of the programme were to have a flexible structure of freestanding modules. These have an open and distance learning style, allowing minimum time to be absent from the workplace, which benefits both employer and student. All modules have an associated tutor who has accredited University status and results are moderated by an accredited external examiner - rigorous quality assurance is carried out by the University of Manchester.

There is a range of entry options; a minimum of an HND is usually required for a Diploma, and a degree level scientific qualification is usually needed for an MSc. No prior learning is required for individual modules, but four credited modules with a pass mark of 50% equate to degree equivalence. The course is very flexible and students can upgrade from a Diploma to the MSc. Recently we enrolled students with MBAs and law degrees!

Individual course modules have a workload of 150 hours per module, and the course content consists of a workbook of 150-300 pages, written assignments, and a workshop (tutorial) of 2-4 hours with the module tutor. There is a 2-hour written examination required for 14 out of the 17

PIAT modules. Other benefits include fulltime contact with a tutor, available via e-mail, and continual updates of Modules on an annual basis.

University awards include Module credits, 15 per module, a Certificate for 4 x 15 credits, a Diploma for 8 x 15 credits, and an MSc is gained after the Diploma, plus Dissertation of 60 credits, making a total of 180 credits. The degree awarded for this is an Industrial Pharmaceutical Sciences MSc. Distinctions are awarded for marks of $\geq 70\%$ in all the Modules and the Dissertation, and 12 have been awarded over the last 4 years. The modules cover basic principles, pre-formulation studies, the science and production of the major dosage forms, QA, packaging, regulatory affairs, safety and sterilisation.

Pharmaceutical Engineering Advanced Training (PEAT) was established in parallel with PIAT in UMIST (now part of the New University of Manchester), and has a similar format. This is administered from the PIAT office, and the modules cover the areas of engineering problems encountered within the industry, including those of a range of dosage forms and packaging. To date there have been over 200 MSc awards, and 3000 individual modules gained in these two programmes. Students have come from a wide range of employers including major Pharma, biotech companies and the NHS, and have mainly been staff from Production, and R & D. Worldwide take-up of the programmes includes S. America, N. America, the Far East, and Europe.

The current new initiatives include programmes in:

Clinical Trials

Toxicology

Pharmaceutical Microbiology Advanced Training

Pharmaceutical Business Development & Licensing Programme

Two of these programmes were funded by HEFCE & NWRDA, and others by the University of Manchester, or via collaboration. The first modules were available in February 2007, and this allows for a greater selection of modules for an MSc. The benefits for students include programmes tailored to their individual needs, particularly with the new programmes, allowing selection from all of the different programmes. Other benefits include improved work performance, and career development. One extreme example is that of one student who developed to become a Module author. These new modules are believed to be ideal for continual professional development (CPD), which is increasingly important to both employers and employees in the pharmaceutical industry. Lastly, financial benefits accrue to both students and employers in terms of time and money spent.

The next speaker was Mike Frodsham, who listed his career progression with PIAT. He graduated in 2000 with a Pharmaceutical and Chemical Science BSc (Hons), and in September 2000 he was employed as a Pharmaceutical Development Scientist at SSL International. In February 2001 he enrolled on the PIAT Course, and later in July 2004 he moved to Galpharm International as a Development Projects Manager, and in July 2005 was appointed as Pharmaceutical Development Manager at Quay Pharmaceuticals.

Mike described his personal experience of the PIAT course, and explained why he chose the course and how he chose particular modules to study. He explained that his BSc course was very broad ranging and gave an overview of formulation, development techniques and processes, but these were not sufficiently specific for his role as a Formulation Scientist. Therefore, he needed further theoretical training to support the practical undertakings that he was involved with on a day-to-day basis. His line manager had just completed the PIAT course, and thought that this would be beneficial to his own development, and to the growth of the department. Personal benefits included further qualifications, which significantly expanded his CV with the only personal expense being his time.

The selection of Modules was not defined from the outset! Initially, Mike studied Basic Principles. Next he considered what knowledge he was lacking for his role, and chose Modules specific to projects he was working on. Mike described the process of undertaking the Course; he had contract with all his employers to take 2 modules per year, all of which had to be completed in his own time (except workshops and exams). He had help available from colleagues/tutors to solve issues with questions posed in the text and assignments, and considered that workshops were really useful, and should be attended. Initially the workload was easily manageable, but as his career progressed, it was more difficult to keep on top of the work and found working long hours followed by studying similar material was hard going at times. The personal gains, which he recorded were theoretical support through his training as a formulator, hand in hand with practical activities during the role.

The Modules were a consistently useful reference source for his employment tasks. He quoted improved technical awareness and ability, including his approach to practical investigations and theoretical data interpretation and reporting, awareness of alternative functions and ‘the bigger picture’ within the Industry.

Lastly, Mike described his expectations as an employer, which included growth of staff in terms of technical ability (investigational planning, interpretation and reporting) and confidence. As a result, a more experienced workforce is created, which can be used to lead and train less experienced staff. This was most important because it is currently difficult to find experienced, competent staff for practical roles, and retention of staff through contractual terms for support of the course is a great bonus.

A lively discussion ensued concerning the ease of arranging time off for PIAT study in large companies where one day per week may be allowed, and small companies, where half a day per week would be impossible.

Next **Linda Ambrose**, a Qualified Person and QP Tutor outlined the QP programme and described the role of the QP. The primary legal responsibility of the QP is to certify batches of Medicinal Product prior to use in a Clinical Trial (Human Medicinal Products only) or prior to release for sale and placing on the market (Human and Veterinary Medicinal Products).

EC Directive 2001/83/EC Article 48 states that:

Member States shall take all appropriate measures to ensure that the holder of the manufacturing authorization has permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in Article 49, responsible in particular for carrying out the duties specified in Article 51.

UK interpretation finds that no existing single First Degree or other qualification awarded in the United Kingdom meets the conditions in full. Linda discussed the contents of the Qualified Person in the Pharmaceutical Industry-Study Guide 2006, which include The Three Foundation Knowledge Elements:

Pharmaceutical Law and Administration
The Role and Professional Duties of a QP
Quality Management Systems

Additional knowledge requirements include basic pharmaceutical sciences. Linda next described how to use the PIAT programme to satisfy QP status. This consisted of selection of modules and parts of modules and courses relevant to QP training only. Linda considered the PIAT modules to

be an ideal source of training for intending Qualified Persons (QP) allowing the additional information to be acquired to build up the required body of knowledge. Outlining exactly how the PIAT modules cover the contents of the Study Guide, Linda clearly defined which PIAT modules and parts therein, covered the requirements for QP status. These included PIAT modules 6, 9, 10, 11, 13, 17, and 18, and PEAT 2, 10, 11, and 13. Linda also specified other courses and documents required for full compliance with the regulations, lastly summarizing the benefits of using PIAT and PEAT modules: these included individual assessment & tailored advice for the student, access to an experienced tutor, and a timescales to suit the applicant.

Sharon Finch, the Non Executive Chairman of UK PLG described the Pharmaceutical Business Development and Licensing programme. PLG is the professional association for people in business development and licensing and it is a not for profit organisation, industry based, and has no service providers. The primary role of PLG is networking and continuous professional development.

In the UK there are over 200 members covering all areas of the Pharma industry, OTC, biotech, drug delivery and generics, and there are nine other PLGs in Europe plus Japan and Canada with over 1,500 members. PLG was founded in 1994, and organises a number of training courses in business professional development. The modules include:

Introduction to the Healthcare Industry

Business Development Operations

Financial Aspects of Business Development & Licensing

Legal issues in Business Development Contracts

Negotiation and Interpersonal Skills

Marketing and Commercialisation

Intellectual Property Rights

R&D and Manufacturing

Robert Johnson, Director of Pharmig and Poly Hajipieris, Company Secretary of Pharmig described the organisation, which was established in 1991 to meet the needs of Pharmaceutical Microbiologists and is a non-profit organisation with a profile of: Manufacturing, R&D, Allied Commercial, NHS & Contract laboratories.

Pharmig has two employees, but is run by an elected Committee, voted for by the Membership at an AGM. They next gave a detailed description of the development and content of the Pharmaceutical

Microbiology Advanced Training (PMAT) Modules. This programme was developed in collaboration with the University of Manchester with the specific help and guidance of Professor Peter Gilbert, Professor of Microbial Physiology at the University of Manchester.

The two organisations discussed the original concept of the course many years ago, and more recently, held brainstorming sessions to define the module contents, and carried out a training needs analysis of their Members in Mar 2006. This was truly an industry-moulded course as specified by the Membership. They elaborated on the numerous advantages of choosing the University of Manchester for the MSc.

The modules were designed to meet the needs of those responsible for and/or working in the area of Pharmaceutical Microbiology in the industry, and feedback from the industry highlighted the need for a flexible learning and development programme. The modules include:

Introduction to Pharmaceutical Microbiology and Technology

Water Aspects

Microbiological Environmental Monitoring & Control

Microbiological aspects of Sterile Pharmaceutical Manufacturing

QA in Microbiological Laboratories

Engineering Principles for Pharmaceutical Microbiologists

Application of Microbiology in Biopharmaceuticals

Antimicrobials

Antibiotics and Vitamins

Key Management Tools

Leon Aarons described the Clinical Trials Programme. This is now being marketed in conjunction with the Institute of Clinical Research (ICR), who currently have an existing network of international collaborators. The modules include:

Introduction to Clinical Trials

Planning, setting up and Running Clinical Trials

Phase I Clinical Trials

Phase II Clinical Trials

Phase III Clinical Trials

Statistical Requirements and Study Design

Pharmacovigilance

Regulatory Issues

John Timbrell: Professor of Biochemical Toxicology, King's College London, and a major author on the programme, described the Toxicology Programme. He gave a thorough background to the need for the programme and explained that toxicology was the study of effects of chemicals on living systems, and then outlined the purpose and role of toxicology. He stressed the importance of this knowledge in the pharmaceutical industry, and what is required of toxicologists and how they are employed. John explained that there are different types of toxicologists in the Pharmaceutical Industry, and that the industry and government requirement for Personnel with training in, and understanding of, toxicology are required. However, currently there is a severe shortage of toxicologists, and this programme should undoubtedly help this situation. The Toxicology Programme consists of 9 Modules:

Principles of Toxicology

Assessment of Toxicity

Biotransformation and Kinetics

Regulatory Toxicology

Target Organ Toxicology (1)

Target Organ Toxicology (2)

Mechanisms of Toxicity

Molecular and Cellular Methods in Toxicology

Integration and Risk Assessment

Concluding remarks involved the novelty of the new modules and the three programmes being launched, in collaboration with industry interest groups, Pharmig, PLG and IRC who have their own membership lists, newsletters and conferences to promote the new programmes. The Toxicology programme is being promoted via web links on related professional sites.

www.pharmacy.manchester.ac.uk/postgraduate/piat/.