

Industrial *Pharmacist*

May 2007

FOREWORD

Dear Reader

The Industrial Pharmacists Group committee has worked hard to develop the factors that will enable pharmacists to succeed in the pharmaceutical industry, to highlight them and provide resources to access them. Rona Dunn and Steve Moss have developed a CD-ROM that explains the cradle-to-grave development of terfenadine to foster an understanding of the broad range of activities involved in bringing a drug from the drawing board to patients.

With Nigel Hodges (chairman of the Society's Qualified Persons Panel of Assessors) and his accreditation team, we continue to highlight the QP as an attractive and well rewarded career choice for pharmacists. We continue to work closely with the Academy of Pharmaceutical Sciences to promote scientific careers in the pharmaceutical industry. I am delighted to report that Gino Martini has just been elected as president of the European IPG.

The industrial pharmacy voice is strong in the Society and this has never been more important as we enter into a period of major change to the way that the profession is governed. I now leave the IPG committee in good hands to focus on the English Pharmacy Board and to support the President in his Pharmacy 20:20 initiative. I would like to thank you for your support for the IPG and hope that this will continue through the Society's transformation. I would also like to acknowledge the enthusiastic support of Sadia Khan, Angela Canning, Robert Clayton and David Pruce of the Society for the work of the IPG.

As always, I hope that you enjoy this edition of *Industrial Pharmacist*. You can contact me at steve.wicks@pfizer.com with comments and feedback.

Steve Wicks

IPG chairman

Prague hosts annual assembly of European industrial pharmacists



Delegations from 16 countries attended the general assembly of the EIPG

The annual general assembly of the European Industrial Pharmacists Group (EIPG) was held in Prague on 14 and 15 April. During the meeting, Great Britain was re-elected to the presidency and France to the treasury of the group.

The EIPG Guidance for Continued Professional Development of the Qualified Person was approved and will be posted on the website (www.eipg.eu) and sent to the European Medicines Agency (EMA) for consideration. It was agreed to propose to the European Commission that it should form a

project group to produce a suitable online system for the capture of continuing professional development data.

Product traceability techniques were discussed. The French delegation indicated that a decree has just been published making it compulsory for all packs of medicinal products in France to be printed with a data matrix bar code based on EAN 13 by 2010. This code is to include not only the reimbursement number but also the individual batch number and expiry date.

In view of the concerns over counterfeits, it was agreed to write to the European Commission requiring that all wholesalers should employ "responsible pharmacists" in place of the "responsible persons" which is currently advised in some member states (for example, the UK through the Medicines and Healthcare products Regulatory Agency).

Several working groups were agreed:

EIPG

EIPG exists to represent the interests of all Industrial Pharmacists working in Europe. Its strategic aims are:

- To maintain professional standards
- To increase the recruitment of pharmacists into the Industry
- To influence technical directives and guidelines which will affect industrial pharmacists
- To maintain partnerships with other European associations of pharmacists
- To encourage the formation of national groups of industrial pharmacists in accession countries
- To maintain a strong communication network to all the national associations

- The Swedish and Danish delegations will take forward the working group for undergraduate education and training in conjunction with the European Association of Faculties of Pharmacy
- The delegation from the Netherlands will draft guidance on CPD for pharmacists working in regulatory affairs
- The Italian and Irish delegations will produce a draft update to Annex 16 for discussion



Miroslav Janousek, corporate regulatory affairs and quality director, Zentiva, gave an interesting review of the development of the pharmaceutical industry in central and eastern Europe. Zentiva is the number one generic company in the Czech Republic and has recently acquired the Turkish company

Eczacibasi. The development of competence with quality as a driving factor has led to a number of new positions for pharmacists in Zentiva.

Miloslava Rabiskova, head of the host Czech delegation, gave a comprehensive presentation on academic research in the two

schools of pharmacy in the Czech Republic. Her own school in Brno is working on new forms of pellets and coating systems.

The newly formed Industrial Pharmacists Section of the Pharmaceutical Society of Latvia became a member of EIPG. — *Gino Martini and Jane Nicholson.*

How a student learnt about regulatory affairs during one summer at Bristol-Myers Squibb

For me, regulatory affairs was a relatively unknown corner of the huge playing field that is the pharmaceutical industry. As a Nottingham University student, I was equipped with a fantastic and vast experience of the drug development side of this industry, so when confronted with an advertisement for a summer placement at Bristol-Myers Squibb, I was keen to see where regulatory affairs slotted in.

I began my eight-week placement with Bristol-Myers Squibb at the beginning of July last year, armed with only my knowledge of the Medicines and Healthcare products Regulatory Agency, a rather over highlighted copy of 'Medicines, ethics and practice' and the BNF I need not have worried. A thorough programme with plenty of opportunities to work with all members of the regulatory affairs team as well as other departments had been scheduled for me. The site at Uxbridge housed, among other things, the pharmacovigilance, medical information, clinical trials, marketing, legal and commercial business departments. By the end of my first week, I was fully aware that as a regulatory affairs associate, you can expect to interact with every one of these departments.

A regulatory affairs associate can be asked to advise on anything from marketing presentations for sales representatives, to press releases and packaging designs in a regulatory capacity. Regulatory affairs personnel are experts in interpreting and keeping up to date with the regulatory machinery of the world, such as the US Food and Drug Administration and the European Medicines Agency, ultimately to ensure that the company is acting within the guidelines. This in turn, renders the products safe, efficacious and marketable, so it is wise to follow these. On top of these responsibilities, regulatory affairs also ensure all product licences are up to date, apply for product licences, update summaries of product characteristics and patient information leaflets, and keep track of products that are in clinical trial phases.

Essentially based in regulatory affairs, I spent most of my placement working on licence applications, licence renewals for products marketed in the UK and Ireland and



Leonie Reid: an exciting, challenging and rewarding career

updating a medical imaging product's history for the company's database. I attended brand team meetings with my supervisor and worked with departments strongly affiliated to regulatory affairs, such as medical information and pharmacovigilance. I also spent time with brand team managers and colleagues who work with the NHS and the National Institute for Health and Clinical Excellence, developing local health strategies and budgeting.

I was tutored once a week by members of the department who were all more than happy to impart their knowledge and help to consolidate my understanding of their role. These began with a tutorial on clinical trials and the associated regulatory considerations such as the application for a clinical trials licence to the MHRA, the involvement of an ethics committee and how to submit variations to protocols throughout the trial. My tutorials on the various procedures to gain a licence for a medicine were fascinating and formed the basis of a presentation I gave comparing the procedures needed to satisfy the FDA and the EMEA. My lifecycle management tutorial addressed all the key stages of a product's "life", not only integrating the regulatory affairs role but also that of marketing and commercial business. If getting in-

involved in pre-launch marketing strategies, growth drivers and post-launch sales sounds appealing to you, I cannot think of a more fast-moving, competitive career to be in than the pharmaceutical industry.

I found that, as a pharmacy undergraduate, the clinical knowledge I gained from my degree was not at all wasted here. On the contrary, having an understanding of the mode of action of particular drugs, an appreciation of the professions to which pharmaceutical companies market and knowing that the patients requirements are always the priority to these professionals and the company was a real advantage.

Needless to say, I have discovered a whole other side to the pharmaceutical industry that pharmacists are just as suited to as research and development. From regulatory affairs to medicines information or commercial business, pharmacists working in a pharmaceutical company will find themselves in an exciting, challenging and rewarding career. I have been told by several colleagues that, contrary to popular belief, a preregistration placement or PhD is not the only route into the pharmaceutical industry, so I would strongly encourage anyone to go for a placement wherever they see an opportunity. — *Leonie Reid, fourth-year pharmacy student at Nottingham University.*

IN BRIEF

FIP Careers Centre

The International Pharmaceutical Federation Career Centre website provides details of industry job opportunities. It can be accessed at www.fip.org/careercenter.

IPG committee election

Voting papers for the 2007 IPG committee election have been posted to members. Completed papers should be returned as soon as possible. The closing date for receipt is noon on 12 May. For further details contact IPG administrative support (tel 020 7572 2412).

Spread the word — talk to undergraduates

Many students have little or no idea of the kinds of roles and activities that go on in “the industry”. Despite several years of undergraduate learning covering everything from pharmaceutical regulation to product formulation, organic chemistry to immunology, toxicology and beyond they largely, and for most of them correctly, consider that their future belongs in a community or hospital sector role. Nothing wrong with that . . . before anyone gets upset.

The Industrial Pharmacists Group works with the schools of pharmacy to try to promote at least the idea that there is life beyond these alternatives. There are now 23 schools. Each of these has a team leader appointed, volunteered from the industry, to liaise with an academic contact at that institution. Each school receives at least one visit a year from an industrialist, much like me. The IPG is continually trying to get new people to become involved with these visits.

Two formats are generally in use. A group meeting where a number of us, usually about four or so, are put into a lecture hall to try to enthuse as many students as possible.

Normally, we set aside time afterwards for the curious to ask as many questions as they want. This is usually best achieved one to one, or with small groups, since in a large group nobody wants to ask “the daft question”. Some things never change. The alternative is that we attend career fairs. These are normally well attended (everyone wants a job, right?) and a great venue for spreading the word.

Dispelling myths

Undergraduates still have the same myths that they had 10 years and more ago: everyone working in the industry has a first class honours degree and a PhD and your entire life will be spent in some “formulation” laboratory. Dispelling these myths is one part of the contacts role. Trying to show a varied, interesting, motivational and sometimes international job that pays and rewards well, while developing a career, is the other challenge. Initial pay in the community sector is hard to resist but salary growth is good in many industry roles and sectors. Selling these short-term losses can be difficult, given the increasing levels of student debt.

Although a number of companies offer holiday jobs for students there are still few positions for preregistration trainees in the industry, and little prospect of this increasing substantially. Our message to students is that they should be aware of this but not be deterred by it. After they have registered they are welcome to apply for positions. Our sector welcomes their abilities.

Being controversial, I would suggest that no sector of our profession has a greater variety of job roles. This is the message that we must get across to students: we like pharmacy graduates. They are broadly educated in many of the skills that make up the pharmaceutical industry. Talking to students is still an interesting pastime. They give a fresh perspective on our profession. It is for us, within the industry, to promote it whenever and wherever we can.

If anyone has an idea that can promote our message to the thousands of students out there who want to hear our messages but don't, I will be the first to listen to it. — *Steve Robertson, strategic projects director of Controlled Therapeutics, based in East Kilbride, near Glasgow (e-mail steve.robertson@ctscotland.com).*

New pharmacy teaching and research facilities at UCLan

The School of Pharmacy and Pharmaceutical Sciences at the University of Central Lancashire (UCLan), was established in 2007 to address a shortage of pharmacists in Cumbria and Lancashire. Indeed, the pharmacy community in the region have been extremely supportive of the initiative and actively contribute to the external advisory board that was set up early on in the School's development.

The new MPharm course has already attracted considerable interest from students in the area and has been one of the most popular courses in the Faculty of Science and Technology (number two in terms of applicants) with approximately 80 per cent of applicants for the 60 available places being from the north-west. The arrival of pharmacy is a major development in the growth of the University of Central Lancashire. This year also sees the opening of a School of Dentistry and there are plans, too, for a School of Medicine.

In recent years the profession of pharmacy has undergone an unprecedented level of change and the new course at UCLan has been specifically designed to prepare students for a new era in pharmacy. This is an exciting opportunity that has allowed us to devise an innovative and truly modern patient-centred course, which instils the knowledge and skills that are necessary to work as a pharmacist today. Pioneering aspects of the course in-

clude practice-based placements in all four years and the undertaking of a research project in the third year. Consequently, students will spend the final year studying cross-cutting master's level modules, which combine rigorous and relevant science elements as well as high level, clinically focused aspects of pharmacy practice. This will not only ensure genuine master's level achievement but will also prepare students for the preregistration year. The placement scheme was a major undertaking and was possible only because of the strong support of stakeholders in the region. The school is working with Medicines Management Network North West to develop and manage the extensive scheme.

The aim at UCLan is to recruit a high proportion of pharmacists to the staff. The university has provided strong support for the School. I was appointed in 2006, and the

school will launch in September with five pharmacists as permanent members of staff, a pharmacologist, plus two teacher practitioners and a number of clinical tutors. Several staff from the departments of biological sciences and of forensic and investigative science will also contribute to teaching during the early years of growth, but the school will eventually have a complement of 17 full-time staff.

A number of new teaching and research laboratories are at various stages of development. An aseptic suite was recently opened and a 300m² state-of-the-art pharmacy practice suite will be built this summer. Two new pharmaceuticals laboratories will also be built in the summer. Pharmaceuticals will be a particular strength at UCLan. The teaching facilities will include a laboratory where students will be able to formulate, manufacture and test solid dosage forms. Pharmaceuticals features in all four years of the course, culminating in a final year module on the drug development process. The university has invested over £1m in pharmaceuticals research and laboratories have been fully equipped for research in a range of areas including polymeric drug delivery, solid dosage forms and aerosols.

Further information about the school is available at www.uclan.ac.uk/pharmacy. — *Antony D'Emanuele, professor of pharmaceuticals and head of school.*

Launch conference

To celebrate the launch of the school of pharmacy at the University of Central Lancashire a conference has been organised which will consider the changes in the profession of pharmacy, how pharmacy education is evolving to meet these changes, and the way in which new and emerging technologies will affect pharmacy practice and science. For further information see www.pharmweb.net/futurepharmacy2007.html.



How industrial pharmacy teaching was developed for the new school at the University of East Anglia

The school of pharmacy at the University of East Anglia (UEA) is the first of the “new” schools of pharmacy and has just recently (March 2007) been granted full accreditation status by the Royal Pharmaceutical Society.

One of the advantages of being a new school was that we could design the course and the teaching methods from scratch (keeping in mind the Society’s indicative syllabus), without having to worry too much about existing timetabling constraints and entrenched viewpoints about what was required.

We also started out with another distinct advantage, namely, that I had spent nearly a decade in the pharmaceutical industry, in research and development, so I had a broad-ranging experience that could be directly translated into the teaching of industrial pharmacy.

One of the aims of UEA’s MPharm degree programme is to produce well-rounded pharmacists who have been exposed to all areas of pharmacy during the university course, thus allowing them to make informed decisions about the future careers. With this in mind, industrial pharmacy is not presented to the students as something separate from the rest of pharmacy, but rather as a part of a coherent whole. We believe that it is vital for the science and practice of pharmacy to be seen to be mutually responsive and, to that end, we have introduced a series of placements for our students from their first semester at industrial, hospital and community settings, while at the same time developing their general scientific and pharmaceutical knowledge.

Galenical formulation is taught in level I, with a range of lectures, workshops, demonstrations and practicals. Our standpoint here is that understanding and application of the basic science is vital to the development of medicines. To take the example of suspension formulations, the DLVO theory is taught in lectures, along with relevant information on excipients, formulation development and testing. In workshops, we present the students with a range of industrially based scenarios, in which they have to apply their newly acquired knowledge. A typical scenario may be that they are developing an oral liquid formulation of a new drug for both elderly patients and children, and they have some information on the solubility of the drug in various solvents and some information on the dose required. From this they have to determine whether or not a solution or a suspension is the most appropriate choice, explain their formulation strategy and identify any

possible issues. Practical skills are taught via demonstrations of small scale manufacture and repeated attempts at such until the students have displayed a reasonable level of ability at preparing such medicines.

Tableting is taught in level II via a research-based industrial scenario, in which groups of students have to develop a tablet formulation of a drug which exists in, for example, different hydrated forms or different polymorphs. This involves investigation of the solid-state properties of the drug, preparation of the granules and tablets, and testing of the finished product. The practical course culminates with an industrial review, in which the students have to present their work and their conclusions (and be grilled about them) to a panel composed of one of our local industrial pharmacist colleagues and one of our academic staff, simulating a project team review by a senior manager in industry.

The development of new drugs, including an in-depth study of the pre-clinical and clinical testing required for licensing, is taught in level III via lectures and a group project. In this, the students form the project management group for a hypothetical new drug for which there is only limited information given, extracting supplementary information from the medical, pharmaceutical, chemical, clinical and regulatory affairs managers (the academic staff) and identifying any issues that

may arise in the development of their drug. Fast-forwarding about 10 years, they are then given some clinical data on their drug and asked to develop a trade name and a slogan for their product, an advertisement for the professional press and a patient information leaflet. Some of these adverts are at least as good as those in the *PJ*.

In level IV, all students perform an individual research project, with the results being presented in the form of a scientific paper, rather than the mini-thesis traditionally used. Projects this year have included investigations into oesophageal drug delivery, the use of atomic force microscopy and Raman spectroscopy in understanding drug-excipient interactions and various novel formulations.

We have found that the students love formulation science because of its hands-on nature (everyone likes making things) and the fact that it is so easy for them to relate the science to the practice of pharmacy, in all its guises. Having academic staff with extensive industrial experience is also beneficial because students get the direct benefit of it. Many of our undergraduates are actively looking for vacation experience and future careers in industrial pharmacy, so I would like to think that at least some of our enthusiasm has rubbed off on them. — *Susan Barker, senior lecturer in pharmaceuticals, School of Chemical Sciences and Pharmacy, University of East Anglia.*

Industrial Pharmacists Group liaison visits



The annual IPG liaison visits meeting was held at the Royal Pharmaceutical Society’s headquarters on 17 November 2006. It was attended by around 20 team leaders and school of pharmacy delegates