



# Industrial *Pharmacist*

June 2006

## FOREWORD

### Dear Reader

The Industrial Pharmacists Group's series of continuing professional development roadshows is now complete and has been a great success. Janet Halliday was instrumental in driving this initiative forward and I would like to reiterate my thanks to her for her hard work. I would like to extend my thanks to the companies that hosted the roadshows and provided hospitality, and the staff of the Royal Pharmaceutical Society for their help and technical support.

Looking forward, we are now keen to promote the Qualified Person qualification as a serious career choice for pharmacy students and newly qualified pharmacists. This newsletter provides more information about the opportunity and we will continue to campaign to increase the number of members active in this important and well-rewarded field of industrial pharmacy.

Although some way in the future, we are planning an IPG session at the British Pharmaceutical Conference. The theme this year will be "Personalised medicines" and will consider the impact of the genomics revolution on the pharmaceutical industry and pharmacy practice. The IPG reception will be on 4 September and the seminar will follow on in the afternoon. This breaks the tradition of the Wednesday "slot" so please make a note in your diaries to be sure that you can join us.

Finally, as always, your comments and views on this newsletter, or any other aspect of the IPG are most welcome. Please contact me via [steve.wicks@pfizer.com](mailto:steve.wicks@pfizer.com).

### Steve Wicks

IPG chairman

## Athens hosts annual assembly of European industrial pharmacists

The annual general assembly of the European Industrial Pharmacists Group (EIPG) (see [www.farmacevtforbundet.se/eipg/](http://www.farmacevtforbundet.se/eipg/)) was hosted by the Greek delegates in Athens on 6–7 May.

The working group for "Continuing professional development" discussed a draft guidance document for Qualified Persons, Technical Directors and other Responsible Persons. The aim is to publish these guidelines to assist industrial pharmacists in Europe with continuing professional development.

The Royal Pharmaceutical Society's CPD process was also reviewed. This included a review of the CPD portal on the Society's web page. Feedback from delegates was that the impressive work of the Society should be followed and similar systems of assessing CPD should be adopted in other European countries.

The working group for "Undergraduate education and training" focused on how the EIPG could influence what is taught about



industrial pharmacy in the curriculum of undergraduate courses. One recommendation, agreed by the general assembly, was the setting up of a network of European universities and industrial pharmacists' associations to benchmark a curriculum for the future industrial pharmacist, under the auspices of a commission research project.

Other recommendations were to urge the pharmaceutical industry to encourage industrial pharmacists to act as guest lecturers at schools of pharmacy, to highlight the importance of industrial lectureships and chairs in industrial pharmacy and to upgrade the EIPG website to include a page on careers in the pharmaceutical industry. The advertising of careers materials will be discussed with the European Pharmaceutical Students Association.

The meeting was addressed by Panayotis Macheras and Dimitrios Rekkas from the School of Pharmacy, University of Athens. They described proposals for revisions of the undergraduate course, the status of the Bologna process in Greece and their participation in the meetings of the European Association of Faculties of Pharmacy.

The president of the European Hospital Pharmacist Group, Jacqueline Surugue, who attended the meeting as an observer, described moves to harmonise the labelling of



Kiriasis Savvas, Greek delegate for the EIPG and host of the meeting in Athens



drug concentrations for liquids, including injections. One recommendation the EHPG has made to the European Medicines Agency is to move away from expressing any concentration as a percentage on all labels of medicinal products because this has caused confusion and administration errors among the nursing profession.

The status of mutual recognition agreements was discussed. The prospect of the US Food and Drug Administration joining the Pharmaceutical Inspection Convention

Forum was welcomed as it will allow verification of standard operating procedures and may reduce the number of FDA inspections of European pharmaceutical sites in the future.

A survey in April across a broad spectrum of stakeholders (medical doctors, pharmacists, patients and industry) has shown inconsistencies in the reporting of adverse events. It was suggested that the reporting of adverse events was being hampered by the fear of litigation that faced reporters of such events. It was

agreed the position would be improved if other countries followed the example of the Danish government, which has passed a law giving immunity from such litigation to the reporters.

At the end of first day, there was a presentation by Manolis Mitakis on the history of pharmacy in ancient Greece.

The Italian and Irish delegates were elected as vice-presidents of EIPG. — *Jane Nicholson and Gino Martini, IPG committee members*

## Industrial pharmacists gather to hear President speak about CPD

The President of the Royal Pharmaceutical Society, Hemant Patel, visited GlaxoSmithKline in Ware on 21 February to deliver a keynote speech regarding the recording of continuing professional development.

The evening was hosted by Gino Martini, of GSK, and was one of a number of sessions co-ordinated by the Industrial Pharmacists Group. Previous sessions had been hosted by Pfizer, AstraZeneca and Controlled Therapeutics, but this was the first time that the President of the Royal Pharmaceutical Society had attended and presented at such an event.

The session was open to all industrial pharmacists working in the local vicinity and there were attendees from Roche, Merck, Sanofi-Aventis and Wyeth. In all, around 100 industrial pharmacists attended, making this the largest CPD roadshow ever staged by the IPG.

During his visit Mr Patel met a number of pharmacists from GSK as well as pharmacists from other companies and from the Industrial Pharmacists Group. — *Gino Martini, IPG committee member*



Hemant Patel, President of the Royal Pharmaceutical Society, addresses industrial pharmacists at a CPD roadshow coordinated by the IPG

### GSK seeks preregistration trainees for 2007–08 entry

GlaxoSmithKline is looking for preregistration trainees for 2007–08 entry. For further information please contact Pauline Geraghty ([pauline.geraghty@gsk.com](mailto:pauline.geraghty@gsk.com)).

### New therapies for the 21st century

The European Association of Hospital Pharmacists will be holding its 12th Congress on "New therapies for the 21st Century" at the Congress Centre in Bordeaux, France.

The congress will take place on 21–23 March 2007.

For further information contact [congress@aehtonline.org](mailto:congress@aehtonline.org)

CONGRESS



The President of the Society meets some of the industrial pharmacists attending the CPD roadshow: From left, John Jolley, Member and Treasurer of the Society's Council, Pauline Geraghty, GlaxoSmithKline, Gino Martini, GSK, Janet Halliday, Controlled Therapeutics, Hemant Patel, Society President, Jo Craig, GSK, Graham Leonard, GSK, Ann Duffton, GSK, and John Hemenstall, GSK

# New edition of study guide for Qualified Persons

A new edition of the "Study guide — guide to the knowledge and practical experience required by Qualified Persons in the pharmaceutical industry" by the joint professional bodies administering the QP scheme (the Royal Pharmaceutical Society, the Royal Society of Chemistry and the Institute of Biology) was launched in May.

The guide aims to help applicants applying for certification as a Qualified Person by setting out the body of knowledge and practical experience required when certifying medicinal products suitable for release within the pharmaceutical industry. It has been compiled by an expert working group and approved by the Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate.

The revised version takes into account changes in manufacturing legislation and includes minor changes to requirements and a revision of dosage form requirements. It is used by the joint professional bodies to interpret the requirements of the Pharmaceutical Directive 2001/83/EC and the Veterinary Directive 2001/82/EC.

The new edition has replaced the previous edition issued in 2000 and is available on the Society's website ([www.rpsgb.org](http://www.rpsgb.org)), along with other essential documents for those applying for QP status, including a revised Qualified Person application form. The documents collectively aim to provide detailed information on the requirements for certification and the application process.

As candidates sometimes complete their application forms over a period of time, the

joint professional bodies will continue to accept both the new and previous version of application documents until the end of 2006, although from 1 January 2007, only applications submitted on the new forms will be processed.

Pharmacists or sponsors wanting to find out more about the study guide and aspects of the oral assessment process can contact the Society's assessors for an informal discussion via Sadia Khan (e-mail: [sadia.khan@rpsgb.org](mailto:sadia.khan@rpsgb.org) or telephone 020 7572 2537).



A training day for QP assessors was held at the Royal Pharmaceutical Society's headquarters on 12 June. Assessors, chairmen, vice-chairmen and officers attended the meeting that focused on changes to the QP study guide and implications for the oral assessment process

SYMPOSIUM

## Changes in the QP world

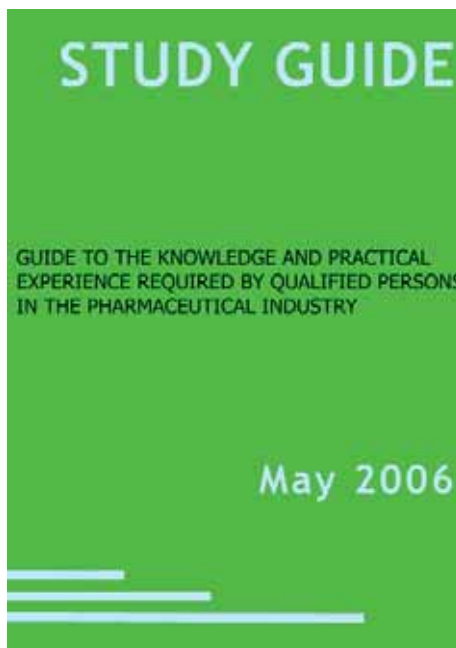
A one day symposium entitled "Changes in the QP world" will be convened by the Royal Pharmaceutical Society, the Royal Society of Chemistry and the Institute of Biology.

The programme is in the process of being drafted and further details will be available on the Qualified Persons section of the Society's website ([www.rpsgb.org](http://www.rpsgb.org)) in early September. The programme will be similar in format to the 2005 Qualified Persons symposium entitled "Legislation: understanding the practicalities".

Speakers' presentations from last year's meeting are available on the Society's website ([www.rpsgb.org](http://www.rpsgb.org)).

**Date:** 7 November

**Venue:** Royal Pharmaceutical Society, London



Front cover of the new edition of the "Study guide" for Qualified Persons

## How to join the Industrial Pharmacists Group and keep abreast of developments

The Industrial Pharmacists Group is a special members' section of the Royal Pharmaceutical Society. The aim of the group is to represent pharmacists working in pharmaceutical companies, regulatory agencies and consultancies.

The IPG is open to all pharmacists engaged in industrial practice and welcomes participation by any pharmacists with an interest in industrial pharmacy.

Many pharmacists who are academics are also members of the IPG because education plays a vital role in the pharmaceutical sciences.

To join all you need to do is e-mail [angela.canning@rpsgb.org](mailto:angela.canning@rpsgb.org) and state whether you would like to be contacted by e-mail or post.

To find out more about the IPG visit our page on the Society's website ([www.rpsgb.org.uk](http://www.rpsgb.org.uk)).



## MEETINGS

Contact for all meetings: Lisa Gilbert at [science@rpsgb.org](mailto:science@rpsgb.org).

### Parallel workshops on manufacturing science and practice for the pharmaceutical industry

Held by the Industrial Pharmacy Section of the International Pharmaceutical Federation and Febrafarma  
Date: 24–25 August  
Venue: Brazil, before FIP Congress

### British Pharmaceutical Conference

Date: 4–6 September  
Venue: Manchester International Convention Centre

### Towards computational pharmaceuticals

Held by the Academy of Pharmaceutical Sciences  
Date: Autumn 2006

### Inhalation workshop

Held by Academy of Pharmaceutical Sciences  
Date: October (to be scheduled)

### Tableting technology

An intensive course on the formulation, production and properties of pharmaceutical tablets. The basic concepts of equipment selection, granulation and end-point determination, formulation optimisation and prediction, in-process monitoring, film coating and official and non-official dissolution tests. Development pharmaceuticals for registration purposes.  
Date: 27–29 November 2006  
Venue: The Moller Centre, Cambridge

## Calling all pharmaceutical companies

The Student Exchange Programme is offered to pharmacy students all over the world via the International Pharmacy Students' Federation and is administered in the UK by the British Pharmaceutical Students' Association. The BPSA would like to encourage all members of the pharmaceutical industry to consider being a host. For more details and an information pack e-mail: [seo@bpsa.com](mailto:seo@bpsa.com).

# Formulating a career in industry — a pharmacist's success story

From my school days I was interested in working in the pharmaceutical industry, my motivation coming from an inspirational chemistry teacher. I had a place to study chemical engineering at Heriot-Watt University in Edinburgh but instead I studied pharmacy at the same institute; the department there is now closed.

I entered the pharmaceutical industry through the then most obvious route, ie, via a preregistration position, although with fewer industry preregistration places this is not so easily done now.

I had a combined hospital and industry preregistration training post. I spent my first six months at Ashington General Hospital in Northumberland and with the pharmacists at St George's Psychiatric Hospital in Morpeth, with whom I had some of my most interesting experiences. Working there whetted my appetite for formulation, with standard doses and special formulations being required for this group of patients.

I then moved on to Sterling Winthrop in Alnwick. I so much enjoyed my time there that I accepted a full-time post in the formulation department. The pharmacists I worked with at Sterling Winthrop were highly supportive.

I wished to follow a career in research and returned to university. After obtaining my PhD from the University of Strathclyde, with support from Glaxo, as GlaxoSmithKline was then, I joined Controlled Therapeutics as a bench scientist in the formulation group. Again, it was the encouragement of pharmacists in the company that enabled me to progress steadily through the organisation from bench scientist to scientist supervisor and then section manager, looking after increasingly larger groups of people and becoming involved in more and more different projects.

I now look after a group of 17 scientists in our research and development department. Our department's responsibility is to develop

novel formulations of existing well-characterised drugs and provide improved treatment options. The team includes chemists, microbiologists, biochemists and chemical engineers, but, for the last 12 months only, no pharmacists.

I have found that working with a small company has given me the opportunity to get directly involved with a variety of projects in different therapeutic areas. There is always scope for someone with enthusiasm and knowledge to become involved in different areas which are in need of attention. I find that in a small company you can grasp an opportunity without feeling as though you are taking over someone else's job and you can see the results of your efforts from beginning to end.



Janet Halliday enjoys the benefits that a smaller company can provide

During my career I have seen several products coming through development and eventual launch on to the market. As a scientist, as well as a pharmacist, I find this particularly satisfying since I get to see the circle of steps from the science right round to the patient. I would advise any pharmacist with an interest in the science of therapeutics to explore the varied opportunities within industry.

I have been involved in the formulation of oral solid dose products, as well as some more exotic formulations, eg, a tablet for disinfecting contact lenses — a particularly challenging product to work on. My work now is focused on women's healthcare products which utilise a controlled release technology invented just 12 miles from the facility, at the department of chemistry at Strathclyde University. We are also working on developing our own new technologies.

In addition to my job as a scientist I maintain my professional responsibilities as pharmacist. I was involved in the implementation of CPD and with the Industrial Pharmacists Group I have arranged a series of workshops to assist fellow industrialists in recording their CPD. — Janet Halliday, IPG committee member