



Industrial *Pharmacist*

October 2006

FOREWORD

Dear Reader

Welcome to the latest edition of the Industrial Pharmacists Group's newsletter.

The 2006 British Pharmaceutical Conference was a great success and the pharmaceutical industry was well represented in many aspects of the event. Many more industrial pharmacists appeared on stands at the exhibition this year to explain the mission and purpose of their companies to potential recruits. Exhibition stands at the BPC are now becoming an important medium of outreach for the IPG and not just those from the larger pharmaceutical companies — this year there was a strong presence from smaller companies, the specials sector and the Medicines and Healthcare products Regulatory Agency. Why not start planning your stand for BPC in 2007? If I can help contact me at steve.wicks@pfizer.com.

I can report that the 2006 IPG seminar at BPC was a great success and an excellent report, written by Harriet Adcock, can be found in *The Pharmaceutical Journal's* September BPC supplement (ppB9–B10). I would like to extend my thanks to Paul Morgan from Pfizer, Linda Dodds from the University of Greenwich, Bruce Jordan from Roche and Gino Martini, a member of the IPG committee and GlaxoSmithKline, for their excellent contributions.

I am delighted that this newsletter contains an article by two pharmacists who have recently achieved Qualified Person status. I hope this will inspire all pharmacists, not just IPG members, to find out more about this important and rewarding career-development opportunity.

Steve Wicks
IPG chairman

Is the MPharm still a useful degree for a career in industry?

The Royal Pharmaceutical Society is currently consulting on draft principles of pharmacy education and it seems timely to reflect on current practice, particularly relating to careers in the pharmaceutical sciences. The past 20 years have seen immense changes in pharmacy education with the rapid development of practice-related topics and the introduction of a four-year master's level course after many years of a three-year undergraduate degree.

A major problem for many courses was the need to incorporate more practice-based programmes alongside scientifically intense curricula and the constraints of the time available. The four-year course has helped but it took some years to move from a "more of the same" mindset to a "let us design a course fit for purpose" and current courses are still continuing to evolve on a changing landscape. It is an issue that policy development does not always allow the four- to six-year time frame to change course content and see implementation in its first cohort of students.

For many years careers in pharmacy or the pharmaceutical sciences both started with a pharmacy degree but more recently a number of institutions have introduced degrees in pharmaceutical sciences per se. My own survey of pharmacist employment in the pharmaceutical industry (1999) showed pharmacists in almost 50 different job descriptions ranging from discovery science through to development, regulatory affairs, project management, and sales and marketing. In the main, pharmacists had joined companies either as scientists or as part of marketing operations. My sense in 2006 is that both pharmacists and pharmaceutical scientists can achieve these satisfying careers and it is to be hoped that the new "Principles of pharmacy education" deriving from the consultation will continue to support these access opportunities for pharmacists. Those people with views on the subject should ensure that they contribute to the debate.

Current courses in many schools of pharmacy have succeeded in melding science and practice around therapeutic areas or around platforms such as diagnosis and counselling. Solutions to educating pharmacists in such



disparate disciplines vary from school to school but in my role within the Royal Pharmaceutical Society's accreditation team I have been impressed by the creativity demonstrated by staff and teacher practitioners to ensure that the connectivity is clearly demonstrated. I believe that it is much more important that students are able to relate these strands effectively and think widely about problems rather than to have valuable contact time lost by having too many exemplars of key principles.

Chemistry, pharmacology, analysis, formulation, ethics, law, patient needs and communication skills, to name but a few, all have their place in the current course and in my view should be maintained in the future. The key is to encourage students to think in an integrated way with the data sets they have and a modern course must maintain all these building blocks. Thought given to teaching methods, student experience, entry-level skills and the characteristics of a well trained, newly qualified pharmacist or pharmaceutical scientist will be time well spent.

The newer disciplines in the pharmacy curriculum such as health economics, psychology and social sciences all bring valuable insight into patient care and currently bridge this experience into the science-based world of medicines discovery and development. It might be possible to unbalance courses in the future by overemphasis of these new areas and that would be a pity. The past 10 years have seen separation of science and practice and then reintegration and it would be tragic if this hard-won experience was sacrificed.



Certainly the pharmaceutical industry sees the benefits of these new disciplines and their application to the total world of provision of effective therapies to patients.

The essence of these careers is the integrative nature of pharmacy with its multi-stranded curriculum and its key training in competencies. There is no room to consider these as separate elements — rather, all are essential for the well-rounded graduate who is able to develop a career in fundamental scientific research or to use an excellent science

base in practice oriented to patients and health care. I do not believe it is possible to consider a course which does not meet both requirements and the key is to recognise the wide flexibility and career potential which derive from a pharmaceutical qualification. I do believe that an MPharm is a useful degree to begin a career in pharmaceutical sciences and will provide wider scope for some career strands in industry than other pharmaceutical science entry degrees. — *Bill Dawson, IPG committee member*

Launch of the 2020 consultation

The British Pharmaceutical Conference in Manchester saw the launch of the Royal Pharmaceutical Society's Pharmacy 2020 consultation. The aim of the Pharmacy 2020 consultation is to:

- Identify the challenges and drivers that affect the pharmacy profession's ability to fulfil their potential as health care providers
- Identify good practice in pharmacy
- Prepare a forward strategy to take pharmacy to the year 2020

The project will look to achieve similar goals to the "Pharmacy in a new age" (PIANA) project that took place about 10 years

ago. The original PIANA project set out where pharmacy wanted to be in 10–15 years' time. Much of the strategy that PIANA set out for the profession has influenced current pharmacy policy for the English, Scottish and Welsh health departments.

To inform any future forward strategy a full picture of what is happening in pharmacy today is needed so that the profession can

move forward, understanding the difficulties and these can be articulated to the Departments of Health. The initial phase of the project will include a consultation on what the barriers and drivers are that currently affect the pharmacists as health care providers for the public. This will provide a foundation to consult with the public and the profession as to what their needs and expectations will be as we move forward to 2020.

The project is led by the Society's President, Hemant Patel. Steve Wicks (chairman of the IPG) is a member of the steering

group along with representatives from other sectors and England, Wales and Scotland.

The project will run over two years and there will be a

number of consultations conducted under the Pharmacy 2020 banner. The first phase of the consultation will be finding out what the barriers and drivers are that currently affect the pharmacy profession's ability to fulfil their potential as health care providers for the public. A consultation is already being undertaken around the high level aspects of the Code of Ethics. The education review consultation started in the autumn of 2006.

These consultations will take place over three to six months. The consultation on the main question on a forward strategy for what the profession should look like in 10–15 years will take place after the first consultations. This consultation will involve the profession as well as other professions, patient groups and the public.

It is important for the future that all pharmacists take the opportunity during the main consultation to tell the Society what they want the pharmacy profession to be in the year 2020. Further information on Pharmacy 2020 can be obtained from Michele Savage, project manager (michele.savage@rpsgb.org or 020 7572 2564). — *Michele Savage, Royal Pharmaceutical Society*



Counterfeit medicines

The World Health Organization's current initiative to combat counterfeit medicines, the "International medical products anti-counterfeiting taskforce", was a topic at the 2006 Congress of the International Pharmaceutical Federation presented by Valerio Reggi, from the department of technical co-operation for essential drugs and traditional medicine at the WHO. A summary of the proceedings will be available on the Royal Pharmaceutical Society's website (www.rpsgb.org).

IN BRIEF

MEETINGS

Principles of pharmacy education

Date: 6 November
Venue: Riverbank Plaza, London

Tabletting technology for the pharmaceutical industry

Dates: 27–29 November
Venue: Moller Centre, Cambridge

Materials functionality and fitness for purpose in solid dosage forms

Date: 7 December
Venue: Hesperia Hotel Victoria, London

Bioval 2007

Dates: (potential) 24–26 January, 31 January–2 February, 8–9 February 2007
Venue: TBC

Stability testing of pharmaceuticals

Dates: 19–21 February 2007
Venue: Moller Centre, Cambridge

Arden House: The development and manufacture of parental dosage forms — quality and regulatory issues

Dates: 12–14 March 2007
Venue: Conference suite, Royal Pharmaceutical Society, London

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

How to join the Industrial Pharmacists Group

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 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).

Achieving QP certification — the category A route

The Medicines and Healthcare products Regulatory Agency and the Veterinary Medicines Directorate have delegated to the Royal Pharmaceutical Society, the Institute of Biology and the Royal Society of Chemistry (the “joint professional bodies”) responsibility to assess the eligibility of their members for Qualified Person status. Suitability for inclusion on a manufacturer’s licence as a named QP is determined by the appropriate regulatory agency (MHRA or VMD).

There are four categories of practitioner eligible for certification by the joint professional bodies under permanent and transitional provisions. They have been designated Category A (permanent provisions) and Categories B, C and D (transitional provisions). Each of the three professional bodies has responsibility for certification of its own members.

This is an overview of the application process for pharmacists registered in Great Britain applying for eligibility via the Category A route. This route follows a more formal procedure compared with the applications via the transitional routes. Detailed information on applications via the different routes and useful documentation is available on the Society’s website (www.rpsgb.org).

Administration

Each professional body has a QP officer and panel of assessors with a chairman and vice-chairman. The members of the Society’s panel of assessors are all experienced, practising-pharmacist QPs. Administrative support for the Society’s scheme is provided by Angela Canning (angela.canning@rpsgb.org).

Step 1: Application preparation

Before applying, candidates should refer to the documents mentioned below and ensure that the requirements for qualifications, knowledge and practical experience set out in the study guide are met:

- Study guide 2006
- Guidance notes for applicants and sponsors
- Application form
- Sponsor form
- QP Code of Practice

The joint professional bodies do not recommend or endorse particular QP training courses. However, details of different course providers are available on the Society’s website.

Pharmacist applicants should have at least one year’s relevant practical experience in one or more undertakings, with an authorised full manufacturing licence for medicinal products or investigational medicinal products for clinical trials. Institute of Biology and Royal

requirements and all areas of the study guide have been covered. The candidate is invited for interview provided that the assessors are satisfied that the candidate meets the required standard from their paper assessment. Occasionally the office may need to contact the candidate for further details or clarification on the application.

Step 3: Interview

The candidate is invited for interview at the headquarters of one of the joint professional bodies which have a joint programme of interviews and will offer the first available date regardless of location.

The QP interview panel usually comprises one assessor from each professional body and is chaired by an assessor from the candidate’s own professional body. The Society’s QP officer attends to minute questions from Society candidates. An observer may also occasionally attend.

The assessment includes a mixture of factual and scenario-type questions. The assessors ask questions in turn and aim to determine

the candidate’s application of knowledge and experience across all dosage forms. At the end of the interview the panel makes a pass or fail decision.

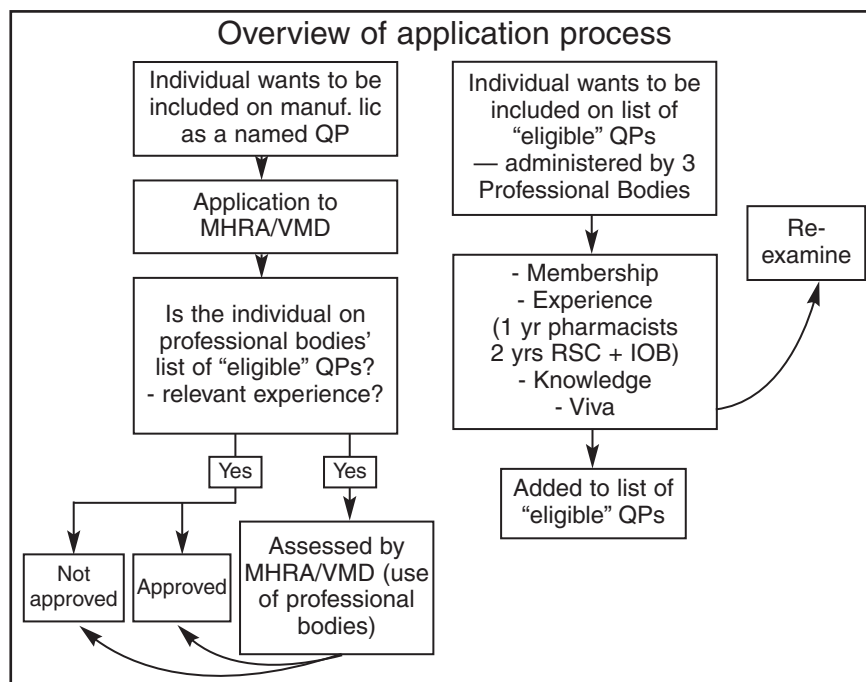
Step 4: Result

The outcome of the interview panel’s decision is relayed to the candidate at the end of the viva, and via a letter indicating a pass or fail.

If the candidate passes they are added to Society’s register of eligible QPs and receive a certificate. If they fail the candidate is advised how to proceed (may require further study, possible reapplication, etc).

Each professional body maintains its own separate QP register of eligibility, details of which are communicated to the MHRA.

Further information can be found on the Society’s website. Pharmacists and sponsors wanting to find out more about any aspects of the oral assessment process can contact the Society’s assessors for an informal discussion via Sadia Khan, the Society’s QP officer (e-mail sadia.khan@rpsgb.org tel; 020 7572 2537). — Sadia Khan, Royal Pharmaceutical Society



Society of Chemistry applicants require two years’ experience.

Applicants need to provide evidence of knowledge and relevant practical experience. A completed application form, sponsor’s report and application fee should be sent to the Society’s QP officer.

The sponsor’s report is used to verify details provided by the applicant. The sponsor should preferably be a practising Qualified Person who has known the candidate for the qualifying period of experience and must be a member of one of the three professional bodies. The “Guidance notes for applicants and sponsors” set out the requirements for completion of the application form and sponsor’s report.

Step 2: Initial assessment

The office undertakes a preliminary assessment of documentation to ensure that the application is complete and that requirements for qualifications, Society membership and manufacturers’ licences are met.

Copies of the documents are sent to two members of the Society’s QP panel of assessors to ensure that the experience cited meets



Becoming a Qualified Person is realistic and achievable — two new QPs tell how they did it

Clare Richer

I wanted to become a Qualified Person to maximise the knowledge I gained from my pharmacy degree coupled with my industrial experience. It was a natural self-development opportunity which would open up more avenues in a changing and challenging environment. It would allow me to do my job better and give me increased job satisfaction.

The study required for QP status encompasses most of what is covered during the pharmacy degree course — still, there are few QP pharmacists. I had the added benefit of the experience of the pharmaceutical industry to enable me to apply the theory and put it into perspective. Becoming a QP has allowed me to see the bigger picture.

I obtained a first class honours degree in pharmacy at Bath University in 1990. I did my preregistration training at St Bartholomew's Hospital in London and GlaxoSmithKline in Ware, Hertfordshire. I then moved to ICI Pharmaceuticals (now AstraZeneca).

I spent my early years on commercial production sites in the UK, France and Italy providing technical support and validating product processes and facilities and equipment. I then changed to quality assurance supporting commercial active pharmaceutical ingredients manufacturing. Following this, I moved into research and development to provide quality assurance support and release of investigational medicinal products for use in clinical trials. After implementation of the Clinical Trial Directive 2001/20/EC in 2004, I attained transitional QP status for investigational medicinal products.

I started the Brighton University postgraduate diploma course in industrial pharmaceutical studies in May 2004. The course comprises six modules over two years. Each module includes personal study, a residential week and several assessments. I attended the first module in September 2004 and thoroughly enjoyed being back in university life. It was great to meet other QP trainees and make new contacts.

I completed the course in June and was awarded a postgraduate diploma with distinction in pharmaceutical studies. It was challenging because I became pregnant on starting the course and my second child arrived mid way through in March 2005.

I did an internal mock QP viva. I chose a



Clare Richer and Vicki Whyte show off their certificates

panel of QPs knowing that they would challenge me and make me feel uncomfortable but only to my benefit. Having got through this it would never be as bad on the day.

My date for the QP viva was 26 July 2006 and I was so relieved that this was before the summer holidays. It was at the Institute of Biology and the last one for the day. As customary for interviews, I arrived in plenty of time and tried to find somewhere comfortable to relax beforehand. The viva itself goes quickly. I had mainly scenario questions.

Was it all worth it? Yes it was. Despite all the difficulties, I enjoyed the learning experience. I want to use it to further my career development and given the confidence, knowledge and experience I acquired during my QP studies, I am 100 per cent confident that I have a promising future ahead of me.

Vicki Whyte

For me there were two main reasons for deciding that I wanted to train to become a Qualified Person. The first was job security and career progression and the second was because I wanted to make a difference to patients' lives. Although it is rare for me to come into direct patient contact working in the pharmaceutical industry, I am always aware that the products we manufacture are life-saving treatments taken by millions of people worldwide.

I studied pharmacy at Robert Gordon University in Aberdeen between 1992 and 1996 and graduated with a first class honours degree. I did my preregistration year in hospital and worked as a hospital pharmacist for a year after qualifying.

In September 1998 I joined AstraZeneca as a quality assurance adviser supporting manufacturing activities at its Macclesfield site. I like to think of the QA department as being the conscience of the company. I work closely with my production colleagues investigating quality related manufacturing deviations, promoting a "right first time" philosophy, auditing for compliance with regulatory standards and recommending material suitable for sale to the site QPs.

AstraZeneca has a long history of training people to become QPs and during 2004 it was agreed that I could start my training. The first thing I did with my sponsor was to go through the QP study guide and identify areas where I lacked knowledge and experience. I then drew

up an action plan to address these gaps. The activities I identified were typically things like attending internal or external training courses and shadowing people within other departments at AstraZeneca.

I am lucky to work for a large manufacturing company with a wide range of formulations produced on site. I exploited this to its full potential to gain knowledge and experience in a breadth of areas that are relevant to QPs.

My viva was held at the Institute of Biology on the 26 July 2006. I was only asked a few theory questions and most of my assessment was based around scenarios. I was able to call upon my experiences and knowledge, having worked in a manufacturing environment for many years, to answer these questions.

The viva passed quickly and when it finished I was told that I had passed and my name would be entered into the register of eligible QPs.

So, was it worth it? Having a pharmacy background I am constantly aware that everything we do during manufacturing can have an impact on the patient. QPs are people of great importance within industry as they have the decision on whether to certify a batch as being acceptable or not. Although I am not named on the "Manufacturing licence" as yet, I have enjoyed learning the theory surrounding the legal requirements that pharmaceutical companies must comply with and having a breadth of practical experience has helped round me as an individual. So yes, it was a lot of hard work studying for the viva but it was worth it.