

The Global Faculty

This edition of the Faculty Newsletter is themed around the experiences and insights of UK physicians who have developed their careers internationally. This should be of no surprise given the global nature of drug development, regulatory affairs and pharmacovigilance.

Currently, 35% of the membership of the Faculty is based outside the UK. Also, many members who are based in the UK have an international remit in their roles as physicians. Given this, an even greater proportion of the Faculty Membership is actually 'international.'

The articles in this edition offer some insight from experienced physicians and recognises the many members of the Faculty who have responsibilities or have worked and lived in other parts of the world. There is also an article on the development of a certified course in Pharmacovigilance which has been set up in India.

*Dr Jit Solanki MFPM
Communications Committee*



The Faculty of Pharmaceutical Medicine
Advancing the science and practice of pharmaceutical medicine for the benefit of the public



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Japan

I worked in Japan on secondment for two and one half years from 2004 – 2006. I was head of the Clinical Division, and was also head of the Clinical Science Group and of the Physicians' Group (7 MDs). There was also a cross functional Physicians's Forum (13 physicians plus myself and the R&D Director).

The remit covered many of the traditional aspects of a head of department/medical director (global and local clinical trials, interactions with Marketing, local portfolio management and people management) although Regulatory activities were handled separately. Since Japan is part of our global drug development programmes the product strategy was set by the global teams after consultation with teams in Japan.

In considering the role of pharmaceutical physicians in Japan there are three major topics I'd like to cover: the relative infancy of pharmaceutical medicine in Japan; the unique clinical trial environment and the lack of external training suppliers.

I went to Japan initially to develop a physicians group, including recruiting new physicians and providing training. Japan is different in terms of the number of physicians working in the industry and the roles of such physicians. In many respects it mirrors the situation in Europe 15-20 years ago. There are many domestic companies who do not have any physicians and who rely on external advisors. Some companies have only one physician who is an internal advisor but who doesn't get involved in the operational aspects of clinical trials. Increasingly companies are recruiting more physicians but this trend is mainly driven by the global companies.

There is no standardised higher medical specialist training system in Japan so physicians are dependent on their local hospital and professor for their training and careers. This makes it more difficult to leave the hospital system to join the industry, since it is much harder to get back in once one has left. Working in the industry is still not as well accepted as it is in other parts of the world. Very few Japanese physicians actually realise that it is possible to work in the pharmaceutical industry!

Since there have been few pharmaceutical physicians in Japan the various teams are not used to working with physicians. Traditionally, physicians in Japan have enjoyed a very high professional and social status. This

has made it difficult for them to move into a team-based, non-hierarchical working environment. However, times are changing and many younger physicians, especially those who have spent time working abroad are making the transition more easily.

The clinical trial environment in Japan is still characterised by daunting bureaucracy resulting in small numbers of patients per clinical trial site (typically less than 5), hence multiple sites and expensive trials. There is little or no incentive for investigators to run clinical trials as this is an additional burden to their already heavy clinical workloads. Unlike their colleagues in other parts of Asia (Singapore, Hong Kong, Taiwan, & Korea) they have not had support from the government to simplify and facilitate the running of clinical trials (training and accreditation for investigators, standard ethics committee submissions and clinical trial centres of excellence). Interesting the Japanese Government has recently recognised that it has fallen behind its neighbours and is now addressing this.

There are very few external opportunities for training industry physicians. Japanese Association of Pharmaceutical Physicians (JAPhMed) has recently started a programme but it is still in its infancy in comparison with Europe and the US. Therefore, there was a greater emphasis on running internal training programmes. To support the physicians group we introduced: regular medical forum meetings where we linked via VC into our office in Shanghai since the physicians in China also had limited opportunities for training; an Introduction to Pharmaceutical Medicine course; Drug Safety courses and media training.

Working in Japan was a thoroughly enjoyable experience. However, because of the language barrier it would be difficult to work in a non-managerial position.

*Dr Mike Hardman FFPM
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Having completed MRCP I back-packed around the globe for 2 years in my late 20s. While this was essentially a late “gap” year I also took locum positions in English speaking countries. One key learning was the speed with which clinical practice adjusts to financial incentives, because it took only about two weeks for British GPs trained under the capitation system to move from astonishment to practicing like the locals who had trained under fee-for-service. More broadly the chance to work with remote Aboriginal groups or the world’s elite jet-set on equally remote Pacific islands provided unique social and cultural insights.

Returning to the UK and entering pharma in 1990 I was surprised how little the industry valued my international clinical experience....a first lesson that the benefits of international experience appear greatest to those who have it.

12 years later I was working in relatively rural South East England at the EU HQ of a large American company as the team leader for a program in Phase 2. My subsequent move to the US was definitely relocation-lite in that I moved to the US HQ in relatively rural New England and continued in the same role on the same project. My expectation was that the move would be straightforward and indeed by noon on Day 1 it was pretty much business as usual. I wasn’t expecting any “see the world” benefits but had simply two drivers—the move was the best way to advance my project and US experience was an obvious—but ill-defined—career advantage. Oh and at the exchange rate at that time I got paid more.

Learning 1: Although I had previously visited my US colleagues for up to two weeks at a time, you do see things anew when you lose all vestiges of jet lag and the visitor tag. Face to face people’s thoughts and feelings immediately become clearer but it took weeks and months of reinforcement for my underlying perception and assessment of people to change.

So for anyone working in a global context I would recommend spending 2-3 months at other site(s). The benefits of greater insight into individual colleagues will diminish as your network turns over but insights into the specific culture will remain as will the greater cultural flexibility. I’d argue that for most of us the barrier to such a short stay is habit rather than real financial or social hurdles.

Learning 2: The standard advice about the challenges of the “trailing spouse” is correct. If/when I move again I will focus on enabling my family’s new social networks. (More details available orally!)

Learning 3: Regarding human behaviour, processes, systems and adminstrivia: Try not to judge/compare with where you have come from. Most Faculty members are used to analyzing data and situations, generating options and making decisions. As a recent immigrant you are in another universe...one that you will pass out of more rapidly if you avoid unnecessary spins. Concentrate on the wonder of being free to turn right on red rather than the nuisance of 4 way stops at every junction. Or the benefits of optimism and individual energy rather than the absence of a coherent plan. In the natural human search for order it is easy to attribute the random or inexplicable to your new location.

Learning 4: Differences within a company or country may be larger than those between companies or countries and anyone considering a move should pay attention to this. Having now worked for some years in central New York, I would consider our New England site much more similar to the UK than New York.

Learning 5: If your role is global your external contacts, tasks and learnings may be relatively independent of the country in which you live. If you want to deeply understand a specific market you are probably best with a role that focuses on that market. A part time clinical attachment while overseas would be a great learning opportunity but I don’t know anyone who has done this.

Learning 6: After a few years abroad you will better understand the UK’s role in the world and have career and personal choices that wouldn’t otherwise be available. Expatriates have remarkably different memories of the details of life in the UK and even more divergent views on life there now.

Learning 7: Homo economicus would move around the globe according to life stage. More practically those who have moved from EU to US over the last 7 years would advise you to minimize currency and housing market exposure unless you are sure you have reached your final resting place.

*Dr Neil Mackillop FFPM, Developmental Team Leader
Pfizer Global Research and Development, New York*

Asia Pacific

"We will not move again!" we said as we moved to Sydney. Six years later, my current role is Vice-President, Regulatory Affairs and Pharmacovigilance, Asia-Pacific for Baxter Healthcare, based in Shanghai, where I have been living since January. I am responsible for regulatory, pharmacovigilance and oversight of development activities in the region which stretches from India across to Japan and down to Australia/New Zealand. This is a new role, so much has involved mapping what is going on, what the areas of need are, and putting processes and procedure in place to address the growing ever more sophisticated needs in this exciting region. I am hoping to get involved with the local pharmaceutical medicine group, and be able to contribute to help with education in China. It is wonderful to be in China and see the changes and be part of it.

I qualified in the UK and after several years in practice, joined the industry in the UK as research physician in a Phase I unit, moving into a role in global Phase II/III development. I then moved to Japan with my husband and worked there for 5 years, working for a global multinational and then a CRO, supporting local Japanese development.

Subsequent to this role, I worked as a Regional Medical Director, based in Hong Kong, for a multinational, and worked for the same company in the USA, before taking up a regional Medical Affairs Director role for a Japanese company based in the Netherlands.

At this point, my family had never lived in Australia, despite being Australian, so having decided that we needed to go home, I accepted a Medical Director role with a European company, building up their research capability in Australia and New Zealand and going through a merger. Here I was also involved in working with the University of New South Wales to set up a Diploma in Pharmaceutical Medicine, which will have its first graduates at the end of the year, and will hopefully then be accredited by IFAPP. We are very proud of this!

The role of the Pharmaceutical Physician is different depending on where you are, and the role you have. Being competent and adding value, while protecting the interests of patients, is accepted and valued everywhere.

My biggest mantra is: Don't assume anything! Don't assume that medical practice is the same, don't assume that if we speak the same language we understand each other, don't assume that people understand you, don't assume that if someone says it cannot be done it really cannot – keep asking questions! Don't assume that yes means yes and no means no – sometimes they mean 'maybe' or 'I know this is what you want to hear'. Listen more than you talk!

Learn as much as you can about the culture you are going to, and at least some of the language as if you do this you may understand more about the 'don't assumes' above, and your efforts with the language are very much appreciated.

Smile – it is universal – and be prepared to eat some really unusual food!

Use your emotional intelligence to put yourself into other people's skins and look at things with their 'eyes' from their perspective – it can be surprising how much this helps.

Learn how to adapt your leadership style to the one appropriate for the situation – different cultures have very different expectations, and getting things done is easier if you know what people respond to best.

The Faculty has been a support and a font of knowledge, and has always been a source of professional updates. I very much value the contacts I have made through the Faculty, for example being able to talk to people about education in pharmaceutical medicine.

Being a Pharmaceutical Physician is a very transferable skill, and I would encourage you to get out and try another country – or a few – for a period of time – in this age of globalisation it is great for you and your family to be part of it!

*Dr Victoria Elegant FFPM
Vice-President, Asia-Pacific
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USA

A world of opportunity exists for a physician in the pharmaceutical industry if you are willing to embrace it. No matter what your medical background or current pharmaceutical areas of interest are, there are numerous possibilities available. All that is required is the interest, planning, adaptability and a willingness to challenge oneself.

If one of these opportunities happens to be outside the UK and this is a direction that intrigues you, how does working as a pharmaceutical physician in the UK prepare you for such a role? In my experience, quite well in fact.

I am an Irish educated and trained physician, who left clinical medicine to work in pharmaceutical medicine in the UK and I've found that my time spent in the UK was an excellent experience and training ground for my role as a Global Medical Director based in the US. The UK is a large enough market to give you exposure to large-scale pharmaceutical practices, both medical and marketing related, but also small enough to still allow you experience working directly with customers and the sales force. It also gives great opportunities for interacting with important institutions to the pharmaceutical industry, such as regulatory (MHRA), research (Wellcome Institute), pharmacoeconomic and market access (NICE). Indeed, many of these UK-based organisations are recognised as world leaders in their own right.

From Medical Adviser in the CNS therapy area in the UK, I moved to a Global Medical Director position in Psychiatry and working in a global capacity has been an excellent experience. The role can be quite varied from a day to day perspective, but basically involves being the global medical expert for a particular product in order to oversee all the medical aspects in relation to that product, including clinical research and development, publications, pharmacovigilance, outcomes research, medical information and regulatory. It also requires close

cooperation with Global Marketing colleagues in relation to global campaigns, strategic lifecycle planning and interaction with global opinion leaders.

The one thing that I really enjoyed about working in a global capacity was the feeling of ownership for driving the direction for a particular product. It gives you a sense of really being able to affect change for the greater good of patients.

The Faculty of Pharmaceutical Medicine and HMT programme in Pharmaceutical Medicine programme were very helpful in terms of exposure to and training in the different aspects of pharmaceutical medicine, which helps make you a well rounded pharmaceutical physician and you really notice this difference when working with others who have not had this benefit.

*Dr Anil Jina
Previous Global Medical Director,
Pfizer Global Pharmaceuticals
New York*



Certificate Course in Pharmacovigilance & Pharmacoepidemiology in India

Symogen, based in New Delhi has taken the initiative and started the first of its kind of a Certificate Course in Pharmacovigilance & Pharmacoepidemiology in India with a view to train students who want to be part of the national pharmacovigilance program and pharmacovigilance in general in an effective way.

Dr Susan Bews, President, Faculty of Pharmaceutical Medicine, Royal College of Physicians, London, UK inaugurated the Certificate Course on the 1st September 2007, in New Delhi. She addressed senior dignitaries from various government institutions like the Drug Controller General of India Office (which is the Regulatory Authority of India), Ministry of Health, Department of Science & Technology, Department of Biotechnology, etc, Business Process Organisations (BPOs), a number of Clinical Research Organisations (CROs) and pharmaceutical company representatives, students and others. Faculty members from various Medical Colleges, Universities and Hospitals throughout India also attended the inauguration ceremony.

Dr Bews, in her address, reiterated the need for a Pharmacovigilance system and stressed on the need for qualified and trained experts to meet patient safety which is the prime concern throughout the world at present. She motivated and encouraged the students on important issues like betterment of clinical research in India and stated that India is “fast becoming the centre” for conducting many studies due to reasons like quick regulatory approvals for clinical & PMS studies, multi-dynamic, multi-faceted, multi-ethnic patient groups among others, English speaking Investigators and physicians and qualified healthcare professionals.

Addressing the gathering, Dr Venketaswarlu, the Drug Controller General of India (DCGI), spoke about the National Pharmacovigilance Programme and mentioned the difficulties faced by the DCGI's office for non-compliance of guidelines by pharmaceutical companies and CROs. He stressed the need for a dynamic, voluntary and able system to meet the needs for Pharmacovigilance in India and encouraged the private sector to join hands with the Public Sector to build a



Mr Rakesh Rishi; Dr Manish Pahwa; Dr Susan Bews; Dr Pipasha Biswas; Prof Santanu Tripathi; Prof Arunabha Ray; Mr Partha Chakraborty; Dr Bhawana Awasthy; Dr Syed Ziaur Rehman; Prof Nilima Kshirsagar and Mr S Sengupta

strong system to support the program. Dr Pipasha Biswas, Director, Symogen U.K., promised to support the National Pharmacovigilance Program and along with Cognizant Technology Solutions, will help develop a National level Indian Safety Database for Adverse Drug Reactions (ADRs). She also mentioned that Symogen would help BPOs, CROs and Pharmaceutical companies on Pharmacovigilance services and requirements.

Pharmacovigilance is still in its infancy in India and there exists a very limited knowledge of the discipline. While major advancements in the discipline of pharmacovigilance have taken place in the Western countries, not much has been achieved in India. However, with more and more Clinical Trials and other clinical research activities being conducted in India, there is an immense need to understand the importance of pharmacovigilance and

how it impacts the life cycle of the product, so as to integrate Good Pharmacovigilance Practices in the processes and procedures to help ensure regulatory compliance and enhance the quality of clinical trials safety and postmarketing pharmacovigilance.

This course will provide the knowledge to prospective students about all aspects in Pharmacovigilance, which can then be applied in respective work environments ranging from Pharmaceutical Companies, CROs, BPOs companies, Regulatory Agency i.e. DCGI Office & CDSCO, hospital settings and the academia. At this moment there is an immense need for professionals with good understanding of medical ethics, clinical research,

pharmacovigilance practices and patient safety, western regulations and effective communications in India, which this course aims to provide.

*Dr Pipasha Biswas
Principal Consultant & Director
Symogen Ltd, UK*

This comprehensive course consists of 12 modules covering all aspects of Pharmacovigilance and Pharmacoepidemiology, which is taught by an International Faculty. The classes are held every Saturday for eight hours with an additional four hours per week of self study by the students. The course is open to Doctors/Physicians of all disciplines (both fresh graduates with at least one year of clinical experience working in hospitals & Post graduates); Post graduates in Pharmacy and Bio-sciences (both MSc and PhD); Junior professionals working in Pharmaceutical and IT Industry, Clinical Research Organisations, BPOs, Academia and Regulatory Agencies. At the end of the course students will take a written exam and also submit a short project.

Faculty of Pharmaceutical Medicine
2008 Annual Meeting and Dinner
Monday, 17th November



Royal College of Physicians London publications

Guidelines on the practice of ethics committees in medical research with human participants

Fourth edition

The fourth edition of the RCP's practical guidelines for ethics committees, offers a concise summary of the ethics of biomedical research involving human participants. It has been designed to be compact and accessible but comprehensive enough for everybody involved in research, and will contribute to the development of research to help improve human welfare.

This guide will be a valuable and much used source of advice for those contemplating a clinical trial or other medical study and will help those who sit on ethics committees to do their job more effectively.

For more information and to order a copy, please call 020 7935 1174 ext 358 or visit <http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=232>

Would you like to contribute to the Faculty Newsletter?

The aim of the Faculty Newsletter is to provide updates on some of the current issues that may be of interest to our wide readership. Some Newsletters have been themed editions when it was felt that certain topics were sufficiently relevant.

The Faculty is always interested in hearing ideas of future topics to ensure that the Newsletter remains topical and of relevance. Should you have any ideas for future editions or wish to contribute as an author we would be very pleased to hear from you.

Please feel free to discuss your ideas with Dr Jit Solanki, a member of the Communications Committee via the Faculty Office (c/o b.muzzeroll@fpm.org.uk or 020 7224 0343).

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