

# europaean INDUSTRIAL PHARMACY



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Tel: +44 (0) 1428 752222

Fax: +44 (0) 1428 752223

Email:

info@euromedcommunications.com

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Cover photo: A patient with their medicines (see The importance of understanding the 'lived experience' of patients in pharmaceutical development programmes on page 4)

# editorial

Dear Colleagues

Many thanks to the Bulgarian Industrial Pharmaceutical Association for the organisation of the EIPG General Assembly. A special "merci" to Valentina Belcheva and Evgeni Grigorov for all the arrangements. It was a real pleasure to have our General Assembly in Sofia. The Scientific Symposium on Friday afternoon was a great success. There were excellent presentations on clinical trials and a large number of interactions from the various attendees.

The General Assembly was very pleased to receive our guests Roberto Frontini, President of the European Association of Hospital Pharmacists, Jamie Wilkinson from the Pharmaceutical Group of the European Union and Tiia Metiäinen, President of the European Pharmaceutical Students' Association. I must say that I was also very pleased to welcome my friend Rachid Lamrini, President of the National Council of Industrial and Wholesale Pharmacists in Morocco. Morocco is now an official observer to EIPG.

A lot of effort has been undertaken by the Working Groups on European good

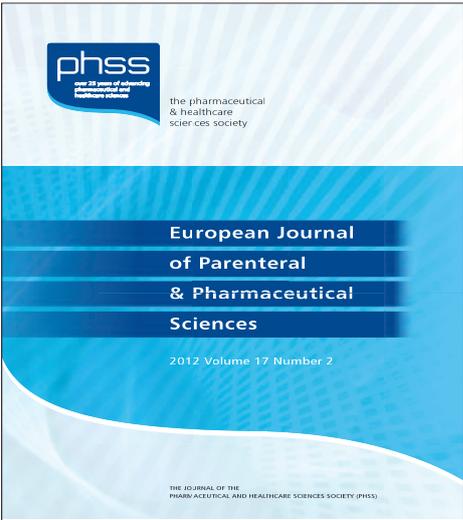
manufacturing practice and on competencies for biotechnology. I would like to say a particular thank you to Amon Wafelman (the Netherlands) for his proposal to lead different Special Interest Groups. All interested members from each delegation are encouraged to participate in their specific areas of activity and interest.

We were pleased to re-elect Claude Farrugia (Malta) as Vice President Communications and to welcome Anni Svala from Finland as Vice President Education and Training. As you can imagine this General Assembly was very busy with many positive outcomes.

I would like to thank Jacques Morenas, Deputy Director, Inspection Division from the French Agency (ANSM) especially for his contribution who not only gave different presentations but also participated in our discussions and Working Groups over the 3 days.

I look forward to meeting representatives from all delegations in Edinburgh next April for the General Assembly 2015.

Jean-Pierre Paccioni  
EIPG President



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# THE IMPORTANCE OF UNDERSTANDING THE 'LIVED EXPERIENCE' OF PATIENTS IN PHARMACEUTICAL DEVELOPMENT PROGRAMMES

by Kay Fisher

**Improving the 'patient experience' is a hot topic, but capturing the patient voice early on in the development cycle is also crucial to drug effectiveness. We look at the 'real life' trade-offs patients are making around their treatment programme and consider ways of using this data to improve the process of drug development. We challenge existing codes of practice and regulatory guidelines – originally designed to protect the patient, but which now seem to be stifling their very important voice.**

Kay Fisher is founder and Chief Executive of leading customer experience company Experience Engineers. She is a patient experience specialist and her work has been fundamental in paving the way to driving measurable, improved patient reported outcomes for pharmaceutical companies (Pfizer, Vertex, Boehringer-Ingelheim, Bristol-Myers Squibb) and many healthcare deliverers (Addenbrookes, RNOH, cancer care groups, Bupa).  
Email: [kay@experienceengineers.co.uk](mailto:kay@experienceengineers.co.uk); [www.experienceengineers.co.uk](http://www.experienceengineers.co.uk)

Here we seek to challenge the current thinking on the data inputs that are currently used to guide decisions around drug development. The pharmaceutical world is defined by condition and disease, and the scientific impact of drugs, within a controlled environment. However our ultimate customers – our patients – live in a world that is not defined by their condition, but where life takes over, and the impact of their unscientific behaviours around their treatment regimes can literally be the difference between life and death.

We are beginning to see a 'taste' for gathering real world data now, which is a positive step forward, but these new data sets are still clinically led rather than patient led...the 'patient record' is still completed by clinicians, the treatment reviews are written with a clinical bias. Where is

the patient voice in all of this? Has anyone asked the patients what success looks like for them? Where is it captured?

## **How can we make sure we look beyond the science and capture the 'human being' in our data?**

There is clearly a lot of work going on in the 'social research' space, and many pharmaceutical companies are investing in patient engagement programmes which are designed to examine and improve the relationship a patient has with their drugs or treatment regime. Increasingly, the industry is factoring in new data around how we live our lives, and working hard to uncover the truth about those individual lifestyles and behaviours that affect outcomes, alongside the clinical evidence base derived from clinical

effectiveness data.

It is crucial to build in these additional layers of data if we want to address the whole truth. As patients, we will all make our own decisions about the sacrifices we are prepared to make for the sake of our health – and, ultimately, that decision does rest with us as individuals. We make trade-offs all of the time in our life choices, and our health is no exception. There are thousands of examples of the trade-offs some patients are making around their treatment regime, which, if known, can have a huge impact not only on the narrative that doctors might have with their patients, but also on the way drugs are developed.

Exploring the lived experience of patients, I've met a woman who has been told that she has glaucoma and may become blind, but she won't take her eye drops on a regular basis because they make her eyes go red, and she doesn't want to be seen looking like she's been up all night. A teenager who won't take his methotrexate because he knows how nauseous it makes him feel, and he would prefer to be focused for his school day, even though he knows that this might lead to more pain further down the line. A working woman with cystic fibrosis who has chosen to sacrifice regular early morning preventative treatment in order to pursue the career she loves, knowing that she is shortening her life expectancy.

The social science is surely as important as the clinical science here. When we are all patients, the decisions we make aren't necessarily logical, but are largely driven by emotion and a need to stay in control of our lives. On occasions, the fact that a drug might save our lives just isn't a good enough reason to take it if it affects the way we want to live.

## **Is the pharmaceutical industry brave enough to let patients contribute to driving the research agenda?**

If we understand these influences, once a drug is being used in the market place, why can't we gather this data further back in the

development process? There are very few social research studies being used to complement the scientific research, yet we are relying on unpredictable human behaviour for the science to work effectively. Where is the patient voice in the R&D departments?

If we gather lifestyle data at the very outset of a drug's development and throughout its journey to market, we will all have a better understanding of how the regime, side effects, or delivery mechanism will impact on efficacy in the real world. We will understand how to maximise a patient's engagement with his or her treatment. Ultimately, this critical patient insight may even influence WHAT goes into the R&D programmes.

Most – if not all – other industries have the end user as a start point to developing their strategy, and, if we look outside of the world of pharmaceuticals, we see very different approaches to capturing the voice of the customer. Amazon has a laser-like focus on their customers – their entire offer starts and ends with customer. They make it easy for customers to get on with their lives by merging their own product and services into their lifestyle.

The pharmaceutical industry tends to start with disease need, or a population need, followed quickly by the scientific possibilities. However, it is our idiosyncrasies as human beings, and our life context, which can play a very big part in contributing to the success or otherwise of a certain therapy or drug regime.

### How can we benefit from this sort of research?

There are real benefits of introducing the patient voice earlier on. The earlier we can start to uncover more data around personal preferences, the earlier a product is tailored to a patient's needs and the fewer problems have to be dealt with further down the line. We have to create a better environment where information flows from patient to provider and through to

pharmaceutical development from the outset – human patient data, not just clinical data sets.

If we can invest more in this data flow, we can build real 'patient value' throughout the process, and we will know so much more about the things that matter most to patients...things which can have a huge influence on their response to treatment, and potentially offer more choices with different trade-offs, which will make treatment feel more individualised.

### So what can we do to drive change?

In a way, the codes and regulations, which are in place to protect the patients, are stifling their voice. Approaching patients for their views has always been very difficult for the pharmaceutical industry, and they have, therefore, used the clinician's voice as a proxy for what patients value most. However, patients spend very little time with their clinician, and most of their time living their lives outside of the clinical environment, so it is the patients who must be cast as the experts here, and it is the 'lived experience' data that we must seek to capture.

Clinicians will benefit from this too – whenever they are exposed to this data, they value it, address it and act on it. The pharmaceutical industry can help with this; they can build this softer, yet essential, life science insight into their patient data. If we really start to understand what success looks like to the patient, as compared to the scientific outcome, we might be very surprised, and we certainly shouldn't presume to know without first consulting them.

The new world has to engage patients as an equal third party stakeholder, whose interests may sometimes be aligned with health providers and sometimes aligned with pharma, or both, or neither. Ultimately, with this framework in place, we might make better decisions around which drugs are developed and how that development evolves. A good place to begin this change would be with rare diseases – it would not be

difficult to talk to every single patient in these cases, thus ensuring 100% sample rate.

### Why bother?

From a purely commercial point of view, if patients influence and support drug development from the start, then it ticks regulator and purchaser boxes ahead of time and makes it harder to resist at later stages. Industry leading best practice would always feature the patient voice throughout drug development. This is not exploiting patients, who can and will decide for themselves how vocal they want to be. One of the biggest issues is persuading patients that their lifestyle issues really matter and that drugs can't really be developed in a scientific vacuum if they are to be optimally effective, so we really do need their input.

Patients as equal partners in the development process? It seems ridiculous doesn't it, what do patients know about science? Yet, they often have the casting vote in the success or otherwise of the drugs they take, because of the choices and trade-offs they make on a day-to-day basis. The sooner we all understand the value of this, the sooner we can evolve the pharmaceutical industry model into one that puts patients at the heart of its work.

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# THE SUPPLY CHAIN DIAGNOSIS: WHY LSH COMPANIES MUST ADAPT THEIR BUSINESS MODELS AND SUPPLY CHAINS FOR THE CHALLENGES OF THE 21<sup>st</sup> CENTURY

by Lisa Harrington

**F**or most industries, experiencing two or three complex challenges at one time is enough to cause major disruption. But the global life sciences and healthcare (LSH) industry is contending with far more issues. The net effect is that business as usual is over, and the supply chain that supported it is no longer fit for purpose. The LSH sector is at a turning point. It faces a constellation of challenges that are occurring simultaneously and – taken together – constitute a seismic shift in the very nature of business.

At the Robert H. Smith School of Business, University of Maryland, Lisa is Associate Director of the Supply Chain Management Center and Faculty Lecturer on Supply Chain Management. She is also President of the Harrington group LLC, a firm providing strategic consulting services across global supply chain strategy, operations and best practice.

Shrinking margins, escalating cost pressures, burgeoning regulatory and compliance requirements, changing product characteristics and growing consumerism are transforming the LSH business paradigm. What is emerging is a business model that looks and acts like the consumer goods industry, where the customer – not the manufacturer – holds the power.

The traditional and currently operating LSH supply chain is not built to deliver the agility, flexibility, cost reduction and resiliency required in this new environment. Simply put, a new leaner, more resilient LSH supply chain is the key to future success for global LSH enterprises. But before going into this, it is important to gain a fuller

picture of the business environment in which LSH companies are navigating.

## **The symptoms of a shifting business model**

The emerging LSH supply chain must tackle a difficult agenda that includes a wide array of issues. These issues can be grouped into three high-level categories: the patent cliff, changing products and profit erosion; emerging markets, demographic shifts and healthcare policy; and regulations, compliance and product integrity.

Worldwide prescription drug sales are falling and this is being exacerbated by the loss of patent protection on a number of major drugs. In 2012, \$38 billion of sales

were lost as a result of expired patent protection, including Lipitor losing \$5.6 billion, Plavix \$4.5 billion, Seroquel \$3 billion and Zyprexa \$2.9 billion against an at-risk level of \$55 billion, a 70% reduction<sup>1</sup>.

At the same time that this profit erosion is occurring, LSH companies face increasing pressure from direct customers, governments, insurance companies and consumers to reduce prices. Consumers will play a bigger role in healthcare decisions and choices, reflecting a switch in mindset from being “patients” to “consumers”. Armed with greater access to product information, patients are better informed about drugs, products, devices, procedures, treatment options and healthcare providers. As a result, they are exercising a greater degree of control over their healthcare decisions, particularly in developed markets.

Three factors are driving this trend towards consumerism.

- 1) Technology – mobile applications will enable comparison of treatment options, costs and the list of providers who adhere to best practices.
- 2) Coverage – high-deductible plans and a growing individual insurance market, as well as private healthcare for the middle classes in developing markets, is expected to drive price and quality sensitivity.
- 3) Transparency – regulators will require increased access to performance data from health plans, hospitals, drug manufacturers, long-term care providers and physicians<sup>2</sup>.

As LSH companies adapt to these pressures, one trend which could mitigate the profit erosion issue is the changing nature of pharmaceutical products themselves. Companies’ product portfolios are evolving away from sole reliance on blockbuster prescription drugs, towards more structurally complex biologics. These require specialist handling due to their sensitivity to humidity and temperature. Failure to maintain

these appropriate conditions in the supply chain risks the loss of a costly shipment.

The product shift is one significant trend, another is the demographic one. Established markets will still generate 59% of the LSH industry's total revenues. But that ratio will slowly change as huge emerging markets, such as China and India, expand access to healthcare services and products<sup>3</sup>. Thus, it is no surprise that LSH companies see emerging markets as key to their future. For example, pharmaceutical sales in the BRIC countries (Brazil, Russia, India and China) rose by 22.6% in 2011<sup>4</sup>, with these markets expected to exceed \$300 billion by 2020 as expansion to healthcare continues.

In their efforts to serve emerging markets, therefore, LSH companies are adopting variable strategies that range from providing a full portfolio of their products based on positioning as an innovation leader; or going for the volume-value end of the spectrum, and offering a narrower array of products at lower, differential prices. Obviously, this range of strategies requires appropriately tailored supply chains with cost and service structures matched to product portfolios and margin points.

The rise in volume and scattering of end points can open the supply chain to greater risk of counterfeiting as well. Fuelled by easy internet sales, global supply routes and minimal punishments, counterfeit prescription drugs are an exploding industry, with an estimated market worth \$75 billion a year worldwide. In response, regulators around the world are issuing new requirements aimed at stemming this flood of counterfeit and falsified LSH products. These rules place new and significant burdens for security and data collection on all entities throughout the supply chain.

To comply with such regulations, the LSH industry, and all parties in the supply chain, must adopt rigorous serialisation protocols and track products through the supply

chain, normally by applying a unique identifier at the individual product unit rather than at lot level. This significantly increases the burden for scanning and tracking product, maintaining and sharing collected data, and protecting product integrity and the chain of custody throughout the entire supply chain.

### The diagnosis

From a supply chain development perspective, the global LSH industry is less mature when compared to the supply chain practices found in the consumer, retail or automotive sectors – primarily because the economics of the latter sectors, with their super thin margins, have forced an extreme focus on lean processes, efficiency and cost reduction. The good news is that certain best practices are emerging in the new global LSH supply chain. These are designed to address the issues of cost, service, geographical expansion, security, product integrity and chain of custody – and do so with greater agility.

At present, as a study from PwC<sup>5</sup> points out, there are three distinct supply chains: designing, manufacturing and distributing pharmaceuticals; designing, manufacturing and distributing medical devices; and providing healthcare services (including laboratory work and pathology). Integrating these supply chains so that all the upstream and downstream partners can see the full picture would enable them to plan ahead more accurately and manage demand more cost-effectively.

Such a collaborative model already exists in industries like automotive and technology – and it could be customised to LSH with significant benefits. The model called the supply chain control tower or lead logistics provider (LLP) is executed by some third party logistics companies. At the heart of the control tower concept is real-time visibility across the extended supply chain – incorporating suppliers,

manufacturing nodes, carriers and third party logistics service companies, and customers.

"Visibility is critical to resiliency," observes Alexander Pilar, CIO, DHL Supply Chain. "The more visibility you have, the more time you have to react. If you extend the visibility boundaries of your supply chain, you can see issues earlier in their development cycle, and gain more time to respond. This requires that the whole supply chain cooperates to share data and visibility."

LLPs are also tackling the growing complexity of caring for and handling specialist LSH products. Such providers must be able to provide specialised pharmaceutical and medical device grade facilities that meet specific quality and validation requirements.

Protecting and certifying the integrity of new biologics medicines, vaccines and therapies requires a significant investment in cold chain capabilities. One hallmark of the new resilient LSH supply chain, therefore, is effective cold chain management. This carries significant specialist storage and transportation capabilities, which if executed incorrectly can prove very costly.

Another opportunity of partnering with an LLP is the shared service model. In this model, multiple customers share the same physical platform and the same supply chain operational processes. The model is based on economies of scale – i.e. spreading the cost of a best practice LSH distribution operation across multiple companies.

"Having six different deliveries to a hospital, going to six different wards, with four different highly trained drivers doesn't make a lot of sense," explains Scott Cubbler, President, Life Sciences and Healthcare, Americas, DHL Supply Chain. Instead, a third party logistics company could create a shared services hub, consolidate shipments, eliminate overlapping deliveries and provide full delivery service with fewer redundant assets.

In developing markets, where distribution channels are fragmented and lack transparency,

this shared services model can provide significant benefits to LSH companies. In these markets, pharmaceutical and medical device manufacturers typically have customer overlap, meaning that multiple companies are shipping to the same group of customers. This means that across manufacturers there is considerable duplication of supply chain assets, resources and costs – all geared towards serving the same customer cluster.

### The prescription

The constellation of challenges facing LSH companies today is unprecedented. The counterfeit drug trade is reaching epidemic proportions. A blizzard of new regulations is governing safety and security. The market is changing rapidly – with a focus on cost

control, robust growth in emerging economies, profits under attack as blockbuster drugs come off patent protection and requirements for personalised medicines. Burgeoning demand is running up against the diminishing willingness or ability of government and private payers to fund those demands.

In order to prosper in this new environment, LSH companies must adopt a more resilient, adaptive supply chain model. This means working collectively with all business partners and service providers to craft supply chains for optimal end-to-end flexibility. The new LSH supply chains must be able to embrace the unpredictable – to anticipate and mitigate risk, manage globally extended operations with real-time visibility and facilitate truly adaptive execution.

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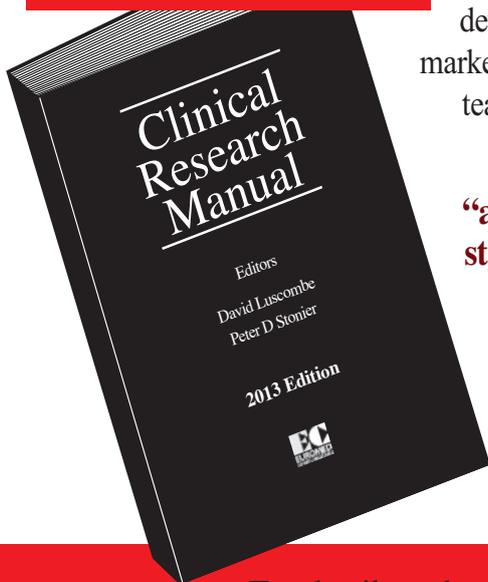
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# LINKING INDUSTRY AND ACADEMIA IN TEACHING PHARMACEUTICAL DEVELOPMENT AND MANUFACTURE (LIAT-Ph)

by the LIAT-Ph Consortium

**The pharmaceutical industry continues to develop to respond to challenges of an ageing population and more complex medicinal products. Advances in pharmaceutical development include a shift towards quality-by-design, the increasing importance of biopharmaceutical products and the move to stratified medicines, which will result in company product portfolios becoming much more expansive. Industrial pharmacists should be equipped to respond to the challenges of the rapidly changing environment in which they work. In order to respond to the learning needs and educational demands posed by such a dynamic environment, a rapidly increasing knowledge base, a need for specialised knowledge, and the necessity for partnership and closer collaboration between academia and industry has been recognised on the national, as well as wider, regional and EU level.**

The LIAT-Ph Consortium contact persons are: Anne Marie Healy (School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Ireland; Contact email: healyam@tcd.ie), Jelena Parojčić (Faculty of Pharmacy, University of Belgrade, Serbia), Stane Srčič (Faculty of Pharmacy, University of Ljubljana, Slovenia), Anne Juppo (Faculty of Pharmacy, University of Helsinki, Finland), Gavin Andrews (School of Pharmacy, Queen's University Belfast, UK), Nigel McSweeney (Amebis Ltd., Ireland), Brian Glennon (APC Ltd., Ireland), Matevž Luštrik (Brinox inženiring d.o.o, Slovenia), Ian Jones (Innopharma Labs Ltd., Ireland), John Milne (National Institute of Bioprocessing Research and Training, Ireland), Brian Corrigan (Pfizer Ltd., Ireland), Maura Kinahan (Pfizer Ltd., Ireland), and Rosemarie Tully (Sigmoid Pharma Ltd., Ireland).

The LIAT-Ph Consortium brings together five higher education institutions (HEIs) and seven companies from different countries across Europe (Ireland, Serbia, Slovenia, Finland and United Kingdom), and has been granted EU funding for a 2-year project under the Knowledge Alliances Lifelong Learning Programme.

The objectives of the project are as follows.

(i) To explore the learning needs of pharmacy students (at the undergraduate and postgraduate level) and practising pharmacists, in the different participant countries, in relation to the competencies in industrial pharmacy which have been identified through a previous EU-funded Pharmine project<sup>1</sup> and in relation to any additional competencies identified by the

industrial and academic partners in the context of current developments in the bio/pharmaceutical sector.

(ii) To work together (academia and industry from all participant countries) on the development of curricula (content and teaching/learning methods and educational materials) that will ensure the required competencies for industrial pharmacists are covered at an appropriate level. Focus will be placed on enhancing student engagement, developing problem-solving skills and encouraging innovation and entrepreneurial thinking. Academic staff upskilling will form part of the curriculum update and delivery process.

(iii) To develop and deliver joint modules, as part of a structured PhD programme and/or continuing professional development courses for industrial pharmacists and other professionals working in the bio/pharmaceutical industry with a focus on bio/pharmaceutical product development and manufacture.

The project objectives are aligned with the outcomes of the Pharmine project<sup>1</sup>, PEARs report<sup>2</sup> and PQPharm project<sup>3</sup>.

It is anticipated that the project will result in proposals for changes to the undergraduate Pharmacy curricula in an industry-informed manner. Structured placements will be developed by academia and industry in a collaborative manner, and will be offered by industry partners to PhD postgraduate students or academic staff with a view to upskilling in defined areas with practical application to industrial practice. The first of these placements will take place in the summer of 2014.

Courses with a focus on innovation in the product development and manufacturing phases of the product life cycle will be developed and delivered to students undertaking PhDs in Schools of Pharmacy in the participant countries and to academic staff as part of an

upskilling process. The first of these intensive courses will be delivered in May 2014 and will be focused on bioprocessing and biopharmaceuticals. Courses developed during the project will also be made available to pharmacists currently working in industry, in response to their continuing professional development needs.

The project is unique in the European context as it will bring together a number of HEIs across Europe, covering both Western and Eastern regions, as well as small and medium enterprises, a large bio/pharmaceutical company and a number of other bodies with specific interest in the pharmaceutical sector and the lifelong learning needs of

individuals employed in the sector. The consortium includes pharmacists and non-pharmacists (chemists and engineers). The group in developing teaching materials will do so in a manner which addresses the increasingly interdisciplinary nature of pharmaceutical product development and manufacture.

The LIAT-Ph knowledge alliance will facilitate and strengthen the exchange of experience and ideas between academia and industry in the area of pharmaceutical development and manufacture and contribute to the development of not just technical skills but also problem solving, innovation and entrepreneurial skills in undergraduate and postgraduate pharmacy students.

The LIAT-Ph Consortium will be holding a satellite symposium (open meeting) on 20th September, following the 10th Central European Symposium on Pharmaceutical Technology in Portorož, Slovenia ([www.cespt2014.org/](http://www.cespt2014.org/)). This will include a keynote address from Professor Suzi Jarvis of the Innovation Academy, Trinity College Dublin and University College Dublin on the topic of "Introduction of Active Learning in Innovation, Creativity and Entrepreneurship for 4th Level Pharmacy/Pharmaceutical Technology Students".

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Members of the LIAT-Ph Consortium at the project kick-off meeting at Trinity College Dublin, November 2013.

Further details and updates on the LIAT-Ph project may be found at: <http://www.liatph.com>

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# INTERNATIONAL SUMMIT ON MEDICINE SHORTAGES

by Betty Chaar and Luc Besançon

**In June 2013, the International Pharmaceutical Federation (FIP) hosted an inaugural International Summit on Medicine Shortages in Toronto, Canada. It was attended by representatives from governments around the globe, healthcare practitioners and professional bodies, the pharmaceutical industry and patients. The aim of the Summit was to provide a forum to discuss the causes and contributing factors, as well as impacts of medicine shortages, and to offer solutions to address the global issue using a multi-stakeholder approach.**

Dr Betty Chaar is a Senior Lecturer at the Faculty of Pharmacy, University of Sydney, Australia. Her research, publications and teaching centre around ethical aspects of pharmacy practice. [betty.chaar@sydney.edu.au](mailto:betty.chaar@sydney.edu.au); <http://sydney.edu.au>

Luc Besançon is the General Secretary and CEO at the FIP, which is the global federation gathering 126 national associations of pharmacists and pharmaceutical scientists.

It was an intriguing forum, in which the profound impact and worldwide scope of the problem was debated and scrutinised, including the manner in which some countries have attempted to mitigate the inevitable issues associated with medicine shortages in the clinical setting<sup>1</sup>.

The causes of medicine shortages are many and varied, in some cases coincidentally overlapping, which makes for a complex, difficult-to-resolve problem in healthcare<sup>2-4</sup>. During the Summit, two components explaining the occurrence of medicine shortages were highlighted: causes (leading to a shortage) and contributing factors (weakening the environment which is then less resilient to medicine shortages).

Shortages often appear to be caused by lack of raw materials. It is often the case that the source cannot cope with higher than usual demand, as the world intensifies its medicinal needs, whether as a result of population growth, an ageing population, an epidemic or simply the fact that there are so many

therapeutic and innovative treatments available to the human race. Contributing factors for medicine shortages include reliance on one source of these raw materials, which can be hazardous.

Other shortages have occurred due to stringent clampdowns by health authorities on quality assurance at the manufacturing level. The need to close down some plants for repair or maintenance has, in some cases, ironically caused major, widespread disruption of supply and harm to consumers.

The Sandoz plant in Canada is a critical example. In early 2012, Sandoz announced it had to scale back production of several medicines, including analgesics, antibiotics and anesthetics, after quality control assessment by the US Food and Drug Administration found the factory fell short of standards of production. Exacerbating the situation, a fire erupted in the factory, rendering continuation of manufacturing almost impossible. The subsequent shortages in medicines, such as injectable opioids used in palliative

care in particular, were extensive and affected many countries, with much distress inflicted on both patients and healthcare providers alike.

Changes in patterns of demand can also affect supply of medicines. For example, Australian government supported an evidence-based Quality Use of Medicines project, which not only promoted, but strongly encouraged, physicians to use Penicillin G instead of higher grades or generations of antibiotics for treatment of community-acquired pneumonia. The promotion was highly successful, but demand exceeded supply and, ultimately, shortages began to appear in hospitals around Australia. As a result, a rationalisation of this product was organised as the only provider was unable to meet the sudden surge in demand.

Similarly, in Brazil, the increasing demand for benznidazole (used to treat Chagas disease) could not be met by the sole world manufacturer (which is state owned) which resulted in medicine shortages. For whatever reason changes occur, the manufacturer may have little time to adjust its manufacturing capacity to meet the increase in demand.

Often products become no longer financially viable to the manufacturer (in particular, orphan drugs and generics), and consequently are simply discontinued, frequently with little or no warning.

Medicine shortages may also be associated with contributing factors, such as purchasing capabilities, tender processes, the global financial crisis, corruption, natural disasters, pandemics and the emergence of the "grey market" (i.e. where unscrupulous dealers exploit shortages by providing the market with previously stockpiled products at exorbitant prices, thereby exacerbating and exploiting the issue). There are several other reasons for medicine shortages, some of which remain unknown, but the reasons listed briefly here give the reader an indication of the many complexities entangled in the supply of medicines around the world.

Characteristics of medicine shortages also vary greatly from country to country. There is a lack of reliable information at a global level, but most active shortages are in antimicrobials, chemotherapy, cardiovascular medicines, central nervous system medicines and nutritional supplements. Injectables have been particularly prone to shortages due to manufacturing issues<sup>4</sup>.

In some countries, the problem has been longstanding; the USA, for example, has had a track record of medicine shortages for more than a decade, according to the representative of the American Society of Health-System Pharmacists (ASHP). In 2001 (although shortages had started to appear earlier), as a result of the implications on practice, the ASHP started reporting medicine shortages on a national level, and in the first year reported 120 medicines in short supply, with an average of 70 new reports yearly since then. The University of Utah Drug Information Center reported an increase in the number of new shortages from 58 to 88 from 2002 to 2007, and to 267 in 2011 and 204 in 2012<sup>5,6</sup>.

In Canada, there has also been a relatively longstanding problem with medicine supply. The national medicine shortages reporting system ([www.drugshortages.ca](http://www.drugshortages.ca)) listed approximately 300 products in short supply as of June 2013. In Europe, 346 hospitals were surveyed by the European Association of Hospital Pharmacists and it found that 98.8% of participating hospitals experienced shortages over the past 12 months, while 63% reported that problems associated with shortages occur at least weekly.

The impact of medicine shortages can be substantial on a number of levels. Primarily, a significant degree of patient care can be compromised as a result of medicine shortages. There is a plethora of evidence to support this claim. Medicine shortages can result in delayed or unavailable treatment, or a change to an alternative (often less effective)

regimen may be necessary. There are also safety implications to consider, including errors incurred as a result of administering alternative treatments with which some healthcare professionals are unfamiliar.

Adverse patient outcomes have resulted. Medicine shortages can, therefore, result in deterioration of the patient's condition, hospitalisation and even death. There is evidence that at least 15 deaths in the USA in 2010–2011 could be attributed to medicine shortages<sup>6</sup>.

Similarly, medicine shortages have challenging implications on decision making, the impact on patient care and the crucial role of government bodies. There are often painful decisions to be made by physicians. Some circumstances have required medical doctors to reluctantly prioritise among their patients for limited medicinal resources (those who could not survive without treatment versus those who could be delayed or cancelled)<sup>7</sup>.

The Summit concluded with six major recommendations, which may be of assistance for healthcare systems around the world to take into consideration:

1. To advance transparency and increase communication between all stakeholders on existing shortages, each country should establish a publicly accessible means of providing information that is timely; as complete as possible; and focused on current shortages and their causes, expected duration and action(s) taken. This may involve the Ministry of Health, medicines regulatory authorities, professional bodies and/or industry trade associations and other stakeholders.
2. A global process to determine a list of critical or vulnerable products should be developed. This would be executed by a multilateral organisation within the United Nations structure.
3. All procurers of medicines are urged to move towards active

procurement processes that assure the continuity of supply of quality medicines. Elements of high-quality active procurement processes would include the following.

- i. Improved quantification (e.g. forecasting).
  - ii. Direct communication between procurement agencies and manufacturers regarding sustainable capacity to supply.
  - iii. Deliberated and considered approaches tailored to the specific situation for each product (long-term, short-term, split contracts, etc).
  - iv. Responsible pricing that values quality.
  - v. Meaningful binding/contracting.
4. All countries are encouraged to remove unnecessary variability of regulatory practices within and between countries.
  5. All countries are encouraged to establish a national body responsible for gathering and sharing information about demand for and supply of medicines within their jurisdiction. This body could also develop an ethical framework for decision-making relating to resource allocation at times of scarcity, and could coordinate the dissemination of information about the national available stock.
  6. All countries are encouraged to develop evidence-based risk mitigation strategies, which might include strategic buffer stocks and stockpiles, contingency planning, pandemic planning, and capacity redundancy appropriate to their national needs.

### Conclusion

Many countries have already suffered immensely from the alarming trend of medicine shortages, whilst some may be privileged to have the opportunity to benefit from the insight and

hindsight of those who have already experienced consequences of medicine shortages. It is important to know that there are lessons to be learned and warnings to be heeded, as the problem does not seem to be under control quite yet and could affect any country at any time.

The recommendations of the Summit are valuable and noteworthy for all governments and health departments around the world. It is hoped that they provide a generic framework within which countries can adopt the suggested points of

action to minimise or avoid medicine shortages, which impact on patient safety, welfare and quality of life.

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Volume 7 Number 3/4 Nov 2013

# PHARMACEUTICAL FIRMS CAN'T KEEP IGNORING INFORMATION RISK

by Phil Greenwood

**Knowledge is the lifeblood of the pharmaceutical sector. From raw experimental data to complex chemical formulae, from carefully regulated drug trials to patented IP – without information the industry couldn't survive. It wouldn't have the robust evidence base it requires to launch safe and effective new medicines confidently, or to meet the increasingly stringent demands of the regulator, or to protect organisations in the sector against legal action. The development cycle for new drugs takes years and is growing more expensive. Consequently, any loss, damage or exposure of information that is, inevitably, highly sensitive and confidential could irrevocably damage that process and put the organisation at risk. The understanding and management of information risk is, therefore, vital to the long-term health of Europe's pharmaceutical sector.**

Phil Greenwood is Director of Information Management and Business Outsourcing at Iron Mountain. He is responsible for delivering information and records management solutions into the UK's largest public, private and NHS customers. He has over 10 years' experience working with UK and international records management. He is involved with the UK Information and Records Management Society.

Phil has worked within service delivery and customer facing roles, as well as in general management roles within the outsourcing and information management industries. Legally qualified, Phil has also spent time as a fee earner within law firms and has a strong understanding of the way that information and services drive the core business of client organisations.

It is worrying that research now suggests that, just at a time when data volumes are exploding and market conditions have never been tougher, Europe's pharmaceutical sector has not yet committed to taking information risk seriously. This complacency is cause for concern. The research shows businesses are choosing to insure their organisation against the financial impact of data loss, rather than doing something to protect against the loss in the first place. Surely, it would be more cost-effective and better for long-term prosperity to invest money in closing the gaps in data-protection programmes and keep information

from getting into the wrong hands, given the cost of data breaches.

The latest estimates reveal that the cost of a data breach in more heavily regulated industries, such as pharmaceutical and financial services, significantly exceeds that of other industry sectors. For example, the average per capita cost of a data breach in the UK's pharmaceutical sector is £103, compared to £53 for media and £69 for the retail sector. With the average number of data breaches across all sectors now growing at a rate of 50% a year, the cost impact alone should be enough of a wake-up call for the sector. And that's before you consider the

implications a data breach would have on competitive advantage, brand reputation and customer confidence.

Having an effective information risk strategy in place is a good place to start, but it is not enough to guard against a breach on its own. According to our research, a reassuring 90% of pharmaceutical firms do have an information risk strategy in place. However, only around half (47%) check whether it works or is indeed acted upon in the event of an incident.

The report conducted by Iron Mountain with PwC found complacency and inconsistency are not unusual when it comes to the management of information risk despite a high level of awareness of the threats to information.

Interestingly, younger firms are more likely to feel comfortable managing structured and unstructured information in digital and physical formats across multiple locations (55% compared to 38% for older firms.) The PwC report also revealed significant differences in the way younger firms perceive and address their information risk. Just 3% of younger firms agree strongly that cutting cost is more important than reducing risk, compared to 28% of older firms. Perhaps this is because two-thirds of older firms believe the risk of a data breach to be low, compared to one-third of younger ones – who are also more likely to feel overwhelmed by the ever-growing risk of a data breach and the relentless pace of change.

In the pharmaceutical sector, three in four firms recognise that a responsible attitude to information is critical to success, close to half (47%) expect the risk of a data breach to increase and over three-quarters (77%) believe it would damage the business. However, this concern is not mirrored at board level: just over half of those surveyed (52%) say the board does not see data security and protection as a big issue. Increasing investment in managing information security is likely to be a challenge for many, with 62% of pharmaceutical firms believing that reducing costs is more important

than reducing exposure to risk.

Mitigating information risk should be a concern for every employee. Again, the difference in perception between older and younger businesses is an interesting one. Despite trusting their employees more, our research found just over half (52%) of younger firms say employees do not see data protection as a big issue. These firms are, it seems, quite willing to trust people who they suspect might not be concerned about keeping company information secure. Two-thirds of the mature businesses surveyed say employees do regard information security as a serious concern.

Perhaps most worrying of all is the fact that, while over half (54%) of pharmaceutical firms claim they would refuse to do business with an organisation that had suffered a data breach, more than one-third (35%) see data loss in their own company as an inevitable part of daily business.

For the pharmaceutical sector, the recent trend towards downsizing, outsourcing and mergers has placed information management under the spotlight. The need for rigorous due diligence in advance of a proposed merger and seamless record integration afterwards can highlight potential risks, such as inadequate document retention policies, inefficient and even incompatible document management, and storage systems.

Business relationships depend on being able to share information through secure and well-managed central information systems, while downsizing often forces firms to consider what to do with their vast paper-based information legacy. The last thing any firm wants is to be called before the Information Commissioner because boxes of confidential data were left unprotected in an abandoned research facility.

The need for professional information management within this sector has never been greater. Corporate Social Responsibility (CSR) developed out of a growing

demand for organisations to be held to account for their environmental and social values, actions and impact. We believe the time has now come for organisations to hold themselves to account for the way they handle and manage information.

Organisations of all sizes need to demonstrate a formal commitment to safeguarding information assets, including confidential customer, employee and business data. We call this commitment "Corporate Information Responsibility" (CIR). CIR is about establishing a company-wide culture of respect for and protection of information, maximising its value and minimising the risk of data loss, security breaches and non-compliance.

Visibility and control is also essential. You need to know what information you are creating, collecting, processing and storing; where it is at any moment in time; who is accountable for it and what the plans are for secure storage and legally compliant destruction at the end of its journey. The back-up of digital information, archiving of paper documents, scanning, shredding, day-to-day storage – on or off site, with or without a third-party provider – as well as search, retrieval and access restrictions are all vital elements that should form part of a robust, company-wide information management plan.

What makes this difficult is that Europe is awash with complex document retention laws. There are different laws for different types of records – ranging from a few months to 20 years or more. These laws differ between countries and between industry sectors; and, most confusingly of all, keep changing all the time, so pharmaceutical firms must take note.

There are many threats to information and the business risks need to be addressed calmly and strategically now, not in haste when the proposed new data protection legislation becomes law. It needs to be addressed as the highly complex, regulated, knowledge-based pharmaceutical sector

prepares to meet the demands and potential of the next decade.

Information risk touches us all. Just as firms hold their employees' and suppliers' data, not to mention their own precious knowledge and intellectual property, many also hold personal information about the consumers of their products and services. This information needs and deserves to be protected. Achieving that means seizing every opportunity to discover how best to reduce risk. When it comes to best practice and managing information risk it would appear that pharmaceutical firms still have much to learn.

By law, organisations are liable for the loss of their own data, even if the loss occurs while the information is stored with a third party. It is, therefore, up to those in the pharmaceutical sector to scrutinise, mitigate and manage their own information risk supply chain, from the board of directors down to every employee. Whether or not your plan succeeds will depend on people.

Managing information is not simply an IT or business process issue; it's about culture and people. People produce most of your information, and it's usually people who are going to lose or misuse it. If you don't know what information you have, where it is and who is keeping it safe, then you risk losing it and you may well not realise the impact of the loss until it is too late to act.

*A summary of the report, Beyond Awareness: the Growing Urgency for Data Management in the European Mid-market can be found at [www.ironmountain.co.uk/risk-management](http://www.ironmountain.co.uk/risk-management).*

# regulatory review

**The current review period has seen a number of changes in the regulation of medicines and regulatory guidance in the European Union (EU), International markets and the USA.**

## USA

### **Secure supply chain program**

Thirteen prequalified companies have been accepted for participation in this 2-year program and will receive expedited entry for the importation of up to five selected drug products into the USA. If the Food and Drug Administration (FDA) determines the program to be effective, a more permanent program may be established/extended to additional companies.

### **Guidance for industry: CMC post-approval manufacturing changes to be documented in annual reports**

This guidance provides recommendations to holders of New Drug Applications and Abbreviated New Drug Applications regarding the types of changes to be documented in annual reports.

### **Allowable excess volume and labelled vial fill size in injectable products**

Injectable vial misuse, including unsafe handling and injection techniques, has led to an increase in vial contamination and an increased risk of blood-borne illness transmission between patients. This draft guidance clarifies FDA requirements and regulations pertaining to allowable excess volume in injectable vials and reinforces the importance of appropriate packaging sizes for injectable drug and biological products.

### **Medical device tracking - guidance for industry and FDA staff**

This guidance announces that both the list of devices subject to medical

device tracking requirements and the list of medical devices released from tracking requirements have been updated.

## Europe

### **European Commission (EC) Update on the implementation of the Falsified Medicines Directive (FMD)**

The FMD had to be transposed and applied by Member States as of 2 January 2013. Final stage infringement procedures are being implemented against five Member States that still have not notified the EC of the transposing national laws. Additionally, Heads of Medicines Agencies taskforce noted that no shortages, disruption of trade or other critical situations were reported. Most active substance manufacturers exporting to the EU are now covered by a written confirmation.

The equivalence assessment listing of Brazil, however, cannot yet be granted. Brazil will be given the opportunity to provide an action plan to address the shortcomings. Then, following a second on-site visit, a decision on listing will be made.

### **Good distribution practice (GDP) for medicinal products for human use Q&A**

There are 25 Q&A regarding the EU GDP guideline. Of particular interest may be the following.

- Q&A 15 indicates that electronic separation for falsified, expired, recalled and rejected medicines is not allowed.
- Q&A 17 indicates that anti-tampering devices will become compulsory.

### **European Medicines Agency (EMA)**

#### **Guideline on process validation for finished products (effective 27 August 2014)**

The intention is to provide guidance on the process validation information and data to be provided in regulatory submissions for finished dosage forms. It is aligned

with ICH Q8, Q9 and Q10. The possibility to use continuous process verification in addition to, or instead of, traditional process validation has been added/encouraged. The chapter on design space verification is new, other parts have been updated and the chapter on ongoing process validation has been removed.

### **EU Parliament Destruction of suspected fake medicines**

Steps have been taken to give customs officers the power to seize and destroy suspected fake medicines as they move through the EU.

### **EU GMP Guide Draft Annex 15: Qualification and Validation**

Originating from a 3-page November 2012 EMA Concept Paper on the revision of Annex 15, the current draft takes into account changes to other sections of the EU-GMP Guide plus Quality Working Party guidance on process validation and changes in manufacturing technology.

Section 5 relates to verification of transport; it recognises that validation of transportation may be challenging due to the variable factors involved but requires that specific items are covered. The final draft was delayed but should finally be adopted by October 2014.

### **MHRA**

#### **Guidance for pharmacists on repeal of exemption on wholesale dealer's licences**

This guidance sets out how MHRA will address the implications for pharmacists supplying licensed medicines other than direct to the public.

#### **UK Home Office Changes to Drug Precursor Chemical Regulations**

Amendments to the existing Drug Precursor Chemical Regulations

*Continued on page 17*

## General Assembly 12-13th April

During the April General Assembly, Anni Svala (Finland) was elected as Vice-President Education and Training and Claude Farrugia (Malta) was re-elected as Vice-President Communications for the next 3 years.

The Association from Ireland, PIER (Pharmacists in Industry, Education and Regulatory), became a full member of EIPG and the Association from Morocco, COPRF (the National Council of Industrial and Wholesale Pharmacists), became an official observer to EIPG.

## Working Group on European GMP

It was noted that the upcoming changes in a few key chapters of the EU GMP Part I, along with the proposal for a new guideline on "shared facilities" and the revised version of Annex 16, will have a significant impact on the professional duties of the industrial pharmacist, especially when acting as a Qualified Person.

In particular, there will be an increasing request for knowledge and new competencies due to the extension of areas of activities for an industrial pharmacist. This will require full implementation of a continuing professional development plan in order to maintain the industrial pharmacist's role and position at the appropriate level in the pharmaceutical industry.

New opportunities of employment should arise due to the delegation

of duty process and to specific competencies required for extended application of risk assessment, such as with the issues involving shared facilities. In this respect, the EIPG group reaffirmed its scope in promoting the industrial pharmacist's role, with support for professional development through prompt circulation of key information and by issuing position papers as the result of common views at European level.

The EIPG comments on Annex 15, Qualification and Validation, have just been submitted to the European Commission.

## Working Group: Competencies for Biotechnology

With the huge increase in the number of "blockbuster" Marketing Authorisations linked to biotechnology, there needs to be a greater collaboration between industry and academia on the teaching of biotechnology products.

Molecular biologists and engineers are taking over much of the traditional role of pharmacists in industry and pharmacists need to be able to work with confidence in multi-educational teams. There is a need for distance learning modules in biotechnology for all pharmacists, including those in a patient-facing role so that they are able to provide advice on products, such as biosimilars. Prior to the General Assembly, an initial survey of competencies had been distributed and the EIPG discussed the results.

It had noted that, with the current requirement for all pharmacists to have a more detailed knowledge of body processes in illness, an expansion of the pharmacist's appreciation of medical biology was essential to an understanding of biotechnology products. The need for training in microbiological and genetic profiling was emphasised.

As biotechnology produces the process but not the molecule, it is essential to understand the technology, and the meeting considered this should be introduced early in the pharmacy curriculum.

Specific aseptic processes need to be taught for vaccine production, clean room technology and the classification of clean rooms. Up to date analytical methodology, such as flow cytometry and DNA microarray technology and the basis of individual diagnostic testing, should be understood. The discussion during this Working Group meeting will inform the ongoing PHAR-IN project.

## Symposium

A scientific symposium on "Clinical Trials Research" was held at the Faculty of Pharmacy of the Medical University of Sofia on the day before the General Assembly. The slides from most of the presentations are available on the EIPG website.

Jane Nicholson, Executive Director  
EIPG, [jane@nicholj.plus.com](mailto:jane@nicholj.plus.com)

## REGULATORY REVIEW

*continued from page 16*

came into effect on 30 December 2013 and will impact on exporters of pseudoephedrine and ephedrine (human or veterinary use) outside of the EU.

## International

### China

**Draft amendment to the Regulations for the Supervision**

### and Administration of Medical Devices

The draft amendment consists of 80 articles in 8 chapters. Increased punishments for illegal activities are included.

### Japanese Pharmacopoeia (JP)

The JP is now available online free of charge via the PMDA website.

*For further information on these and other topics we suggest you refer to the websites of relevant regulatory bodies and to current and past editions of "GMP Review News" published by Euromed Communications. To subscribe to this monthly news service contact [info@euromedcommunications.com](mailto:info@euromedcommunications.com)*

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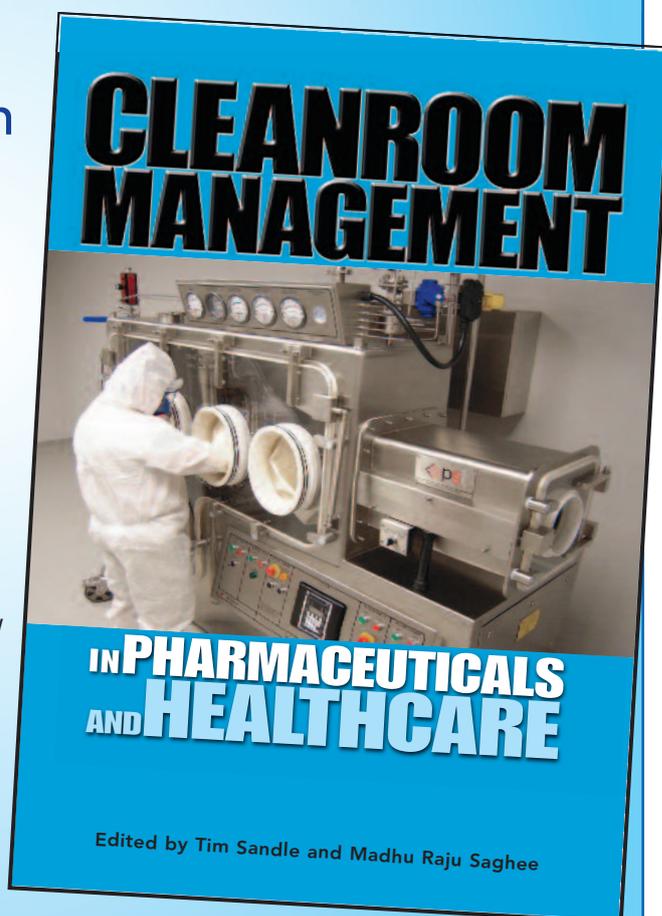
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# events

## JUNE

24–25 June 2014 – Istanbul, Turkey

**Parenteral Manufacturing**  
[www.pda.org](http://www.pda.org)

24–26 June 2013 – Uppsala, Sweden

**5th World Conference on Drug Absorption Transport and Delivery**  
[www.eufeps.org](http://www.eufeps.org)

29 June–1 July 2014 – Singapore  
**GMP 2014**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

## JULY

3 July 2014 – London, UK  
**Assuring the Quality of Medicines II**  
[www.jpag.org](http://www.jpag.org)

## AUGUST

30 August - 4 September 2014 – Bangkok, Thailand  
**74th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2014**  
[www.fip.org](http://www.fip.org)

## SEPTEMBER

7–8 September 2014 – Birmingham, UK  
**The Royal Pharmaceutical Society Annual Conference**  
[www.rpharms.com](http://www.rpharms.com)

8–10 September 2014 – Washington, DC, USA  
**2014 PDA/FDA Joint Regulatory Conference**  
[www.pda.org](http://www.pda.org)

8–10 September 2014 – Hatfield, UK  
**APS PharmSci 2014**  
[www.apsgb.co.uk](http://www.apsgb.co.uk)

9–10 September 2014 – Hotel, Berlin, Germany  
**Formulation for Biologics Conference**  
[www.informa-ls.com](http://www.informa-ls.com)

10–11 September 2014 – London, UK  
**World Drug Safety Congress Europe 2014**  
[www.healthnetworkcommunications.com](http://www.healthnetworkcommunications.com)

16–17 September 2014 – Brussels, Belgium  
**Pharmaceutical Freeze Drying Technology**  
[www.pda.org](http://www.pda.org)

25–26 September 2014 – Valencia, Spain  
**3rd International Summit on GMP, GCP & Quality Control**  
[www.pharmaceuticalconferences.com](http://www.pharmaceuticalconferences.com)

29 September–3 October 2014 – Boston, MA, USA  
**12 Annual Cold Chain GDP & Temperature Management Logistics Global Forum**  
[www.coldchainpharma.com](http://www.coldchainpharma.com)

## OCTOBER

1–2 October 2014 – Heidelberg, Germany  
**GMP for Medical Devices**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

7–9 October 2014 – Paris, France  
**CPhI Worldwide**  
[www.cphi.com](http://www.cphi.com)

8–9 October 2014 – London, UK  
**Pharma Compliance 2014**  
[www.healthnetworkcommunications.com](http://www.healthnetworkcommunications.com)

8–9 October 2014 – Barcelona, Spain  
**11th Annual BioProduction 2014**  
[www.informa-ls.com](http://www.informa-ls.com)

8–9 October 2014 – Barcelona, Spain  
**Flexible Facilities & Manufacturing of the Future**  
[www.informa-ls.com](http://www.informa-ls.com)

12–15 October 2014 – Las Vegas, USA  
**2014 ISPE Annual Meeting**  
[www.ispe.org](http://www.ispe.org)

14–15 October 2014 – Berlin, Germany  
**Pharmaceutical Cold & Supply Chain Logistics**  
[www.pda.org](http://www.pda.org)

## NOVEMBER

2–5 November 2014 – Chicago, MI, USA  
**Pharma EXPO**  
[www.ispe.org](http://www.ispe.org)

4–5 November 2014 – Munich, Germany  
**Parenterals**  
[www.pda.org](http://www.pda.org)

11–12 November 2014 – Geneva, Switzerland  
**World Biosimilar Congress 2014**  
[www.terrapinn.com](http://www.terrapinn.com)

12–14 November 2014 – Brussels, Belgium  
**World Orphan Drug Congress**  
[www.terrapinn.com](http://www.terrapinn.com)

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