FIP Quality International 2010

Managing quality across the drug supply chain: from product inception to patient utilization

Royal Pharmaceutical Society of Great Britain

A two-day international conference organised by the Royal Pharmaceutical Society of Great Britain (RPSGB) in partnership with the International Pharmaceutical Federation (FIP).

Co-sponsored by the American Association of Pharmaceutical Sciences (AAPS)

Thursday 15 – Friday 16 April 2010 at the RPSGB, London

FIP International Pharmaceutical Federation

aaps

AN OVERVIEW FROM THE CONFERENCE CHAIR - Mike Yelvigi, Wyeth, USA

The RPSGB and FIP are pleased to present the return of the Quality International conference for 2010. The conference will explore the process of supplying patients with quality drugs through the supply chain of drug development, industrial manufacturing, distribution and hospital and retail pharmacy dispensing. The key shift in managing quality of medicines in recent years was the introduction of new GMPs for the 21st century and also the initiation of the Quality by Design concept throughout drug development and manufacture. While there have been many conferences on quality concepts, these usually focused on certain aspects of quality in distinct phases of the supply chain such as R&D, manufacturing or distribution. However, it is of paramount importance to understand the impact of quality on the end user - patients. Without such broad understanding the efforts and resources spent on managing quality in isolation in each phase of drug development & distribution can become blurred. **Therefore, this conference will be a first time look at the holistic concept of 'quality of drugs' to patients!**

OBJECTIVES

This international and well-established conference is designed to:

- Explore - through plenary presentations, case studies showing real-life examples, panel discussions and poster presentations - the meaning of quality in the various phases of the drug supply chain.
- Interrelate and discuss the current practice of managing quality of drugs from early drug design, through the development phase to supply chain management and final dispensing to patients.
- Increase delegates' understanding and implementation of quality in a holistic sense as it relates to the development, manufacture and distribution of drugs.
- Clarify and assess the enormous effort in the management of quality from different sectors of the drug supply chain - is it enough or are other approaches needed?
- Provide opportunities to network with leading experts and colleagues in the field through a full social programme.

WHO SHOULD ATTEND

The conference is aimed at:

- Mid to senior level executives in pharmaceutical R&D, manufacturing and distribution
- Hospital pharmacists
- Community pharmacists
- Health care management groups
- Representatives from regulatory bodies
- Consumer advocacy groups

LEARN FROM A TEAM OF EXPERTS

Scientific programme committee: Chair - Mike Yelvigi (Wyeth), Tom Sam (Schering-Plough), Mathew Cherian (FIP), Jayne Lawrence (RPSGB), Vinod Shah (FIP), Linda Hakes (FIP/UCB), Moheb Nasr (FDA), Henri Manasse (ASHS)

Organising committee: Chair - Mike Yelvigi (Wyeth), Tom Sam (Schering-Plough), Jayne Lawrence (RPSGB), Mathew Cherian (FIP), and Julie Churchill (RPSGB)

International speakers from FDA, Abbot, Wyeth, the WHO, Novartis, University of Michigan and more.

WHAT PREVIOUS DELEGATES HAVE SAID ABOUT RPSGB CONFERENCES

"I have definitely learned subjects and topics which I will use back at work."

"This is certainly the best course that I have attended for several years."

"This was a really good conference - very interesting, well organised and well managed. I would happily recommend any similar future conferences to colleagues."

VENUE

The RPSGB is conveniently located in central London with easy access from Waterloo, Vauxhall and Victoria rail and underground stations and the airport express train services.

View of the Houses of Parliament from the RPSGB (Credit: Jon Terry & Jason King)

PROGRAMME

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THURSDAY 15 APRIL

08.00	Registration and coffee
08.30	Welcome address and overview of the conference: Meaning of 'Drug Quality - what we know & what we do not know Mike Yelvigi, Wyeth Research, USA
Session 1:	**Drug product development and manufacturing (I) Moderators: Mike Yelvigi, Wyeth, USA and Lembit Rägo, WHO, Switzerland**
09.00	Design of quality from concept to clinic - application of quality concepts at early development phase (QbD) and impact on clinical outcome Mahdi Fawzi, Wyeth Research, USA
09.45	Using science and risk-based approaches to manage quality across the product lifecycle – what can we learn from other industries? Tom Sam, Schering-Plough, Netherlands
10.30	Coffee break
11.00	FDA's vision for regulation of a globalised drug manufacturing industry Moheb Nasr, FDA, USA
11.45	Does the current thinking of QbD assure quality? - pros and cons Linda Hakes, UCB/Schwarz Pharma, Germany
12.30	Lunch and poster viewing
Session 2:	**Drug product development and manufacturing (II) Moderators: Tom Sam, Schering-Plough, Netherlands and Praful Sheth, Searpharm, India**

13.30	Improving overall quality for commercial pharmaceutical products Azita Gerhardt, Abbott, USA
14.15	Sustaining quality from development to commercialisation Galen Radebaugh, Wyeth Research, USA
15.00	Implementation of quality by design - regulatory considerations Elaine Moorefield, FDA, USA
15.45	Coffee break
16.15	WHO's prequalification programme - what it is, why it is needed and its impact on quality Lembit Rägo, WHO, Switzerland
17.00	Panel discussion
17.30- 19.00	Networking wine reception

FRIDAY 16 APRIL

08.00	Coffee
Session 3:	**Drug distribution and supply chain** **Moderators: Elaine Moorefield, FDA, USA and Linda Hakes, UCB / Schwarz, Germany**
08.30	Managing quality and accountability in outsourced operations Jim Thomson, European Alliance for Access to Safe Medicines
09.15	Managing quality in the distribution of medicines in a supply chain TBD
10.00	Coffee break

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10.30	Counterfeit drugs - impact on quality management of supply chain Andrew Jackson, Novartis Security Operations, USA
11.15	Quality and regulatory framework for prescription drugs, challenges of worldwide variations in regulatory requirements for prescription drugs – pros and cons Praful Sheth, Searpharm, India
12.00	Panel discussion
12.30	Lunch and poster viewing
Session 4:	**Patient Administration** **Moderators: Tom Sam, Schering-Plough, Netherlands & Galen Radebaugh, Wyeth Research, USA**
13.30	Understanding patient needs and physician's intent in the administration of medications-a pharmacist's perspective James Stevenson, University of Michigan, USA
14.15	Managing quality in hospital dispensing Jim Steven, University of Michigan, USA
15.00	Coffee break
15.15	Understanding patient needs in the preparation of medication label - are we there? – from a regulatory and an industry standpoint Isabelle Cliet, Sanofi-Aventis, France
16.00	Managing quality at the local pharmacy level - challenges of storage/handling, segregation, contamination, label control, expiration control Eeva Teräsalmi, Association of Finnish Pharmacies, Finland
16.45 - 17.00	Wrap-up and conclusion

CALL FOR POSTERS

The conference will feature a lively poster session and abstracts are invited on any topic related to the subject of this conference.

Abstracts should be two A4 pages, with a title and the names and addresses (including e-mail addresses) of the authors. Inclusion of figures and/or tables is strongly encouraged. Abstracts should be submitted for review by the organising committee via e-mail as word attachments to events@rpsgb.org by Friday 12 March 2010. Since the number of posters is limited, abstracts will be considered in the order of receipt so early submission is encouraged.

Authors whose abstracts have been accepted will be notified within two weeks of submission.

CANCELLATION AND REFUND

Should you find that you are not able to attend the event after booking a place, please advise us in writing as soon as possible. If a colleague is able to attend in your place and you notify us in writing, we are pleased to accept the substitution at no charge. In the event that it is necessary to cancel a registration, please notify us in writing. A processing fee is payable. For cancellations, the following refunds will apply: Over 14 days: 90% of the fee; less than 14 but over 3 working days: 50% of the fee; three or less working days: nil. The time of notification is taken at the date of receipt of fax or letter. Substitution is permitted at any time if notified in writing. The RPSGB reserves the right to change the programme or cancel the event if necessary. The RPSGB does not accept liability for any expenses incurred by delegates.

FIP QUALITY INTERNATIONAL - 15-16 APRIL 2010
REGISTRATION FORM

Delegates will be registered upon receipt of the completed form and will be liable to pay the fees. Payment must be made before the start of the course. Fees inclusive of lunches, refreshments, wine reception and course documentation.

Register before 12/02/10 and save up to 15 %	**Early Bird (before 12/02/10)**	**Full Fee**
Member of RPSGB or FIP	£555 ☐	£650 ☐
Non member	£595 ☐	£700 ☐

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Please return this form with your payment to: Events Coordinator,
Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN
Fax: 020 7572 2506 Email: events@rpsgb.org (Tel: 020 7572 2640)

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