Supply Chain Risk Management and Compliance for QP's and RP's

Available as an in-house course

Rapidly changing regulatory frameworks, business models and global structures have dramatically impacted the landscape for practitioners in pharmaceutical quality and regulatory compliance. The traditional vertically integrated model has been replaced by a hybrid mix of third party contractors, sponsor companies and licensing partners. The chain of custody has become increasingly complex to plot, making it ever more difficult for QP's and RP's to fulfil their custodial responsibilities within the supply chain.

This 1 day workshop looks at how supply chains evolve through the development process, from pre-clinical, right the way through to global launch. Risk assessment methodologies are explored to help identify critical risk areas and develop mitigation strategies in collaboration with key stakeholders. In effect, adopting processes to build in visibility, traceability and compliance so that risk and opportunity for error are reduced to an absolute minimum. The format of the workshop will be interactive, using case study exercises. Participants will be encouraged to bring along any burning issues current within their organisations for discussion (whilst maintaining confidentiality).

Speaker

Hedley Rees

Hedley has had many years in the pharma and biotech industry working with high profile biotech and emerging specialty pharmaceutical companies to bring new Molecular entities and re-profiled compounds through development stages into full scale commercial launch. He has been a key contributor to trial progression and commercial launch across all phases of development in multiple territories and global markets.

Previously Hedley was responsible for managing global supply chains in big pharma companies such as Bayer and Johnson & Johnson. Here, he built a wide competency base in all the disciplines of supply chain management, implementing and using state-of-the-art information systems enablement. He holds an Executive Master's in Business Administration from Cranfield University School of Management, a degree in production and industrial engineering from the University of Wales and is a full corporate member of the Chartered Institute of Purchasing and Supply (CIPS). Currently, Hedley sits on the Bioindustry Association's Manufacturing Advisory Committee and has previously lectured strategic supply chain management for the CIPS professional stage examinations.

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Just some of the benefits to be derived from this workshop include:

- Ability to more effectively assign ownership for key parts of manufacturing and distribution.
- Better understand how third party relationships can be fostered and advanced.
- Fulfil an effective role in developing Technical, Quality, Supply and Service Level Agreements.
- Influence issues that appeared to be outside control.
- Challenge other functions to prioritise quality and regulatory systems accordingly.
- Focus on the actions that can transform supply chain compliance.
- Reduce risk of delays and failure in getting drug to site or channel.
- Enhance control of inventory investment, availability and traceability.
- Appreciation of how to build shared understanding of quality and regulatory requirements within project management and launch teams.
- Increase confidence in helping drive continuous improvement through your supply chains.

The course will start with coffee and registration at 8.30am, course proper will start at 9.00am on and course will finish at approx 5.00pm

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If you are interested in running this course, or any of our courses in–house please contact:

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GMP Auditor Training: *New Jersey USA - 11 & 12 April 2011*
London - 9 & 10 May, 7 & 8 November 2011

How to Audit API Manufacturers: *New Jersey USA - 13 April 2011*
London - 11 May, 9 November 2011

Supply Chain Management in Pharma/Biotech: *5 & 6 May 2011*

Technology Transfer: *London - 9 & 10 May, 7 & 8 November 2011*

Integrated Tablet Formulation Development: *New Jersey USA - 7 & 8 April*
London - 9 & 10 June, 24 & 25 November 2011

Tablet Process Development, Validation and the application of QbD:
New Jersey USA - 11 & 12 April, London - 13 & 14 June, 28 & 29 November

Pharmacokinetics in Drug Development - an Integrated Approach:
9 & 10 June 2011

An Introduction to LC/MS: *19 September 2011*

Quantitative Analysis: *20 & 21 September 2011*

Writing effective SOPs in a GMP Environment: *13 & 14 October 2011*

OOS investigations in a GMP Environment: *18 & 19 October 2011*

Stability Testing in Pharmaceutical Development: *28 & 29 June 2011,*
12 & 13 December 2011

Introduction to Photostability: *14 December 2011*

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