

A 1-day non-residential course in London

COMPLIANCE with the Falsified Medicines Directive PROTECTING YOUR COMPANY'S / CLIENTS' INTERESTS

TIMETABLE	VENUE
<p>27 February 2014</p> <p>Registration 09.15h</p> <p>Course Begins 09.30h Finish 17.00h</p>	<p>Royal Society of Chemistry Burlington House Piccadilly London W1J 0BA, UK</p>
<p>The Course topics include (this is not necessarily the running order)</p> <p>WELCOME AND INTRODUCTION</p> <p>THE CHALLENGES AND HURDLES OF THE FMD Framework of Official Requirements:</p> <ul style="list-style-type: none">• EU Pharmaceutical Legislation and Legal Provisions• For Active Pharmaceutical Ingredients (APIs) and Dosage Forms• For Investigational Medicinal Products (IMPs)• Official and Other Guidelines and Codes• Inspections, Equivalent Countries, Written Confirmations <p>RECENT FMD-RELEVANT ACTIVITY</p> <ul style="list-style-type: none">• European Commission (EC)• European Medicines Agency (EMA)• Heads of Agencies (HMA)• Trade and Other Associations• Contingency Plans <p>ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)</p> <ul style="list-style-type: none">• API Sources and Associated GMP Risks• How will the FMD impact quality of outsourced APIs ?• Challenges, visibility and control of the global supply chain• Perspectives on Supplier selection• Documentary and Other Options for API Importation and Supply Chain Management• Expectations of the Inspectorates• Impact on Qualified Persons	

EXCIPIENTS AND ATYPICAL SUBSTANCES

- Excipients: What are these, what are their Sources?
- Atypical Substances: What are these, what are their Sources?
- How are they to be Regulated? Strictly or with Pragmatism?
- Available Compliance Standards
- Understanding Appropriate GMP
- Formalised Risk Assessments

SECURING THE WHOLESALE DISTRIBUTION SUPPLY CHAIN

- The British Association of Pharmaceutical Wholesalers (BAPW) and its Role
- What does the FMD mean to the Wholesale Distribution Supply Chain?
- BAPW Preferred Core Principles/Favoured Solutions
- EU Guideline on Distribution

An Extra Feature!

MINI-WORKSHOP BASED AROUND PREPARED EXAMPLES AND DELEGATES' QUESTIONS* ON COMMON FMD ISSUES

Registered delegates can send advance questions for the Mini-Workshop to admin@pharmaqmtraining.eu prior to 7th February 2014. Alternatively, the Course Leaders will address questions you raise at the Course on 27 February 2014

CLOSE OF MEETING