

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

## 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](mailto: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