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A 2-day non-residential course on Regulatory Affairs with emphasis on

Background, Content and Detail of Module 3 of the Common Technical Document (CTD), the 'Quality Module'

AGENDA

Although the following is not the running order, the course content includes:

INTRODUCTION AND WELCOME

INTRODUCTION TO THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH)

- ICH, its guidelines and the Common Technical Document (CTD)
- CTD Module 2.3 and Module 3

INTRODUCTION TO THE EUROPEAN REGULATORY SYSTEM:

- EU and Council of Europe operations and regulatory tasks
- Pharmaceutical legislation
- EU guidelines
- The European Pharmacopoeia

INTRODUCTION TO THE ACTIVITIES AND INFLUENCE OF THE EUROPEAN PHARMACOPOEIA

THE PURPOSE, FORMAT AND CONTENT OF THE QUALITY OVERALL SUMMARY, CTD MODULE 2.3

STARTING TO BUILD CTD MODULE 3

- Understanding how the legislation, official guidelines, European Pharmacopoeia and other Council of Europe publications shape the required content of CTD Module 3

UNDERSTANDING DRUG SUBSTANCE ISSUES AND CONTRIBUTIONS TO CTD MODULE 3

- Starting and other materials in a chemical synthesis
- Chemistry development issues: characterisation, analytical validation, specifications and their justification
- Data provision options for manufacturing and control including Master Files and Certificates of Suitability
- 'Conventional' organic impurities
- Other impurities: residual solvents, residues of metal catalysts and reagents, inorganic impurities, genotoxic impurities, enantiomeric impurities
- Stability
- Specifications
- Common deficiences
- Sourcing of drug substances, GMP, vendor verification, pedigree, QP certification

THE FALSIFIED MEDICINES DIRECTIVE - the new API importation rules from 2 July 2013

- Objectives and Responsibilities
- Status of implementation - UK and across Europe
- Likely impacts on
  - Active substances
  - Medicinal products - EU and non EU manufacturers
  - API producers
  - …. and more
- The next major issues of track & trace and tamper evidence

FMD QUESTIONS & ANSWERS SESSION

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UNDERSTANDING DRUG PRODUCT (DOSAGE FORM) ISSUES AND CONTRIBUTIONS TO CTD MODULE 3

- **Starting and other materials in drug formulation**
- **Pharmaceutical development: composition, functions, optimisation, performance, bioequivalence**
- **Manufacturing process**
- **In-process and end-product control including specifications and their justification**
- **Stability**
- **Numerous examples**
- **Common deficiencies**

MORE ABOUT THE BACKGROUND TO THIS COURSE AND WHO SHOULD ATTEND

This Course will be a comprehensive and group interactive course that builds from first principles and explores numerous pharmaceutical topics that have to be addressed in supporting documentation for Marketing Authorisation Applications (MAAs).

The course has been well developed over many years and has been highly regarded by delegates of varied experience in regulatory affairs and associated departments. Past delegates have been and future ones are expected to be from within the pharmaceutical and chemical industries (chemical development, analytical, formulation and pharmaceutical development, manufacturing, regulatory/registration departments, auditors) and the Competent Authorities (assessors, inspectors, scientific/medical writers).

The course is suitable for people new or relatively new to regulatory affairs, particularly people transferring within a company into product registration work, and for those needing a refresher course or an up-to-date understanding of CTD Module3.

The trainers will be Professor Derek Calam, Paul Fleming and Dr Mike Robertson who between them have many years of experience within UK, European and WHO institutions and have reviewed numerous MAAs.

TIMETABLE				
2 July 2013	Registration	9.15h		
	Day 1 Start	9.30h	Finish	16.45h
3 July 2013	Day 2 Start	9.00h	Finish	16.45h

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