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A 2-day non-residential course on Regulatory Affairs with emphasis on
UNDERSTANDING 'SMALL MOLECULE' GENERIC MEDICINES

TIMETABLE

Date to be advised

Registration	09.15h		
Day 1 Start	09.30h	Finish	16.45h
Day 2 Start	09.00h	Finish	16.45h

AGENDA (Not the precise running order)

INTRODUCTION AND WELCOME

HOW THE EU REGULATORY SYSTEM HANDLES GENERIC APPLICATIONS

INTRODUCING THE CTD MODULES

INTRODUCTION TO THE EUROPEAN PHARMACOPOEIA (PH EUR)

PRACTICAL CONSIDERATIONS IN SOURCING DRUG SUBSTANCES

- **Sources**
- **Available data**
- **GMP**
- **Vendor verification**
- **Pedigree**
- **QP certification**
- **Impact of new EU legislation**

CONSIDERATION OF GENERICS

- **Size of market**
- **First Generics**
- **Range of products**
- **Pharmaceutical development key issues**
- **Process validation**
- **Stability**
- **Data requirements**
- **GMP**
- **Counterfeit medicines**
- **Falsified medicines**

SPECIAL CONSIDERATIONS FOR GENERICS

- **European Reference Product**
- **Organic impurities**
- **Genotoxic and other potent impurities**
- **Miscellaneous impurities**
- **Comparative impurity profiles**
- **Bioequivalence studies**
- **Qualification of impurities**
- **Quality Overall Summary**
- **Non-Clinical Overview and Summary**
- **Clinical Overview and Summary**
- **Pharmacovigilance and its effect on generic manufacturing**

INTERACTIVE SESSION ON COMMON QUESTIONS ABOUT IMPURITIES RAISED EITHER PRE-SUBMISSION BY COMPANIES OR FOLLOWING OFFICIAL EVALUATION OF MA

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APPLICATIONS

Advance Questions will be invited from registered delegates and will be addressed where possible in the course. Please email questions to admin@PharmaQMtraining.eu

MORE ABOUT THE BACKGROUND TO THIS COURSE AND WHO SHOULD ATTEND

This will be a comprehensive course that blends EU pharmaceutical legislation, legal base and other official requirements and guidelines with appropriately-focused elements of pharmaceutical science and clinical investigation that are important to the development and licensing of generic medicines in the Europe.

Building from first principles in several disciplines, delegates will learn about many important aspects of pharmaceutical development, manufacturing and control of the dosage forms, what comparator products are acceptable and the importance of comparative impurity profiles and of key pharmacokinetic parameters.

Submissions (MAAs) for generic medicines must have a substantial Common Technical Document (CTD) Module 3 and much attention in the course will be given to the Chemistry & Pharmacy components. However, some Module 4 and 5 issues will also be addressed, with emphasis on Qualification of impurities and on the importance of bioequivalence study report which has to be lodged in CTD Module 5.

This course is suitable for people (likely to be from analytical, formulation, pharmaceutical development, manufacturing and regulatory/registration departments) needing to understand Abridged Applications for generic and other medicines. It will also be useful to people who want better to understand regulatory science and scientific writing and other skills needed for the creation of successful licensing dossiers.

The Course Leaders will be Professor Derek Calam, Dr Mike Robertson, Dr David Snodin & Paul Fleming. Please sign up for future announcements