

9th – 13th January 2012

Base Module 5: Regulatory Affairs; Drug Safety & Pharmacovigilance

Room: 1096 - Mon. Jan 09

9 a.m. – 12.30 p.m. – Lyn Morgan

MEDICINES REGULATION

CLINICAL TRIAL REGULATIONS

COMMON TECHNICAL DOCUMENT (CTD)

Room: 1095 - 1.30 p.m. – 4.30 p.m. – Olivier Andriollo

GOOD MANUFACTURING PRACTICE; GOOD LABORATORY PRACTICE; GOOD CLINICAL PRACTICE
PRODUCT DEFECTS & RECALL

4.30 p.m. – 5.30 pm. – Ségolène Gaillard

INTERNATIONAL CONFERENCE ON HARMONISATION (ICH)

Room: Salle du conseil a.m. / Amphi A2 p.m.- Tues. Jan 10

9 a.m. – 12.00 p.m. & 1.30 p.m. - 5 p.m. – Judith Jones, Alexandre Kiazand, Fouzia Guenaneche

DRUG SAFETY, PHARMACOVIGILANCE, & PHARMACOEPIDEMIOLOGY

ROLE OF THE PHARMACEUTICAL PROFESSIONAL IN DRUG SAFETY & PHARMACOVIGILANCE

ADVERSE EVENTS (AEs)

BENEFIT / RISK ASSESSMENT

COLLECTION OF ADVERSE EVENTS IN CLINICAL TRIALS

RISK MANAGEMENT

5 p.m. - 6 p.m. – Catherine Cornu

CLINICAL TRIAL REGISTRIES

Room:1095 a.m. / Amphi A4 p.m.- Wed. Jan 11

9 a.m. – 12.00 p.m. & 1.30 p.m. - 5 p.m. – Judith Jones, Alexandre Kiazand, Fouzia Guenaneche, Thierry Vial

SPONSORS AND INVESTIGATORS IN REPORTING

PREDISPOSING FACTORS IN HEALTH & DISEASE

SPONTANEOUS REPORTING POST-MARKETING

DOSAGE, ACCUMULATION, MEDICATION ERRORS, & INTERACTIONS

DRUG ADHERENCE / COMPLIANCE

PERIODIC SAFETY UPDATE REPORTS

PRODUCT WITHDRAWAL PROCEDURES

SAFETY SPECIFICATION

Room: 1095 a.m. / Salle des theses p.m.- Thurs. Jan 12

9 a.m. – 12.00 p.m. & 1.30 p.m. - 5 p.m. – Judith Jones, Ildir Licaj, Laurent Laforest

PHARMACOEPIDEMIOLOGY

EPIDEMIOLOGICAL PHARMACOVIGILANCE INFORMATION

SIGNAL DETECTION, INTERPRETATION, & MANAGEMENT

POST-AUTHORIZATION SAFETY STUDIES

POST-AUTHORIZATION RISK MANAGEMENT

RISK COMMUNICATION

POST-COURSE WORK

Room: 1095 - Fri. Jan 13

9 a.m. – 1p.m. – Marie-Emmanuelle Million

**INTEGRATION OF REGULATORY AFFAIRS INTO PRE- & POST-MARKETING
PHARMACOPOEIAS
PRODUCT INFORMATION REGULATION
ADVERTISING AND PROMOTION REGULATION
DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

2.30 p.m. – 5p.m. – Christine Marey

**CONFIRMATORY DEVELOPMENT
FINAL DEFINITION OF THERAPEUTIC INDICATIONS
PLANNING AND GLOBAL COORDINATION
ESTIMATED TREATMENT POPULATION
CONFIRMATORY CLINICAL DEVELOPMENT PLAN (CDP)
LIFE-CYCLE MANAGEMENT PLANNING
REGULATORY REVIEW OF RESULTS**