OPTIONAL COURSE 5 CREDITS

PROF. JOSEPH BORG

THE AUTHORIZATION OF MEDICINAL PRODUCTS IN THE EU.

1. Part 1 EU Directives and Regulations on Medicinal products
   General Aspects of the EU legislation – covering Named patient basis/compassionate use/ public health authorisations, industrial manufacturing, national marketing authorisations, decentralised and mutual recognition, referral procedures, arbitration at the European Medicines Agency, CHMP.

2. Part 2 EU Directives and Regulations on Medicinal products
   Pharmacovigilance regulations and obligations

3. Part 3 EU Directives and Regulations on Medicinal products
   Risk Management Plans and Advertising of Medicinal products issues and case examples

4. The EU regulatory Framework on Biosimilars
   General aspects on Biosimilars/Quality-clinical programs and regulatory updates.

5. How to assess a medicinal product including an OTC.

6. General aspects on what assessors do when evaluating risk/benefit of medicines and OTC

7. Part 1 the well established use licensing of medicinal products
   Extrapolation of literature data to support a marketing authorisation

8. Does the Regulator face ethical issues
   Updates on the clinical trial regulation and a case example of ECMO.

9. Part I pre-clinical data required to support a medicine's safety - Ion channel of excitable membranes
   General aspects of receptors and electrophysiology

10. Part 2 – pre-clinical data required to support a medicine's safety - Applying basic concepts to understand clinical relevance
11. Part 3 - pre-clinical data required to support a medicine's safety – ICHS7A & ICHS7B explained
    General discussion on how industry assesses cardiac safety of medicines in development.

12. Part 4 - pre-clinical data required to support a medicine's safety – juvenile toxicology studies

13. Part 5 - pre-clinical data required to support a medicine's safety – Non-Clinical Investigation of the Dependence Potential of Medicinal Products

14. Part 6 - data required to support a medicine's safety – Biotech products

15. Part 7- data required to support a medicine's safety – anticancer/DSMBs/Extrapolation of Animal data.

16. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 1

17. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 2