PHARMED

Drug formulation and manufacturing

Module 4

25- 26 April 2018

- Drug formulation
- Nanotechnologies for drug delivery
- Pharmaceutical manufacturing

For more information please contact :

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Phone : 32-02/523 62 82

http://www.ulb.ac.be/medecine/pharmed

DRUG FORMULATION
Jonathan GOOLE

The main aspects of drug formulation will be discussed with special attention being paid on the early physicochemical studies performed on the active compounds. The concept of drug bioavailability will be integrated in the general trends of formulation recommended for non-conventional dosage forms taken as examples, such as oral sustained release dosage forms (single-unit vs multiple- unit dosage forms), transdermal forms and injectable biodegradable microspheres. The role played by in vitro dissolution tests and imaging techniques (gamma scintigraphy) in the development of dosage forms will be highlighted and discussed. The potential of " line extension formulations " in the framework of Life Cycle Management will be explored and several successful cases will be reviewed.

NANOTECHNOLOGIES FOR DRUG DELIVERY
Jonathan GOOLE

For the past few decades, there has been a considerable research interest in the area of drug delivery using particulate delivery systems as carriers of small and large molecules. Particulate systems like nanoparticles have been used as a physical approach to alter and improve the pharmacokinetic and pharmacodynamic properties of various types of drug molecules. Various nanostructures, including liposomes, polymers, dendrimers, silicon or carbon materials, and magnetic nanoparticles, have been tested as carriers in drug delivery systems. They have been used in vivo to protect the drug entity in the systemic circulation, restrict access of the drug to the chosen sites and to deliver the drug at a controlled and sustained rate to the site of action. However, due to their size, nanoparticles have also the potential for crossing the various biological barriers within the body, leading to toxicity. Therefore, formulation of nanoparticles for drug delivery still presents great challenges to increase therapeutic benefit, while minimizing potential side effects.

PHARMACEUTICAL MANUFACTURING
Hugues HINANT

This course will discuss the major issues related to industrial pharmaceutical technical development (i.e. formulations, primary packaging, delivery system) including the manufacturing of clinical supplies, and its transfer to manufacturing with a special emphasis on quality known more now as Quality Management Systems (QMS), Quality by Design (QbD, ICHQ8) and Process Analytical Technologies (PAT, ICHQ8) during the development phase.
This will be presented through real examples, development cases of product and life cycle management for Chemical entities and Biological entities (i.e. Mab, Fab), in order to get more insight into the reality of challenges along development.
The course will also describe the required structures of departments/systems in development and in manufacturing according to the cGMP regards to US FDA CFR (Code of Federal Regulation), European Regulation – Eudralex (mainly Vol.4) and ICH guidelines Q (International Conference on Harmonization). Finally, this course will also try to provide underpinning knowledge of the EMA and FDA agencies and inspection-operating environment for product development and manufacturing again through real examples and development cases. In this view, the concept of inspection readiness will be presented.

Jonathan GOOLE
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Hugues HINANT
Pharmacist, ULB, Master in Pharmaceutical Engineering, UCL, Process Material and Primary Packaging Development principal Scientist, UCB Pharma

WEDNESDAY 25 April 2018

Welcoming participants
09.30–10.00

Drug formulation
Jonathan GOOLE
10.00-13.00

Pharmaceutical manufacturing-chemical entities
Hugues HINANT
14.00–16.00

Coffee break
16.00–16.15

Pharmaceutical manufacturing-GMP
Hugues HINANT
16.15–18.00

THURSDAY 26 April 2018

Drug formulation
Jonathan GOOLE
10.00-10.50

Coffee break
10.50–11.10

Drug formulation
Jonathan GOOLE
11.10-13.00

Lunch
13.00–14.30

Nanotechnologies for drug delivery
Jonathan GOOLE
14.30–15.30

Coffee break
15.30–15.45

Pharmaceutical manufacturing-biologics
Hugues HINANT
15.45–17.45