DRUG DEVELOPMENT: KEY TO SUCCESS FROM CONCEPT TO COMMERCIALIZATION

COURSE DESCRIPTION

The course begins by considering the global pharmaceutical market, important therapeutic areas and the roles of different Pharmaceutical professionals in the development process, as well as a definition of drugs and medical devices. Course include the identification of drug targets, synthesis of chemical drugs and the development of biologics, pharmacokinetics and toxicity screening, pre-clinical development, clinical studies, regulatory submissions, managing post-approval change, pharmacovigilance and an overview of regulations governing drug manufacture and distribution. The drug development process, from discovery to post-marketing surveillance, is then explained

WHO WILL BENEFIT

- Non-scientific employees of pharmaceutical companies who would like to understand how drugs are developed (e.g. IT, human resources, engineering and administrative staff)
- Recently-appointed scientific staff with no previous experience of the pharmaceutical industry
- Research & development scientists
- Clinical Research Associates
- Auditors
- Regulatory Affairs Professionals
- CMC/pharmaceutical research professionals
- Regulatory affairs professionals
- Project managers
- Financial managers
- Brand team personnel
- Senior sales managers
- Strategic planners
- Quality Assurance Personnel
- Manufacturing Personnel
- Medical and clinical investigators
- Statisticians & data management professionals

LEARNING OBJECTIVES

- By the end of this course, you will understand:
- Roles of different pharmaceutical professionals
- Typical costs and timelines associated with drug development
- How new drugs are developed against targets in the human body
- The structure of regulatory submissions
- Reasons why drugs fail during development process
- Factors affecting oral bioavailability
- The size of the global pharmaceutical market and the key therapeutic areas being addressed by innovator companies
- How drugs are screened for toxicity
- The potential influence of polymorphism, salt form and isomerism on efficacy and safety
- How formulation can affect drug performance
- How the safety and efficacy of drug products are ensured during QC release testing
- The information obtained at each stage of clinical research
- How post-approval changes to drug products are managed
- How the manufacture and distribution of marketed drug products are controlled

FACULTY KARL M. NOBERT

Karl focuses his practice in FDA Regulatory law, representing U.S. and international clients in the food and drug industries with regard to pharmaceuticals and OTC drugs, biologics, medical devices, food and beverages including dairy products, cosmetics, vitamins and dietary supplements, and veterinary products.
He has particular experience in the areas of prescription drugs and regenerative medicine, and has counseled numerous clients seeking FDA approval for Rx drugs and cellular-based products to treat both humans and animals.

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2 DAY AGENDA

Drug Development Products Overview
- Product types and routes of administration
- The drug development process
- Risks in drug development

The International pharmaceutical market
- Market shares of chemical and biological drugs
- Roles of drug development professionals
- Size and key therapeutic areas
- Regional differences

Drug discovery
- Drug targets
- The Human Genome Project
- Lead compound identification and optimisation

Regulatory submissions
- The Common Technical Document
- CTD modules
- Regional administrative information
- The application process for chemical and biologic drug products – US and EU

Pre-clinical development
- Optical isomerism
- Formulation options for improving bioavailability
- Common formulation types
- Critical quality attributes
- In-process controls and release testing
- Polymorph and salt form screening
- Solubility, permeability and oral bioavailability

Clinical research
- Clinical study design
- Clinical development Phases
- Establishing safety and efficacy/ bio equivalence
- Adverse event reporting
- Impact of mobile computing on clinical research

Pharmacokinetics and toxicity
- Drug plasma concentration profiles
- Absorption, distribution, metabolism and elimination of drugs
- First-pass metabolism
- Types of toxicity screening

Post-approval change
- Problems concerning product improvement
- New ICH Q12 – the promise of easier post-approval change
- Current situation

US and EU Pharmacovigilance Important elements of regulation
- Drug product manufacture
- Distribution
- ICH guidance

Final questions, feedback and close

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REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

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Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
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