Drug Discovery and Development Processes

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Course Description

This introductory course provides a high-level overview of the entire drug development process for new therapeutics, with a focus on the role of the analytical chemist in this complex, costly and multidisciplinary process. It introduces the pharmaceutical (biopharm) industry (perspectives, challenges and trends), and discusses impacts from generic drugs. Course attendees will learn the current drug discovery approach, from basic research, identification of drug targets, turning of hits to leads, to non-clinical and clinical development. The role of the analytical chemist in supporting discovery, process scale-up, formulations, stability, DMPK, QC/QA, and regulatory affairs functions, will be described. The focus of the course is on new drug discovery and development process of small molecule innovative drugs.

Target audience

This course will benefit scientists working in the biopharmaceutical industry who want better understanding of the drug discovery/development process and for non-pharma scientists seeking more background of the challenges and opportunities in the industry. It is recommended that you have some fundamental understanding of biology, chemistry or biochemistry.

Outline

1. Pharmaceutical industry: perspectives, challenges and trends

- Historical and regulatory background; industry perspectives, challenges and trends.
- Overview of current processes and approaches; case studies.

2. Drug discovery process: from targets to leads

- Overall approaches: phenotypical, molecular and genomic medicines.
- Target: identification / validation and lead ID / optimization.
- ADME, DMPK, toxicology and animal models.

3. Non-clinical and clinical drug development: from candidate to IND and NDA

- Characterization of lead molecules, API process scale-up, pre-formulation, analytical chemistry, stability, development of clinical trial materials (CTM).
- Analytical procedures for assessing and controlling drug quality (physicochemical properties, purity, ID, stability), COA, release testing, quality control, and specifications.

- GLP tox studies, IND filing and case studies.
- Clinical trials: Phase I, II, III and IV, and NDA.

About the instructor

Dr. Michael W. Dong is a principal in MWD Consulting focusing on training and consulting services in HPLC/UHPLC, pharm analysis and drug quality. He was formerly Senior Scientist at Genentech, Research Director at Synomics Pharma, Research Fellow at Purdue Pharma, and Senior Staff Scientist at Applied Biosystems / Perkin-Elmer. He holds a Ph.D. in Analytical Chemistry from City University of New York, and a certificate in Biotechnology at U. California. Santa Cruz. He has over 120 publications and a best-seller book in HPLC. He is an advisory board member of LCGC magazine, American Pharmaceutical Review, and Chinese American Chromatography Association.

Recommended text:

R. G. Hill and H.P. Rang (eds.), **Drug Discovery and Development: Technology in Transition**, 2nd edition, Churchill Livingston, 2012. ISBN 978-0-7020-4299-7.