Drug Development for Analytical Scientists II:
Drug Quality Fundamentals: Quality Control of Small Molecule Drugs and Recombinant Biologics

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Course description

This course provides an overview of drug quality concepts, standards, regulations, and practices in clinical development and manufacturing in pharmaceutical and biotechnology industries. You will learn the roles of quality assurance (QA), quality control (QC), and the chemistry, manufacturing, and control (CMC) drug development process in ensuring safety, efficacy and quality of drug products. It covers industry-standard processes such as qualification/validation, release testing, specifications, certificates of analysis (COA), stability and regulatory filing. Critical quality attributes (CQA) of large-molecule recombinant biologics are described and contrasted with those of small molecule drugs. The course discusses the challenges of maintaining drug quality in a global supply chain and the role of HPLC in these processes.

Target audience

This course will benefit scientists and non-scientists currently working in various disciplines of the pharmaceutical industry who want to improve their understanding of CMC, quality systems, analytical chemistry and quality control processes in the industry. This course is also useful for non-pharma scientists who seek a technical overview of challenges and opportunities for drug development and quality management (QA, QC, regulatory, supply chain management) in pharma related industries (pharmaceutical, biotechnology, generics, over-the-counter and nutraceutical industries). It is recommended that you have some fundamental understanding of biology, chemistry or biochemistry.

Agenda

1. Introduction to Drug Quality and CMC Quality Assurance process
   - Quality attributes recent quality breaches, GLP, GMP, GCP, ICH guidelines, IND, NDA, CTA, QC / QA unit, specifications, and Quality by Design (QbD).

2. QC of Small Molecule drug substance and drug product
   - Specifications, release testing, COA, impurities and stability

3. Critical quality attributes of recombinant biological products (with major input from Dr. Taylor Zhang of Genentech)
   - Approaches to manufacturing and bioprocessing of monoclonal antibodies, analysis of intact proteins, fragments, variants, glycans and other biological testing.

Biography

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, Small Molecule Analytical Chemistry and QC, Research Director at Synomics Pharma, Research Fellow at Purdue Pharma, Senior Staff Scientist at Applied Biosystems / Perkin-Elmer, and section-head in Hoechst Celanese. 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 conducted training courses at national meetings (ACS, Pittcon, EAS, and HPLC) on HPLC, UHPLC, pharmaceutical analysis, drug development process, and drug quality fundamentals. He has over 100 publications in chromatography and analytical chemistry. He authored a best-seller in chromatography - Modern HPLC for Practicing Scientists, Wiley, 2006 and co-edited Handbook of Pharmaceutical Analysis by HPLC, Elsevier/Academic Press, 2005. He is an editorial advisory board member of LCGC magazine and American Pharmaceutical Review.

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.