CMC Workshop
Explore current challenging topics and address solutions within the global pharmaceutical and biopharmaceutical arena.
Chemistry, Manufacturing, and Controls (CMC) systems and processes play a pivotal role in the development, licensure, manufacture, and ongoing marketing of biopharmaceutical products and devices that are consistently effective, safe, and high quality for patients. In fact, CMC (Quality) is one of the three key areas that health authorities consider, along with safety and efficacy, in the review and approval of the product application.

The importance of CMC, which is by nature complex, spans the entire life cycle of the product from the non-clinical phase through the postmarket period. The challenges faced by today’s CMC executives are growing due to the development of new product types and advances in technology. As corporations continue to develop and market therapies around the world, ensuring compliance with evolving CMC regulations throughout the product life cycle is increasingly difficult.
CMC Regulatory professionals have the ultimate responsibility for providing the CMC regulatory leadership and strategy required to achieve approvals and ongoing compliance.

These efforts are further complicated by the continued guideline changes and lack of global regulatory alignment. In the face of a complex regulatory framework, stakeholders must be acutely aware of regional and global requirements and standards, as well as how to navigate through unclear and sometimes inconsistent provisions from the outset of their product development.

Utilizing effective CMC strategies and execution, such as those to be discussed at DIA’s CMC Workshop, can help reduce regulatory burden, enable shorter review timelines, and support post-approval maintenance. In-depth panel discussions and real-time Q&A will allow for conversation on approaches to securing pharmaceutical supply chains in order to ensure patients receive safe and effective medicinal products.
To demonstrate technical excellence, the CMC function must build on a thorough knowledge of science-based regulation and proficiency with the newest technologies and methods.

CMC professionals must build quality-enabling systems and are charged with their management through strong partnerships with internal and external functional areas such as:

- Product development
- Operations
- Product life cycle management
- Business development

Understanding how these functional areas contribute to well-functioning quality systems, change management, and externally facing operations to support CMC can have a considerable impact on an organization’s ability to successfully launch a new drug.

Joint training workshop strengthens regulatory capacity to detect and respond to falsified/counterfeit products in Asia.

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Insights gained on implementing new development pathways and leveraging advanced technologies and science-based regulations will better equip CMC executives to ensure streamlined approvals and availability of safe, effective, and high quality products.

All members of the CMC team, from regulatory strategists to professionals, will learn key concepts to apply the most current strategies to help conquer challenges and create opportunities encountered by those working in regulatory strategy as well as those in functional areas who partner with regulatory agencies to achieve business goals.

Three parallel breakout tracks at DIA’s CMC Workshop will cover GMP/quality, regulatory/dossier, and technical concepts in order to better prepare all members of the CMC team to apply learnings to their CMC challenges and achieve product development goals.
Why you need to attend DIA’s CMC Workshop

The CMC Workshop will benefit those involved in the development and manufacturing of biopharmaceuticals, devices, and combination products, as well as those preparing CMC documents for submission to regulatory agencies.

As scientific advances enable the development of unprecedented numbers of innovative therapeutic products, CMC professionals must address new issues in the development, approval, and life cycle management processes.

This workshop provides a comprehensive view of current regulations and approaches to implementation challenges for a broad range of products. It is unparalleled in its coverage of product types, regional requirements, and balance of regulatory and industry perspectives in examining real-world solutions.
The DIA CMC Workshop is a good meeting with excellent speakers and highly relevant CMC topical coverage...There is good balance between industry and regulatory stakeholders and lots of opportunities for interaction with FDA and other attendees.”
New Features

• More case studies to illustrate CMC challenges of products throughout the life cycle and approaches to resolving regulatory, technical, and quality problems
• Expanded coverage of global regions beyond the US, EU, and Japan
• In-depth updates for the Asia-Pacific, Latin America, and Middle East regions
• Pre-conference short course to prepare entry and early intermediate level professionals for the workshop content

Hot Topics

• Global accelerated programs - CMC challenges and QbD approaches
• Innovative manufacturing technologies – continuous manufacturing
• Myths and realities of the small and large molecule divide
• Complex products and generics
• Special CMC challenges of biosimilars
• CMC for drug/device combinations - human factor studies, stability, and bridging studies
• The EU Medical Device Regulation (MDR) - impact and implementation
• Global alignment of serialization and traceability requirements
• Joint inspections for post-approval changes
• Life cycle management - progress with ICH Q12
Must-Attend Sessions

1. Accelerated Programs in the Global Regulatory Environment
2. QbD Approaches to Accelerated Drug Development
3. Innovative Manufacturing Technologies: Advances in Continuous Manufacturing
4. Technical and Regulatory Considerations of Pharmaceutical Product Life Cycle Management: ICH Q12
5. Process Validation/Continuous Verification (ICH Q10) and Pharmaceutical Quality
6. Generic Non-Biological Complex Drugs (NBCDs): Challenges in Development and Approval
7. Regional Update from Asia-Pacific
8. Global Landscape of Falsified/Counterfeit Medicines and Global Serialization

Speaker Spotlight

Sarah Pope Miksinski, PhD
Director, Office of New Drug Products; Director (Acting), Office of Surveillance, Office of Pharmaceutical Quality, CDER, FDA

Peter J. Richardson, PhD
Head of Quality, Human Medicines R&D Support Division EMA, European Union, United Kingdom

Jean-Louis Robert, PhD
CHMP (EMA) Co-opted Member, Chair, CHMP/CVMP, Quality Working Party CHMP (EMA), Luxembourg

Yoshihiro Matsuda, PhD
Senior Scientist (for Quality) PMDA, Japan

Some of the organizations represented:
FDA, Health Canada, EMA, and PMDA. AbbVie, Apotex, AstraZeneca, Camargo Pharmaceutical Services, Eli Lilly, Emergo, Genentech-Roche, GSK, Merck Research Laboratories, NovoNordisk, Phillips Medisize, Pfizer, Shire, VaxForm LLC.

*There will be other companies represented as more speakers confirm participation.*
CMC challenges may be difficult to solve and require a thorough understanding of regulatory, technical, and quality requirements and strategies. This workshop provides all essential knowledge and information needed for success. Gain the knowledge you need to best navigate current CMC regulatory quality requirements and join us at the CMC Workshop.

REGISTER TODAY!

Don’t Miss These 2017 Events and Learning Opportunities

What’s happening at DIA in 2017? Download the DIA Events and Training Calendar to see where and when DIA will be hosting conferences, meetings, short courses, and training opportunities for you and your team.

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