DIA
CMC Workshop

April 24-26 | Rockville, MD

Explore current challenging topics and address solutions within the global pharmaceutical and biopharmaceutical arena.

CMC systems and processes play a pivotal role in the development, licensure, manufacture, and ongoing marketing of biopharmaceutical and device products that are consistently effective, safe, and high quality for patients.

Ensuring compliance with evolving CMC regulations throughout the product life cycle is increasingly difficult.

Effective CMC strategies and execution help reduce regulatory burden, enable shorter review timelines, and support post-approval maintenance.

Highlights

Expanded coverage of global regions beyond the US, EU, and Japan: In-depth updates for the Asia-Pacific, Latin America, and Middle East regions

More case studies to illustrate CMC challenges of products throughout the life cycle and approaches to resolving regulatory, technical, and quality problems

Co-sponsored with the American Association of Pharmaceutical Scientists (AAPS)

New Feature

Pre-workshop 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

The impact and implementation of the EU Medical Device Regulation (MDR)

Global alignment of serialization and traceability requirements

Joint inspections for post-approval changes

Progress with ICH Q12

Fast Facts

Three Concurrent Breakouts

Cover the topical themes of: GMP/Quality, Regulatory/ Dossier, and Technical Aspects of CMC

22 Sessions

Four plenary sessions – Accelerated Programs, Innovative Technologies with a focus on Continuous Manufacturing, Life Cycle Management using ICHQ12, and the Global Regulators Update

18 breakouts – Complete sessions addressing the regulation, development, and technical issues for large and small molecules

Global Representation

Regulatory and industry representatives discuss new and current requirements and issues from major global regions: US, EU, Japan, Asia-Pacific, Latin America, and the Middle East

New Perspectives

Learn from expert speakers, as well as your peers, and gain the essential knowledge and information needed for success

#DIACMC17
DIAglobal.org/CMC17