

LUNCH & LEARN

ASTM E55.03 Standard Rev. 3: Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing

“The Future of Commissioning & Qualification”

Learn how the proposed ASTM Commissioning & Qualification standard shifts the focus to comprehensive engineering approaches to deliver safe, cost-effective and efficient manufacturing facilities in a timely manner. The guide specifically addresses the process of designing, constructing, commissioning and qualifying facilities, utilities and equipment and complies with all regulatory requirements aligned with US standards and references. The new ASTM C&Q standard will be the guide for specification, design & verification of pharmaceutical and biopharmaceutical manufacturing.

Key Concepts and Principles:

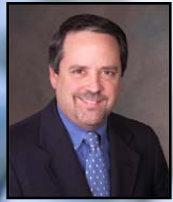
- ASTM Standard Draft for C&Q
- Path Forward
- Quality Built In
- Engineering Approaches and Practices
- Risk-Based Approach
- Science-Based Approach
- Quality by Design
- Critical Quality Attributes
- Subject Matter Experts
- Good Engineering Practice (GEP)
- Use of Vendor Documentation
- Qualification – Old vs. New
- Design Qualification
- Change Management

Resident Experts:



Steve Wisniewski – *Director of Compliance, IPS*

Steve offers more than 30 years of delivering projects for design, construction, facility management and compliance of pharmaceutical facilities. He is currently serving on the ASTM Task Team, is Chairman of the ISPE Community of Practice for C&Q, and is a member of the ISPE C&Q Baseline Guide revision Team.



Chuck Stock, CxA – *Senior Vice President, IPS*

Chuck offers more than 25 years of process/operations and compliance experience in the pharmaceutical, biotech, and medical device industries.



Vince Cebular – *Director, Compliance Operations, IPS*

Vince has more than 16 years of experience in engineering and validation within the pharmaceutical and biotech industries.

To schedule, please contact:

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