



C&Q for New and Renovated Facilities: Guidance and Improvements for Successful Delivery

National Institute for Bioprocessing Research and Training (NIBRT)
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INSTRUCTORS



John Henchion
Qualified Person,
Commissioning Agents, Inc.



Neil Lloyd
CQV Consultant,
Gallo Engineering Ltd.

An ISPE and NIBRT Collaborative Training Course

Deliver world-class training for the Pharmaceutical and Biopharmaceutical industries. This course is designed to improve the way in which the industry delivers regulated manufacturing capacity.

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Course Topics include:

- EU Annex 15, ICH Q8(R2), Q9, Q10, and ASTM Standard E2500-07
- Developing User Requirements
- Applying Risk Management Methodologies
- Identifying the Regulatory Drivers for Design Review
- Creating a Verification Strategy to Include Vendor Testing and Construction Quality Assurance
- Using Risk Assessments to Identify Critical Aspects
- Developing Acceptance and Release Reports
- Defining Change Management Strategies
- Examining Options for Better Utilization of Resources

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