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Live webinar

Pharmaceutical and Biologics Facility Design: FDA and Regulatory Aspects

April
04
2017
10:00 AM PST | 01:00 PM EST

Duration: **60 Minutes**

Instructor: **John R. Godshalk**

Registration

Overview:

This course explores some of the best practices of pharmaceutical facility design with an emphasis on regulatory aspects. FDA and other global regulatory body requirements are discussed and the reasoning behind them.

Areas Covered in the Session:

- Best design practices for Pharma facilities
- Best design practices for biologics facilities
- Regulatory compliance for Pharma and biologics facilities design
- Flow patterns and cross contamination controls
- Design criteria for fixtures and finishes
- Examples of good design
- General specifications for different classification zones
- Examples of design specs for cleanrooms

Who Will Benefit:

- Compliance Manager
- Facility Manager
- Validation Manager
- Regulatory Manager
- Design Team/Architects

About Speaker:

John R. Godshalk
Senior Consultant, Biologics Consulting Group, LLC
John R. Godshalk, currently works for the Biologics Consulting Group as a Senior Consultant. John served as a Senior Review Biochemical Engineer and Lead cGMP inspector in the Division of Manufacturing and Product Quality at CBER, FDA. He contributed to formulation of FDA policy...more

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