Development of the Good Practice Guide to Single-Use Technology

The Disposables Community of Practice

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The Disposables Community of Practice (CoP) was established in 2007 to connect like-minded professionals involved in the Disposables field. It creates a global focal point of support for biopharmaceutical professionals. About 800 members participate, and the Steering Committee is composed of representatives from End-user companies and Supplier companies. The CoP provides interactive forums for discussions, news, and content related to the Disposables discipline. It publishes articles and technical guides relevant to Disposables and Single-Use Technology.
The Good Practice Guide to Single-Use Technology

Gives you a road map

Development of the Good Practice Guide to Single-Use Technology

- Selection & Design
- Implementation & Use
- Case Studies
- Management
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Components
- Extractables & Leachables
- Process Equipment Design
- Product Quality Requirements
- Supplier Quality & Audits
- Facilities Design
- Waste Management

Selection & Design → Implementation & Use

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Case Studies

Management

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Components
- Extractables & Leachables
- Process Equipment Design
- Product Quality Requirements
- Supplier Quality & Audits
- Facilities Design
- Waste Management

Selection & Design → Implementation & Use

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Case Studies

Management
Development of the Good Practice Guide to Single-Use Technology

Components
Extractables (& Leachables)
Process Equipment Design
Product Quality Requirements
Supplier Quality & Audits
Facilities Design
Waste Management

Selection & Design
Implementation & Use

Case Studies
Management

Implementation
Sustainability
URS Development
Change Control
Project Schedules

Tech Transfer
Regulatory Compliance
Validation
Leachables (& Extractables)
Supply Chain
Training

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TOPICS

• Process Equipment Design
• Facility Considerations
• Vendor Quality & Audits
• Leachables and Extractables
• Sustainability
• Waste Disposal Management
• Quality Requirements
• Regulatory Compliance
• Validation
• Management Considerations
• Tech Transfer
• Supply Chain
• Training
• Implementation Management

Ref: Niels Guldager, ISPE Annual Meeting presentation, 2013
* Development of the Good Practice Guide to Single-Use Technology is in progress

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Case Studies being considered

- Hybrid Single-Use Clinical Manufacturing Facility
- Dance Floor Operation with Standardized Single-Use Technology Products
- Adaptation of Single-Use Technology in Pilot Plant Operations
- Development of Procedures/practices to Maintain Batch Integrity in the Event of a Leaking Bag
- Outsourcing as a Means to Control Single-Use Tubing Set Quality
- Tubing Management With Jigs
- BSL-3 with Single-Use Systems

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Ref: Niels Guldager, ISPE Annual Meeting presentation, 2013
Questions?
Please use the microphone indicated so our recording includes audio of your question

Thank You.
Join the CoPs to Learn and Share Experiences.

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