



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

The Disposables  
Community of Practice

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**Disposables**  
Community of Practice

- The Disposables Community of Practice (CoP) was established in 2007 to connect like-minded professionals involved in the Disposables field
- Create a global focal point of support for biopharmaceutical professionals
- About 800 members
- Steering Committee composed of
  - Representatives from End-user companies
  - Representatives from Supplier companies
- Provides interactive forums for discussions, news, and content related to the Disposables discipline
- Publishes articles and technical guides relevant to Disposables and Single-Use Technology



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## The Good Practice Guide to Single-Use Technology

Gives you a road map



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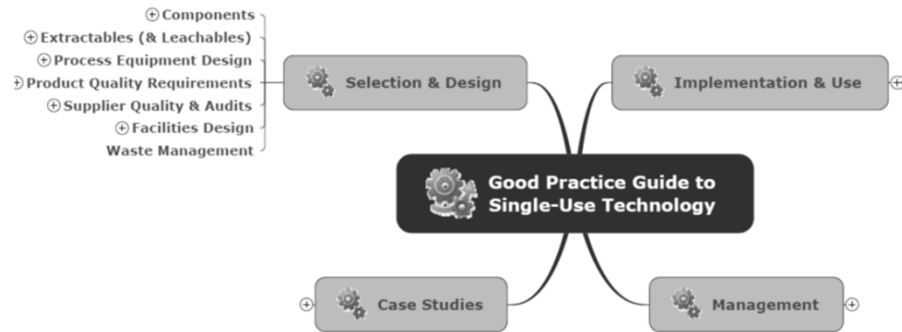
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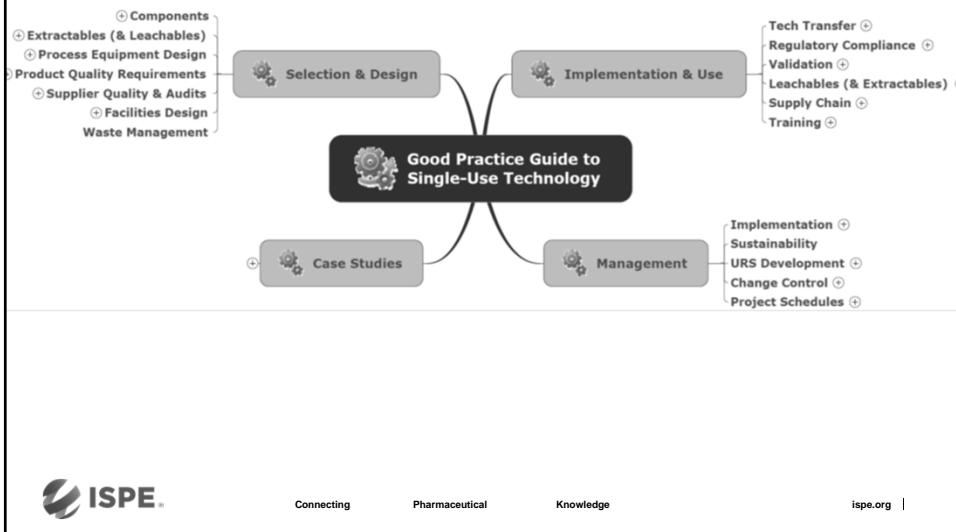
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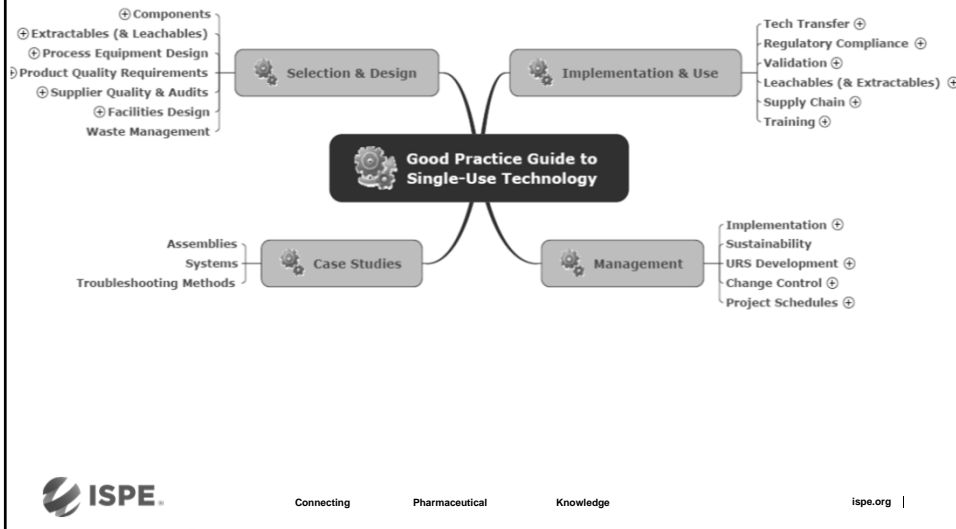
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## Development of the Good Practice Guide to Single-Use Technology

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

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## Development of the Good Practice Guide to Single-Use Technology 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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## Questions?

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question

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## Thank You.

Join the CoPs to Learn and Share Experiences.

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