**Short Course Announcement**

**Applied Cleaning Validation Practices: A STERIS Master Class**

**July 30–31, 2019**

**Course Fee: $1,350**

This two-day intensive course presented by invited industry experts will cover industry practices, regulatory expectations, and trends in cleaning and cleaning validation. It is designed for biopharmaceutical manufacturers who are concerned about developing or maintaining a high-quality, efficient, and most importantly, compliant cleaning process. The training will address several current challenges to cleaning and validation in the biopharmaceutical industry and include case studies, best practices, and hands-on exercises using state-of-the-art bioprocessing equipment located in the BTEC facility. The course will cover numerous topics, including the following:

- Lifecycle approach to cleaning validation
- Cleaning chemistries and application parameters
- Laboratory studies and scale-up
- CIP, COP, manual cleaning methods
- Process and engineering issues
- Cleaning process equipment—bioreactors, rings, membranes
- Cycle development
- Process design and qualification
- Setting acceptance criteria
- Rinse and swab sampling
- Analytical methods and validation
- Protocols, grouping strategies
- Dedicated equipment and campaigns
- Continuous improvement
- Stainless steel maintenance
- Bioburden and biofilms
- Global regulatory documents and citations

For additional information, please contact John Balchunas, BTEC’s Assistant Director of Professional Development Programs, at john_balchunas@ncsu.edu.

**Course schedule**

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<tr>
<th>Day 1</th>
<th>Day 2</th>
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<tr>
<td><strong>Lecture 1:</strong> Introduction to cleaning validation (international regulatory landscape and expectations/aims for cleaning, validation vs. verification, traditional vs. life cycle approach, risk-based and QbD approaches, cleaning process design (biopharma processes, equipment types, types of residues)</td>
<td><strong>Lecture 5:</strong> Process and engineering issues (design space concepts and scale-up, CIP skid overview and design, engineering issues to consider, spray devices, cycle development, efficiency, rinsing time, water savings)</td>
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<td><strong>Lecture 2:</strong> Cleaning chemistry, methods and cleaning evaluations (Stage 1)</td>
<td><strong>Lab 3:</strong> Worst-case locations (identify areas of concern with open bioreactor)</td>
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<td><strong>Lab 1:</strong> Cleaning evaluation</td>
<td><strong>Lab 4:</strong> Coverage testing with riboflavin/sampling stainless steel vessel</td>
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<td><strong>Lecture 3:</strong> Cleaning objectives and qualification (cleaning and microbial control aims, rinse and swab sampling, analytical methods validation principles, recovery studies)</td>
<td><strong>Lab 5:</strong> Derouging/passivation testing demo</td>
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<td><strong>Lab 2:</strong> Demo—Analytical swabbing/sampling and recovery demo</td>
<td><strong>Lecture 6:</strong> Cleaning qualification (protocols, grouping strategies, dedicated equipment, hold times and product build-up)</td>
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<td><strong>Lecture 4:</strong> Calculating limits (applications)</td>
<td><strong>Lecture 7:</strong> Cleaning validation maintenance and regulations (stainless steel maintenance, derouging and passivation, bioburden and biofilms)</td>
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<td><strong>Lecture 8:</strong> CV maintenance and regulations</td>
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<td><strong>Lecture 9:</strong> Cleaning difficult biotech equipment</td>
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**REGISTER NOW:** go.ncsu.edu/btec_short_courses
About the instructors

Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP). Walid earned a master’s degree in Industrial Pharmaceutical Sciences from the University of Liège, Belgium and is a certified Lean Six Sigma green belt.

Beth Kroeger is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. She currently provides global technical support related to process research cleaners, cleaning validation and critical environments. Beth has over 20 years of industry experience in biopharmaceutical and oral solid dose manufacturing operations. Prior to her current position, Beth was employed by Janssen Biotech where her areas of expertise included large-scale fermentation systems, both continuous perfusion and fed batch, and downstream operations including large-scale purification processing, viral removal, UF and final fill. She earned a Bachelor of Science in Biological Sciences from the University of Missouri, St. Louis and most recently completed a Fermentation Technology program at Massachusetts Institute of Technology.

Paul Lopolito is a Technical Services Manager for the Life Sciences Division of STERIS Corporation (Mentor, Ohio). He currently provides global technical support related to process research cleaners and contamination control, which includes field support, site audits, training presentations and educational seminars. Paul has over 20 years of industry experience and has held positions as a technical services manager, manufacturing manager and laboratory manager. Paul is a frequent speaker at industry events including the PDA, ISPE, INTERPHEx, ACHEMA, AALAS, LAMA and IVT. Paul has published several articles and book chapters related to cleaning and cleaning validation. He earned a Bachelor of Arts in Biological Sciences from Goucher College in Towson, Md.

Important information for short course participants

Location

This course is held on site at BTEC. The Golden LEAF BTEC building is located at 850 Oval Drive on NC State University’s Centennial Campus.

Payment

BTEC accepts payment from all major credit cards including American Express, Visa, and MasterCard. If you wish to pay by company check, please email melody_woodyard@ncsu.edu for additional information immediately after registering.

Discounts available

A 20% discount is available to:

• Employees of NC Biotech Manufacturers Forum (BMF) member companies
• Groups of five or more from one company registering for the same offering of this course
• Individuals registering for more than one course at a time
• Society of Industrial Microbiology and Biotechnology (SIMB) members

A 30% discount is available to faculty/staff working in academic environments.

Pre-course communication

Registered course participants will receive an email two weeks before the scheduled course with detailed information regarding travel to BTEC, parking information, and a short pre-course questionnaire.

Short course cancellations

CANCELLATION BY REGISTRANT

To cancel a registration and be eligible for a refund of course fees, you must notify BTEC by email. Fees are refunded according to the following schedule:

• 100% refund – If notification is received at least 15 business days in advance of course start date
• 75% refund – If notification is received 10–14 business days in advance of course start date
• 50% refund – If notification is received 6–9 business days in advance of course start date
• No refund will be issued if notice is received 5 or fewer business days in advance of course start

Substitutions may be made up to two business days prior to the course start date.

CANCELLATION BY BTEC

BTEC retains the right to cancel a professional development short course no less than 10 business days in advance of the scheduled course start date. Registrants will be notified by BTEC if a course is cancelled and will receive a full refund of registration fees paid. BTEC is not responsible for airfare penalties or other costs incurred due to cancellation.