ASME
SETTING THE STANDARD

19th Annual Bioprocess Technology Seminars

October 23 – 27, 2006
Hyatt Regency Montreal
Montreal, Canada
www.asmeconferences.org/bioprocess06

Unparalleled Quality in Bioprocess Technology Courses, including:

NEW! PLUS:

- Aseptic Fill and Finish for Biopharmaceuticals
- Bioreactor Process Technology
- Bioprocess Equipment Design
- Bioprocess Fermentation & Cell Culture Design & Scale–Up
- Bioprocess Technology Implementation
- Bio–Downstream Process Design & Economics
- Bioprocess Purification Process Development
- Cleaning Practices: Practical Implementation of CIP for Success
- Validation of Biopharmaceutical Facilities & Processes
- Bioreactor & Fermentor Design
- Metallic Materials of Construction for Hygienic Services: Fabrication, Finishing, and Corrosion

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Schedule At–A–Glance

Sunday, October 22, 2006
5:00 pm – 8:30 pm . . . . . Registration (avoid the lines on Monday)

Monday, October 23, 2006
7:30 am – 5:00 pm . . . . . Registration Open
7:30 am – 8:30 am . . . . . Continental Breakfast
8:30 am – 10:00 am . . . . . Courses in session
10:00 am – 10:30 am . . . . . Refreshment break
10:30 am – noon . . . . . Courses in session
Noon – 1:00 pm . . . . . Lunch
1:00 pm – 2:30 pm . . . . . Courses in session
2:30 pm – 3:00 pm . . . . . Refreshment break
3:00 pm – 4:30 pm . . . . . Courses in session
4:30 pm – 5:30 pm . . . . . Keynote
5:30 pm – 7:00 pm . . . . . Opening Reception w/ Exhibitors

Tuesday, October 24, 2006
7:30 am – 5:00 pm . . . . . Registration Open
7:30 am – 8:30 am . . . . . Continental Breakfast w/ Exhibitors
8:30 am – 10:00 am . . . . . Courses in session
10:00 am – 10:30 am . . . . . Refreshment break w/ Exhibitors
10:30 am – noon . . . . . Courses in session
Noon – 1:00 pm . . . . . Lunch w/ Exhibitors
1:00 pm – 2:30 pm . . . . . Courses in session
2:30 pm – 3:00 pm . . . . . Refreshment break w/ Exhibitors
3:00 pm – 4:30 pm . . . . . Courses in session

Wednesday, October 25, 2006
7:30 am – 5:00 pm . . . . . Registration Open
7:30 am – 8:30 am . . . . . Continental Breakfast w/ exhibitors
8:30 am – 10:00 am . . . . . Courses in session
10:00 am – 10:30 am . . . . . Refreshment break w/ Exhibitors
10:30 am – noon . . . . . Courses in session
Noon – 1:00 pm . . . . . Lunch w/ Exhibitors
1:00 pm – 2:30 pm . . . . . Courses in session
2:30 pm – 3:00 pm . . . . . Refreshment break w/ Exhibitors
3:00 pm – 4:30 pm . . . . . Courses in session

Thursday, October 26, 2006
7:30 am – 5:00 pm . . . . . Registration Open
7:30 am – 8:30 am . . . . . Continental Breakfast
8:30 am – 10:00 am . . . . . Courses in session
10:00 am – 10:30 am . . . . . Refreshment break
10:30 am – noon . . . . . Courses in session
Noon – 1:00 pm . . . . . Lunch
1:00 pm – 2:30 pm . . . . . Courses in session
2:30 pm – 3:00 pm . . . . . Refreshment break
3:00 pm – 4:00 pm . . . . . Courses in session

4:00 pm – 5:30 pm . . . . . Plant Tour: NRC-BRI Bioprocess Plant – 50 maximum

Friday, October 27, 2006
9:00 am – 10:30 am . . . . . Plant Tour: NRC-BRI Bioprocess Plant – 50 maximum

Visit www.asmeconferences.org/bioprocess06 for detailed descriptions.
NOTE: Changes in the schedule after March 5, 2006, may not be reflected in this program. Please check the website for the most up–to–date information.

PLANT TOUR

Join us for a plant tour of the NRC-BRI Pilot Plant for Bioprocessing. The Pilot Plant is the largest facility of its kind in Canada, which has computer-controlled fermenters of different sizes ranging from 3.5 L to 1500 L. The Pilot Plant also includes a wide range of analytical equipment and instruments for supporting its fermentation and down-stream processing.

Tours will be held on Thursday, October 26, and Friday, October 27. Each tour is limited to accommo-date 50. Advance sign-up is required. First come, first served. Reserve your seat early.

NETWORKING

Join your colleagues in a number of networking functions including Opening Reception, daily meals, cocktail hours, and other social activities to be arranged. Watch our social program take shape.
Visit our website at www.asmeconferences.org/bioprocess06

NEW!

Aseptic Fill and Finish for Biopharmaceuticals

PD578

Course dates: October 24–26, 2006 (Tuesday – Thursday)

CEUs: 2.25

$1,695 (ASME Member)/$1,850 (Non–Member)

Early Bird discounts available

Description

This course will teach the basic aseptic fill and finish theory for biopharmaceuticals. It will cover typical unit operation for aseptic fill and finish, associated equipment design, various operational consideration, related facility and regulatory compliance issues. The course will discuss some key operations, such as sterilization, filling and lyophilization, etc. Other considerations related aseptic filling and finishing operation, such as HVAC design, environmental monitoring and control and process analytical technology will also be reviewed. The course will also discuss technology trend such as barrier isolator technology and their impact on the facility design and daily operation.

What You Will Learn

- Basic theory behind the aseptic fill and finish unit operation
- Typical unit operations associated with aseptic filling and finish operation
- HVAC and facility design consideration for a parental fill and finish facility
- Common design concerns associated with fill and finish equipment
- Environmental monitoring, process validation and case study for aseptic fill
- Regulatory compliance and case study from FDA inspection
- Network with industry peers, share knowledge and experience

Who Should Attend

This course should be useful for process engineers, formulation scientists, validation engineers, project managers, manufacturing technicians, or chemists with 0–4 yrs of experience in process development, research, engineering, validation, manufacturing, etc.

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Overview of Fill and Finish Operations
Douglas Stockdale, President, Stockdale Associates, Inc

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
Cold Chain Management
Douglas Stockdale, President, Stockdale Associates, Inc

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Design of Parental Fill and Finish Facility
Wei Huang, Director of Process, Engineering, Fluor Corp.

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:30 pm
Isolator and Barrier Technology
Wei Huang, Director of Process, Engineering, Fluor Corp.

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Wednesday, October 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
HVAC Design Consideration for Fill and Finish Facility I
Manuel Del Valle, Technical Director, Fluor Corp.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
HVAC Design Consideration for Fill and Finish Facility II
Manuel Del Valle, Technical Director, Fluor Corp.

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Environmental Monitoring and Control I
Steve Chew, Manager, Baxter

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Environmental Monitoring and Control II
Steve Chew, Manager, Baxter

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am –10:00 am
Lyophilization Technology
Dr. Michael Pikal, Professor, University of Connecticut

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Lyophilization Technology
Dr. Michael Pikal, Professor, University of Connecticut

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Sterilization Technology for Aseptic Filling Operation

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Regulatory Compliance for Filling Operation, FDA Perspective
Paula Trost, FDA Inspector, FDA

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioreactor Process Technology

PD315

Course dates: October 23 – 26, 2006 (Monday – Thursday)

CEUs: 3.00

$2,105 (ASME member)/$2,260 (Non–member)
Early Bird discounts available

Description

The fundamental principles involved in the engineering of cellular systems for large–scale production of active proteins and stem cells are presented to familiarize engineers and life scientists with factors activating and limiting their bioreactor systems. Participants will become familiar with the characteristics of proteins, cellular metabolism and physiology as they impact bioreactor development, design and operation. Critical comparisons among mammalian and other culture systems for extensively discusses bioreactor development, selection and design, monitoring and control, and large–scale operational issues. Relationship between large scale bioreactor cell culture and other aspects of production, facility and regulatory compliance are discussed.

What You Will Learn

- Importance of cell culture derived biopharmaceuticals
- Role of molecular biology in the production of biopharmaceuticals
- Bioreactor design and production of biopharmaceuticals
- Bioreactor cell culture as it relates to other aspects of producing a biopharmaceutical; purification, final formulation, facility, clinical development, regulatory compliance

Who Should Attend

Engineers and Scientists who are involved with biopharmaceuticals derived from cell culture and who are part of research, development, production, quality control, quality assurance, regulatory affairs and clinical development will benefit from this course.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open – Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Biopharmaceuticals Derived from Bioreactor Processes, *Ashot Petrossian, GXP Consultants*

10:00 am – 10:30 am Refreshment Break

10:30 am – Noon
Expression of Biopharmaceuticals in Mammalian Cells – Vectors and Host Cells
Arnold H. Horwitz, XOMA (US) LLC

Noon – 1:00 pm Lunch

1:00 pm – 2:30 pm
Improving Expression of Biopharmaceuticals in Mammalian Cells – Industrial Examples
Arnold H. Horwitz, XOMA (US) LLC

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:30 pm
Laboratory Scale Cell Culture Biotechnology
Ashot Petrossian, GXP Consultants

4:30 pm – 5:30 pm KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Mammalian Cell Culture in the Production Scale Bioreactor, *Tom Keuer, Insmed*

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Mammalian Cell Culture in the Production Scale Bioreactor, *Tom Keuer, Insmed*

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Mammalian Cell Culture in the Production Scale Bioreactor, *Joseph Kauten, Lonza Biologics Inc.*

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Mammalian Cell Culture in the Production Scale Bioreactor, *Joseph Kauten, Lonza Biologics Inc.*

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Aseptic Fill/Finish of Biopharmaceuticals
Douglas Stockdale, President, Stockdale Associates, Inc.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Aseptic Fill/Finish of Biopharmaceuticals
Douglas Stockdale, President, Stockdale Associates, Inc.

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Bioreactor Engineering – Mass Transfer, Heat Transfer and Agitation Design
David Marks, DME Alliance Inc.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Bioreactor Engineering – Equipment Design, Instrumentation and Control Design
David Marks, DME Alliance Inc.

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Regulatory Aspects of Biopharmaceutical Product Development, *Paula Trost, USFDA*

10:00 am – 10:30 am Refreshment Break

10:30 am – Noon
Regulatory Aspects of Biopharmaceutical Product Development, *Paula Trost, USFDA*

Noon – 1:00 pm Lunch

1:00 pm – 2:30 pm
Regulatory Aspects of Biopharmaceutical Product Development, *Ash Ramzan, Woodley BioReg Limited*

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:00 pm
Biopharmaceutical Product Development Workshop, *All Instructors*

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioprocessing Equipment Design

PD317

Course dates: October 23 – 26, 2006 (Monday – Thursday)

CEUs: 3.00

$2,105 (ASME member)/$2,260 (Non–member)
Early Bird discounts available

Description

A comprehensive review of the factors that influence the selection, design, specification and placement of bioprocessing equipment. Topics will include: upstream and downstream processing equipment design, cleaning and sanitization, validation and commissioning and an introduction to facility design. Regulatory compliance and biocontainment considerations will be discussed. The program comprises 3 hands–on interactive workshops. The courses are presented by owner/users who have real life experiences to share with their audience.

What You Will Learn

- To apply the information presented in a Process Flow Diagram into a Bioprocessing Facility Design
- The recent trends in Bioprocessing Technology
- Procurement: How to specify. What to look for. The FAT.
- Cleaning and Sanitization Considerations.

Who Should Attend

Engineers, scientists, and other personnel involved in the design of bioprocessing equipment including suppliers, end–users, contracts and component suppliers. Those involved in operation and maintenance will find that the course provides an excellent introductory overview of equipment and system design. This basic program will introduce those whom are about to design a cGMP bioprocessing suite or facility to the design process.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open – Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 9:15 am
Course Introduction – Project Description
Marc Pelletier, MPP

9:15 am – 10:00 am
Cell Culture and Fermentation
Wayne Herber, Merck

10:00 am – 10:30 am Refreshment Break

10:30 am – 11:15 am
Downstream Processing Equipment
Robert Barloga, Alfa Laval; Robert Conway, CUNO

11:15 am – Noon
Vessel Design, *Mark Herr, Stainless Technology*

Noon – 1:00 pm Lunch

1:00 pm – 1:45 pm
Bioreactor Specification and Design
Paul Kubera, Abec

1:45 pm – 2:30 pm
Instrumentation and Automation of Bioprocess Systems, *Tom Warf, LifeTek Solutions*

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:30 pm
Bioreactor Design Workshop
Marc Pelletier, MPP; Tom Warf, LifeTek Solutions

4:30 pm – 5:30 pm KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 9:30 am
Engineering for Cleaning–In–Place
Alan Powell, Merck

9:30 am – 10:00 am
Engineering for Sterilization
Tom Warf, LifeTek Solutions

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – 11:00 am
Engineering for Sterilization (continued)

11:00 am – Noon
System Infrastructure Design Considerations
Marc Pelletier, MPP

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
CIP/SIP Workshop
Tom Warf, LifeTek Solutions; Alan Powell, Merck

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm CIP/SIP Workshop

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 9:15 am
Design and Development of Biopharm Pilot Plant Facilities, *Michelle Gonzalez, Amgen*

9:15 am – 10:00 am
Bioprocess Equipment Design & Specification Overview, *Michelle Gonzalez, Amgen*

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Validation/Commissioning & Integration of the Design Process, *Marc Pelletier, MPP*

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Bioprocess Design Workshop
Marc Pelletier, MPP; Michelle Gonzalez, Amgen

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:30 pm
Bioprocess Design Workshop (continued)

Thursday, October, 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 9:15 am
Regulatory Compliance & Design implication of Multiproduct Facilities, *Michelle Gonzalez, Amgen*

9:15 am – 10:00 am
Single Use Systems in the BioPharmaceutical Industry
Tom Warf; Michelle Gonzalez; Marc Pelletier

10:00 am – 10:30 am Refreshment Break

10:30 am – Noon
Open Forum – Case Studies
Marc Pelletier, Michelle Gonzalez

Noon – 1:00 pm Lunch

1:00 pm – 4:00 pm
Facilities Design Workshop

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioprocess Fermentation & Cell Culture Design & Scale–Up

PD360

Course dates: October 23 – 26, 2006
(Monday – Thursday)

CEUs: 3.00
$2,105 (ASME member)
$2,260 (Non–member)
Early Bird discounts available

Description

This course will cover fermentation / cell culture basic theory, various scale–up and scale–down strategies, related equipment / facility design and regulatory compliance issues. The course reviews some key considerations during fermentation and cell culture scale–up, such as oxygen transfer, power input, agitator and impeller design, environmental control, SIP/CIP. The course will also compare different scale up methodologies, as well as how to use process simulation as a viable tool to assist scale–up. Topics such as bioprocess design as it relates to the different stages of clinical development, regulatory compliance during scale–up, and the integration of large–scale fermentation and cell culture process design with facility design will also be discussed. Case studies are embedded into the course materials, followed by a half day work shop which will allow attendees to form project teams and to apply knowledge from the class directly to simulated process design and scale–up projects.

What You Will Learn

- Identify when to initiate fermentation and cell culture scale–up during the various pre–clinical and clinical phases
- How to scale–up fermentation and cell culture processes during different clinical and commercial stages
- How to establish a basis for comparability during scale–up, including how to apply scale–down systems
- Fermentor and bioreactor design and scale–up
- Common design concerns with large scale fermentors and bioreactors
- How to use process simulation as tool for scale–up and capacity optimization
- How to integrate large scale fermentors and bioreactors with facility design
- Regulatory compliance and process validation for issues for large scale facilities
- Network with industry peers, share knowledge and experience

Who Should Attend

This course should be useful for process engineers, research and development scientists, validation engineers, project managers, manufacturing technicians, biologists, or chemists with 1–4 yrs of experience in process development, research, engineering, validation, manufacturing, etc.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open – Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Overview of Fermentation
Dr. Sy–Dar Wang, AdImmune

10:00 am – 10:30 am Refreshment Break

10:30 am – Noon
Overview of Cell Culture
Dr. Sy–Dar Wang, AdImmune

Noon – 1:00 pm Lunch

1:00 pm – 2:30 pm
Fermentation and Cell Culture Scale–up I
Dr. Sy–Dar Wang, AdImmune

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:30 pm
Fermentation and Cell Culture Scale–up II
Dr. Sy–Dar Wang, AdImmune

4:30 pm – 5:30 pm KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Process Options and Production Overview I
Dr. Steven Meier, Genentech

10:00 am – 10:30 am Break

10:30 am – Noon
Scale–up and Scale–down: Criteria and Strategies I, *Dr. Steven Meier, Genentech*

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Scale–up and Scale–down: Criteria and Strategies II, *Dr. Steven Meier, Genentech*

2:30 pm – 3:00 pm Break

3:00 pm – 4:30 pm
Fermentation and Cell Culture Scale–up Case Studies, *Dr. Steven Meier, Genentech*

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Continental Breakfast w/ Exhibitors

8:30 am –10:00 am
Agitator and Impeller Design for Fermenter and Bioreactor, *Paul Kubera, ABEC*

10:00 am – 10:30 am Break

10:30 am – Noon
Clinical Development and Scale–up Stages
Wei Huang, Fluor

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Scale–up and Facility Design
Wei Huang, Fluor

2:30 pm – 3:00 pm Break

3:00 pm – 4:30 pm
Process Simulation and Scale–up
Wei Huang, Fluor

Thursday, October, 26, 2006

7:30 am – 8:30 am Continental Breakfast

8:30 am – 10:00 am
Regulatory Compliance and Process Scale–Up

10:00 am – 10:30 am Break

10:30 am – Noon
Course Summary, *Wei Huang, Fluor*

Noon – 1:00 pm Lunch

1:00 pm – 2:30 pm
Group Workshop, Case Study
Wei Huang, Fluor

2:30 pm – 3:00 pm Break

3:00 pm – 4:00 pm
Case Study Review, *Wei Huang, Fluor*

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioprocess Technology Implementation

PD477

Course dates: October 23 – 26, 2006 (Monday – Thursday)

CEUs: 3.00

$2,105 (ASME member)/$2,260 (Non–member)
Early Bird discounts available

Description

This course will provide a comprehensive study of bioprocess technology implementation in GMP manufacturing facilities, as well as instruction on the latest trends, strategies and techniques that are employed by industry leaders to successfully execute time & resource limited projects in a regulated environment. Class discussion, workshop exercises and case studies will be employed to explore all aspects of equipment and facility delivery, including strategic planning, technology transfer, programming, bioprocess design, equipment sourcing, automation, construction, commissioning and validation.

What You Will Learn

- Understand and apply key techniques used by leading biologics manufacturers for process technology transfer and implementation.
- Learn industry best practices for the design and delivery of biopharmaceutical facilities and equipment.
- Evaluate the feasibility of new and renovated bioprocess manufacturing systems, and generate a realistic execution plan, cost and schedule to submit for capital approval.
- Apply proven techniques to successfully deliver bioprocess equipment while meeting production, compliance, budget, and schedule constraints.
- Participate in multiple discussions, case studies and workshops while networking with industry peers, sharing knowledge and experience.

Who Should Attend

This course is an essential resource for engineers, scientists and managers who are involved in bioprocess technology development, transfer and implementation via the design and delivery of biologics manufacturing facilities. Our informative and practical approach to bioprocess systems implementation will be especially useful to engineers, consultants, project suppliers and end users that are involved in the creation of new, expanded or renovated GMP facilities. Attendees should have a basic understanding of project management principles and bioprocess unit operations.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open – Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 9:00 am
Introduction & Class Orientation
David Marks, DME Alliance Inc.

9:00 am – 10:00 am
Implementing New Technologies for Bioprocess Manufacturing
Alexandros Fotopoulos, Biogen Idec

10:00 am – 10:30 am Refreshment Break

10:30 am – Noon
Bioprocessing Equipment Technology
David Marks, DME Alliance Inc.

Noon – 1:00 PM Lunch

1:00 pm – 2:30 pm
Bioprocess Automation Technology
Joel L. Hanson, Centocor

2:30 pm – 3:00 pm Refreshment Break

3:00 pm – 4:30 pm
Bioprocess Technology & GMP Facility Delivery – Lessons Learned, *Daniel T. Caparoni, Merck*

4:30 pm – 5:30 pm KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Bioprocess Technology Transfer
Alexandros Fotopoulos, Biogen Idec

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
The Future of Bioprocess Design – Technologies & Trends
Panel Discussion – (all instructors)

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Pilot Plant Delivery – Technology Implementation to Accommodate the Uncertain Process, *Joel L. Hanson, Centocor*

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Startup, Commissioning & Qualification of Bioprocess Facilities
Daniel T. Caparoni, Merck

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Continental Breakfast w/ Exhibitors

8:30 am –10:00 am
Bioprocess Equipment Sourcing Strategies
David Marks, DME Alliance Inc.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Strategic Planning and Conceptual Design for Biopharmaceutical Facilities
Leon Gordon, DME Alliance Inc.

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Workshop – Strategic Planning and Conceptual Design for Biopharmaceutical Facilities, *Leon Gordon, DME Alliance Inc.*

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Workshop – Strategic Planning and Conceptual Design for Biopharmaceutical Facilities (continued)

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Capital Project Execution – Implementing Progress & Performance Measurement Systems, *James L. Whitman, Wyeth*

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
Project Delivery Systems for Bioprocess Manufacturing Facilities
James L. Whitman, Wyeth

Noon – 1:00 pm
Lunch / Course Concludes

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bio–Downstream Process Design & Economics

PD481

Course Dates: October 23 – 26, 2006 (Monday – Thursday)

CEUs: 3.00

$2,105 (ASME member)/$2,260 (Non–member)
Early Bird discounts available

Description

Bio–downstream process design is taught considering the "big picture" including process optimization, economics and the bio–product requirements for FDA approval and customer satisfaction. Chromatographic and membrane separation technologies are highlighted with other important pre– and post– processing unit operations examined. Finally, the total bio–downstream process is studied utilizing simulation strategies to explore individual component compatibility to achieve the desired bioprocess results.

Who Should Attend

Anyone involved with bio–product production, including basic scientists, engineers, business, marketing and legal experts, would benefit from a better understanding of complexities of assembling a bio–downstream process to produce an efficacious bio–product that can meet all federal guidelines.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open – Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 8:45 am
Course Introduction & Overview
Duane Bruley, UMBC

8:45 am – 10:00 am
Analytical Methods/ Centrifugation/ Sedimentation
Roger Harrison, University of Oklahoma

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
Centrifugation/ Sedimentation
Paul Todd, Space Hardware Optimization Technology, Inc.

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Precipitation/ Crystallization
Paul Todd, Space Hardware Optimization Technology, Inc.

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:30 pm
Drying
Roger Harrison, University of Oklahoma

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Introduction to Normal Flow Filtration
John Cyganowski, Millipore Corp.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Membrane Separation System Design
John Cyganowski, Millipore Corp.

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Filtration & Validation
John Cyganowski, Millipore Corp.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Membrane/Filtration Scale–Up
John Cyganowski, Millipore Corp.

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am –10:00 am
Introduction to Chromatography
Jim Neville, Millipore Corp.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Chromatography Modalities
Jim Neville, Millipore Corp.

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Chromatography Process Design
Jim Neville, Millipore Corp.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Emerging Technologies & Economics
Duane Bruley, UMBC

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am –10:00 am
Intellectual Property Patents for Bioprocesses
Cheryl Agris, Ph.D., Attorney at Law

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
FDA Validation of Bioprocesses
Cheryl Agris, Ph.D., Attorney at Law

Noon – 1:00 pm Lunch

1:00 pm – 2:30 pm
Computer–Aided Bioprocess Design, Cost Analysis, & Optimization
Demetri Petrides, Intelligen, Inc.

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:00 pm
Scheduling & De–bottlenecking of Multi–Product Biopharmaceutical Facilities: Industrial Case Studies
Demetri Petrides, Intelligen, Inc.

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioprocess Purification Process Delelopment

PD482

Course dates: October 24 – 26, 2006 (Tuesday – Thursday)

CEUs: 2.25

$1,695 (ASME Member)/$1,850 (Non–Member)
Early Bird discounts available

Description

This course is designed to give the participant a basic understanding of key issues in designing and implementing a purification process for the production of a biopharmaceutical material. Scale–up of chromatographic and filtration operations will be discussed in detail with attention validation issues. Process scenarios for recombinant proteins and antibodies will be used to further the basic concepts.

What You Will Learn

- Understand and apply basic scale parameters in chromatography and filtration.
- Understand the basics of validation and how they impact process design.
- Process requirements and analytical techniques used to judge quality in manufacturing.

Who Should Attend

This course is intended for professionals involved in the design, scale–up and operation of bioprocess systems. Materials presented in this course will be of benefit to process, project and manufacturing engineers and scientists entering the field or requiring further background in specific separation technologies.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open. Avoid the lines on Monday.

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Basic Concepts in Chromatography
Alan Williams, GE Healthcare

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Critical Aspects of Chromatographic Process Design, *Alan Williams, GE Healthcare*

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Process Design I: Membrane Process
Yujing Yang, GE Healthcare

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Process Design I: Membrane Process (continued)
Yujing Yang, GE Healthcare

Wednesday, October 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Production Scenario I: Antibody Production Process, *Tamas Blandl, Abgenix*

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Cleaning and Bio–burden
Gail Sofer, GE Healthcare

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Analytical Responsibilities
Gail Sofer, GE Healthcare

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Scale Down Modeling and Determination of Media Lifetime
TBD

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Process Design II
Tim Breece, Genentech

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
Process Design II
Tim Breece, Genentech

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Validation in the Plant
Lisa Gonzales, GE Healthcare

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:00 pm
Industrial Scale Column Packing
Alan Williams, GE Healthcare

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

ASME Emerging Technology Events

Frontiers in Biomedical Devices
June 8-9, 2006
Irvine, California
www.asmeconferences.org/nanobio06

The Fourth International Conference on Fuel Cell Science, Engineering & Technology
June 19-21, 2006
Irvine, California
www.asmeconferences.org/fuelcell06

The Fourth International Conference on Nanochannels, Microchannels & Minichannels
June 19-21, 2006
Stokes Research Institute - University of Limerick, Limerick, Ireland
www.asmeconferences.org/ICNMM06

. . . . and many more!
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REGISTER NOW. Call 800–843–2763 or www.asmeconferences.org/bioprocess06

Cleaning Practices: Practical Implementation of CIP for Success

PD483

Course dates: October 24 – 26, 2006 (Tuesday – Thursday)

CEUs: 2.25

$1,695 (ASME Member)/$1,850 (Non–Member)
Early Bird discounts available

Enrollment limit:

Description

In critical Bioprocessing and containment environments, Clean–In–Place (CIP) technology is an increasingly vital part of our manufacturing facilities and systems. Application of CIP equipment and systems without consideration of a number of critical factors, and consideration of the processes as a whole, can negatively affect plant functionality and flexibility, despite incorporation of the latest technology. This course will establish fundamental concepts of cleaning mechanisms & chemistry, CIP skid design, distribution systems, equipment design for CIP along with in–depth cleaning validation guidance and regulatory considerations.

What You Will Learn

- Understand and apply basics of cleaning mechanisms and chemistries for soil removal.
- CIP system design for various skid and distribution system configurations.
- Equipment design principles for effective CIP.
- Cleaning validation principles and practices of cleaning validation.

Who Should Attend

This course is intended for professionals involved in the design, operation and validation of bioprocess systems that require a high degree of sanitation. Materials presented in the course will be of benefit to process, project, facilities and validation engineers, technicians, manufacturing managers and supervisors, quality assurance scientists and regulatory personnel.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open. Avoid the lines on Monday.

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 9:00 am
Regulatory & Business Context
Paul Woitach, Solutia Pharmaceutical Advisors

9:00 am – 10:00 am
CIP 101
Daniel Dobrez, Dober Group

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Principles of CIP–Cleaning Mechanisms
Daniel Dobrez, Dober Group

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
CIP and Regulatory Compliance
Rebecca Brewer, Dober Group

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
CIP System Design–Skids
Daniel Dobrez, Dober Group

Wednesday, October 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Spray Devices and Vessel Cleaning
Daniel Dobrez, Dober Group

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
CIP Fundamentals for Piping Systems
Ryan Schroeder, CRB

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
CIP System Design– Distribution
Ryan Schroeder, CRB

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Qualification and Cleaning Validation – Part 1
Rebecca Brewer, Dober Group

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open / Continental Breakfast

8:30 am – 10:00 am
Qualification and Cleaning Validation – Part 2
Rebecca Brewer, Dober Group

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
In Process Control and Quality
Rebecca Brewer, Dober Group

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Equipment Design for CIP–Bioreactors
Ryan Schroeder, CRB

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:00 pm
Integrating CIP into Complex Manufacturing Sequences
Ryan Schroeder, CRB

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Validation of Biopharmaceutical Facilities & Processes

PD485

Course dates: October 23 – 25, 2006 (Monday – Wednesday)
CEUs: 2.25
$1,695 (ASME Member)/$1,850 (Non–Member)
Early Bird discounts available

Description

Validation of facilities, equipment and critical process steps utilized for the manufacture of biological products is required in order to comply with regulatory requirements from government agencies such as the US Food and Drug Administration. The design and execution of an adequate validation program will assure that the facilities used in manufacturing are appropriately established and maintained conforming to design specifications and the production process is under an appropriate state of control. These elements represent a key contribution to assuring the final quality of the biological product manufactured.

This course presents a detailed discussion of the approaches that a biopharmaceutical company can take in order to implement a validation program that will achieve the ultimate goal of complying with the regulatory requirements for validation in an evolving environment. Examples from real case situations will be used to demonstrate such approaches and to guide participants through lessons learned by experienced practitioners.
This is an advanced level course.

What You Will Learn

- An integrated view of the validation efforts required of a biopharmaceutical manufacturer
- Workable approaches for implementing a validation program
- Examples of Validation Master Plan and validation protocol preparation
- The latest trends in FDA regulatory requirements and their relationship to validation
- Strategic thinking skills toward the validation exercises
- How to ask the right questions during validation

Who Should Attend

This course is intended for individuals who are involved with manufacturing, quality functions, engineering, validation, and process development for biological products. Such individuals can be involved with the design and construction of a biopharmaceutical facility, the development, operation, and validation of a bio–manufacturing process, or preparation for licensure.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open; Avoid the lines on Monday

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Principles of Validation
Antonio Moreira, UMBC, SPI USA, Inc.

10:00 am – 10:30 am
Refreshment Break

10:30 am – 12:00 noon
Validation Master Plan
Alison Demarest, Bioreliance, Invitrogen Bioservices

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Preparation of Validation Documents and Protocols
Alison Demarest, Bioreliance, Invitrogen Bioservices

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:30 pm
Facilities Validation: HVAC Systems
Marta Murray, Cambrex Bio Science Baltimore, Inc.

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Facilities Validation: High Purity Water Systems
Rich Yeaton, East Coast Validation Services, LLC

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – 11:15 am
Validation Issues with Disposable Equipment
Antonio Moreira, UMBC, SPI USA, Inc.

11:15 am – Noon
Case Study on Part 11 Compliance
Rich Yeaton, East Coast Validation Services, LLC

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Validation of Bioprocessing Equipment
Antonio Moreira, UMBC, SPI USA, Inc.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Validation of Steam Sterilization Processes
Rich Yeaton, East Coast Validation Services, LLC

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Validation of Bioprocesses
Antonio Moreira, UMBC, SPI USA, Inc.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – 12:00 noon
Cleaning Validation
Marta Murray, Cambrex Bio Science Baltimore, Inc.

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Validation of Removal of Process Contaminants
Antonio Moreira, UMBC, SPI USA, Inc.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:00 pm
Re–Validation Strategies
Alison Demarest, Bioreliance, Invitrogen Bioservices

Thursday, October 26, 2006

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Bioreactor & Fermentor Design

PD519
Course dates: October 24 – 26, 2006
(Tuesday – Thursday)
CEUs: 2.25
$1,695 (ASME Member)/$1,850 (Non–Member)
Early Bird discounts available

Description

Bioreactors and fermenters lie at the heart of systems used to produce both large and small–molecule therapeutics. These reactors must produce an environment that is conducive to and optimizes the growth and productivity of microorganisms ranging from fragile cells to robust bacteria.

This course provides a detailed review of the factors that contribute to successful design and operation of cGMP reactors. Bioprocess, unit operation, hardware design and process automation fundamentals will be presented individually and then brought together in case study and workshop format, illustrating key concepts.

What You Will Learn

- How to define bioprocess requirements.
- Inter–relationships between vessel geometry and agitator mass transfer, heat transfer and blending capability.
- Vessel and hardware design features and their impact on aseptic performance.
- Instrument and automation approaches for control and GMP compliance.
- Integration of CIP/SIP into the reactor process.

Who Should Attend

Engineers, scientists and production personnel involved in the design of bioreactors and fermenters, including component and system suppliers, end–users and engineering design firms. Operations personnel can gain an improved understanding of reactor and ancillary equipment capability and operating strategies.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open. Avoid the lines on Monday.

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

4:30 pm – 5:30 pm
KEYNOTE
5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 8:45 am
Course Introduction
Paul Kubera, ABEC

8:45 am – 10:00 am
Cell Culture & Fermentation
Dr. Wayne Herber, Merck

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – 12:00 noon
Agitator Selection
Paul Kubera, ABEC

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Bioreactor Instrumentation and Control Loops
Jeffrey Hamilton, ABEC

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Vessel Design for Bioprocessing
Mark Herr, Stainless Technology

Wednesday, October 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 9:00 am
Orbital Welding
Barbara Henon, Arc Machines

9:00 am – 10:00 am
Controls and GMP Compliance
Thomas Warf, LifeTek Solutions

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – 12:00 noon
Drain, Sample & Isolation Valves
John Vitti, Saunders Biopharm

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 1:45 pm
Agitator Mechanical Seals
Paul Kubera, ABEC

1:45 pm – 2:30 pm
Reactor Design Workshop
Paul Kubera, ABEC

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Reactor Design Workshop (continued)
Paul Kubera, ABEC

Thursday, October 26, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Engineering for Cleaning–In–Place
Alan Powell, Merck

10:00 am – 10:30 am
Refreshment Break

10:30 am – 11:15 am
Engineering for Sterilization
Thomas Warf, LifeTek Solutions

11:15 am – Noon
Reactor Design "Rules of Thumb"
Thomas Warf, LifeTek Solutions

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Workshop: Integrated Design of CIP/SIP for Bioreactors and Fermenters
Alan Powell, Merck

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:00 pm
Workshop: Integrated Design of CIP/SIP for Bioreactors and Fermenters (continued)
Alan Powell, Merck

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Metallic Materials of Construction for Hygienic Services: Fabrication, Finishing & Corrosion

PD569

Course dates: October 23 – 25, 2006 (Monday – Wednesday)

CEUs: 2.25

$1,695 (ASME Member)/$1,850 (Non–Member)
Early Bird discounts available

Description

Critical details of materials selection and fabrication techniques for hygienic systems will be addressed by industry experts. The focus will be the drainability and cleanability requirements imposed by the ASME Bioprocessing Equipment (BPE) Standard. Topics such as the effect of melting practice on inclusion removal during electropolishing, the practice of and the oxide films produced by electropolishing, a comparison of the surface oxides produced by various passivation technologies, and the response of discolored welds to standardized corrosion tests will be discussed.

What You Will Learn

- Why some materials are more difficult to electropolish than others
- Exactly what a surface finish measurement of 20 Ra means
- That discoloration from welding degrades the corrosion resistance of the HAZ of 316L stainless steel
- How to prevent internal heat–affected zone (HAZ) discoloration during welding of stainless steel tubing
- Under what conditions European materials can be used to build tubing/piping systems to the requirements of the ASME BPE Standard
- How electropolishing changes the surface chemistry and topography of metallic materials
- Technologies which are available to passivate the surface of stainless steels
- The general content of the ASME BPE Standard, including the new part, currently being developed, which addresses materials characteristics, "Metallic Materials of Construction"

Who Should Attend

This is an advanced course for those experienced in the fabrication and inspection of hygienic systems. It is geared for design engineers, project managers, process engineers, manufacturing engineers and technicians, and fabricators with experience in and responsibility for materials selection, project management, fabrication, inspection, etc.

Schedule

Sunday, October 22, 2006

5:00 pm – 8:30 pm
Registration Open. Avoid the lines on Monday.

Monday, October 23, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast

8:30 am – 10:00 am
Overview of ASME Bioprocessing Equipment (BPE) Standard, Introducing the New Metallic Materials of Construction (MMOC) Part
Paul L. Sturgill, Purity Systems

10:00 am – 10:30 am
Refreshment Break

10:30 am – Noon
Alloy Selection and Product Form Usage in Hygienic Systems
Dr. Hira Ahluwalia, Evans Analytical Group

Noon – 1:00 pm
Lunch

1:00 pm – 2:30 pm
Melting Technologies for Corrosion Resistant Alloys and Influence on Microstructure and Surface Characteristics
Dr. Hira Ahluwalia, Evans Analytical Group

2:30 pm – 3:00 pm
Refreshment Break

3:00 pm – 4:30 pm
The Parameters and Technology of Surface Finish Measurement
Dr. Mark Malburg, Digital Metrology Solutions, Inc.

4:30 pm – 5:30 pm
KEYNOTE

5:30 pm – 7:00 pm
Opening Reception w/ Exhibitors

Tuesday, October 24, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
High–Purity Welding in the Biotechnology and Pharmaceutical Industries
Dr. Richard D. Campbell, Purity Systems, Inc.

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Electropolishing of Stainless Steels and Nickel Alloys used in Hygienic Systems
Dr. Gad Elkabir, EGMO Ltd.

Noon – 1:00 pm
Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Techniques for Measuring the Thickness and Composition of Surface Films on Stainless Steels
Dr. Gad Elkabir, EGMO Ltd.

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Passivation Technologies
Dr. Sunniva R. Collins, Swagelok

Wednesday, October, 25, 2006

7:30 am – 8:30 am
Registration Desk Open; Continental Breakfast w/ Exhibitors

8:30 am – 10:00 am
Ferrite Levels in Cast Austenitic Stainless Steels and Rouging in Hygienic Systems
Paul L. Sturgill, Purity Systems

10:00 am – 10:30 am
Refreshment Break w/ Exhibitors

10:30 am – Noon
Weld Discoloration and Corrosion of 316L in Pharmaceutical Systems – Findings of the ASME BPE Materials Joining Subcommittee
Dr. Richard D. Campbell, Purity Systems

Noon – 1:00 pm Lunch w/ Exhibitors

1:00 pm – 2:30 pm
Common Corrosion Failures in 316L Tubing for Biopharm Applications
Dr. Sunniva R. Collins, Swagelok

2:30 pm – 3:00 pm
Refreshment Break w/ Exhibitors

3:00 pm – 4:30 pm
Case Histories and Panel Discussion of Corrosion in Hygienic Systems
Dr. Richard D. Campbell, Dr. Sunniva R. Collins, Dr. Hira Ahluwalia, & Paul L. Sturgill

Thursday, October 26, 2006

4:00 pm – 5:30 pm
PLANT TOUR: NRC– BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Friday, October 27, 2006

9:00 am – 10:30 am
PLANT TOUR: NRC–BRI Bioprocess Plant – 50 Maximum (Advance sign–up required)

Registration and Confirmation Letter

You can register on-line through our secure server or you can call Customer Service at 800-843-2763. To guarantee your registration, ***payment must be received prior to the start of the seminar.*** ASME confirms every seminar registration in writing. If confirmation letter is not received, contact Sharon Albert at 212-591-8132.

Discounts

Early bird discounts:
15% off until July 1, 2006
10% off July 2 - August 2, 2006
Regular course fees apply after August 2, 2006

Team Discounts:
Send 3 people to the SAME course & save 5%. Teams must register at the SAME time.

Hotel information

The Seminars will be held at the Hyatt Regency Montreal.
ASME has a block of sleeping rooms reserved at a special group rate of $179/single or $199/double. The room block and group rates are available through September 29, 2006. After that, current hotel rate is applied and rooms are not guaranteed. For reservations, please call the hotel directly at (514) 982-1234. Room blocks fill quickly. We recommend that you reserve your room early. For more details,
visit our website at www.asmeconferences.org/bioprocess06

Changes to Course Schedules/Cancellations

Updates on course schedules and/or cancellations will be sent to registrants 3 weeks before the event (or sooner). ***ASME retains the right to cancel a course up until 3 weeks of the scheduled event.***

ASME is not responsible for the purchase of non-refundable airline tickets or the cancellation/change fees associated with canceling a flight.

Continuing Education Units (CEUs)

One CEU is awarded for every 10 hours of classroom time. ASME is a member of the International Association for Continuing Education & Training (IACET). You must be present for the entire length of the course to earn a CEU certificate. You must fill out a form on-site indicating that you would like to receive a certificate. Certificates will be mailed one-week after your course has concluded.

Table-Top Exhibit Space & Sponsorships are Available!

Showcase your company's products and services to a captive audience of bioprocess attendees. Reserve your space early. Space is limited. To download the exhibitor application, go to: www.asmeconferences.org/bioprocess06

Exhibiting companies at last year's event included:

- Anderson Instrument
- Applikon Biotechnology
- Aquasyn
- ASEPCO
- Bioengineering AG
- BioPharm International
- BioProcess International
- Biorad
- Broadley James Corp.
- C-Flex
- Commissioning Agents, Inc.
- CUNO, Inc.
- DME Alliance
- Fluid Line Technology
- GEA Westfalia
- Hylok
- ITT Industries Pure-Flo Solutions Group
- Millipore Corp.
- Modentic
- NovAseptic America
- optek-Danulat
- Pall Corporation
- Westfalia Separator
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