ASEPTIC PROCESSING IN THE
MANUFACTURE OF BIOTECH
AND PHARMACEUTICAL
PRODUCTS™

COURSE DIRECTOR: PAUL LAROCQUE

July 24-25, 2017
Malvern, PA

COURSE DESCRIPTION

Whether for biopharmaceutical or pharmaceutical applications, this course presents the technical basics that govern aseptic processing and provides practical advice for attendees to troubleshoot and manage their aseptic operations. Attendees from the sterile medical device industry have also benefited from this training.

Although, the course emphasizes industrial microbiology, various types of sterilization, and facility design fundamentals, these subjects are presented in the context of regulatory compliance, Good Manufacturing Practice, and FDA/international current thinking.

Please be aware that this course is designed to address aseptic filling common to biotech and pharmaceutical products. It does not address formulation development, cell culture, fermentation, preparative separations, or similar upstream or downstream processes.

PAYMENT
$2150.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT
If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS
Contact us at 610-648-7550 or info@cfpie.com for additional discounts on multiple registrations.

CANCELLATION POLICY
All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses
Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CFPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CFPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CFPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 128
Malvern, Pennsylvania 19355

http://www.CfPIE.com

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INSTRUCTOR CREDENTIALS
Paul Larocque is the President of Acerna Inc., a pharmaceutical, biological and medical device consultancy which provides good manufacturing practice and regulatory affairs services to a global clientele. For the past twelve years as a consultant, and previously in industry, Paul’s focus was FDA compliance matters.

Previously, Paul held executive positions related to sterile products with Pfizer, SmithKline/Allergan and Eldan Pharmaceuticals. He also headed the unit responsible for the review of the chemistry and manufacturing parts of drug submissions at Health Canada. In addition, he chaired the industry committee that negotiated the sterile products chapter of GMP regulations at Health Canada.

He received his Bachelor of Science degree in Chemistry from the University of Ottawa. Mr. Larocque is a Chartered Chemist in Ontario, a Member of the Chemical Institute of Canada and was chosen for the Governor General’s Study Group.

He was named a Fellow of The Organization for Professionals in Regulatory Affairs in Europe and has served on several trade association boards or committees; including a Chairmanship on the committee which negotiated Canadian GMP Guidelines. Mr. Larocque has twice been elected Chair of the Canadian Association of Professionals in Regulatory Affairs.

https://ca.linkedin.com/in/paul-larocque-9a2070b8

WHO SHOULD ATTEND
This is a two-day course for people who need to understand the technical fundamentals of aseptic processing or who are responsible for aseptic operations in a lab, pilot or commercial setting. The course is ideally suited to industrial microbiologists, scientists and engineers either with technical or managerial responsibilities in the biotechnology and pharmaceutical industries.

HOTEL INFORMATION
The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $132/night if booked 3 weeks in advance)

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $143/night if booked 3 weeks in advance of the course date)

FIRST DAY
Module 1
- Facility Design
- Grades A-D
- gowning
- crimping

Module 2
- Environmental Monitoring

Module 3
- Risk Management

Module 4
- Equipment
  - sanitary design
  - isolators
  - disposables
  - blow-fill-seal

Module 5
- Containers
  - vials stoppers seals
  - siliconization
  - manual & automatic visual inspection
  - pre-filled syringes

Module 6
- Package Integrity
  - leakage
  - sterility test
  - parametric release

SECOND DAY
Module 7
- Autoclaves
  - lethality, f0, & log reduction
  - types of cycles
  - validation

Module 8
- Depyrogenation

Module 9
- Radiation

Module 10
- Ethylene Oxide

Module 11
- Lyophilization

Module 12
- Spray Drying

Module 13
- Disinfectants and Antiseptics

Module 14
- Water & Pure Steam

Module 15
- Media Fills

Module 16
- Filtration
  - liquids & gases
  - validation