Contaminant Control

in the Manufacture of Drugs and Biologics

Frieder K. Hofmann, Ph.D.
Carl J. Wilson

San Diego, CA

To be announced

Proper control of contaminants in healthcare products is of the utmost importance because of the detrimental effect contaminants can have on the well-being of patients. All regulatory authorities carefully audit products, processes and facilities for appropriate prevention and removal of contaminants.

This course teaches proven, state-of-the-art methodologies and technologies for entry prevention, removal, inactivation and detection of all contaminant classes. Participants will get a solid understanding how individual methods and technologies work, how to apply them in their facilities and what the expectations of regulatory authorities are.

Course Content:

Contaminant Sources
- Product and Process Related Contaminants
- Adventitious Contaminants

Contaminant Classes
- Physical
  - Particles, Fibers
- Chemical
  - Byproducts, Leachables, Process and Cleaning Residues
- Biological
  - Contaminating Proteins, DNA, Microbes, Viruses, Pyrogens

Setting Specifications for Contaminants in Materials, Components, Equipment, Utilities and Product

Methods for Detecting Contaminants
- Product and Process Related Contaminants
  - Analytical Chromatography Methods, Immunoassays, Electrphoretic Methods
- Residues from Previously Manufactured Product
  - Sampling Techniques, Detection and Identification Methods
- Microbes
  - Sampling Methods, Sterility Assays, Test-Laboratory Requirements, Species Determination
- Viruses and Mycoplasma
  - Sampling, in vitro and in vivo Detection and Identification Methods
- Pyrogens
  - Sampling, USP-Rabbit Test, LAL-Test, Cell Culture Assay
- Particulates in Utilities, Environment and Product
  - Sampling Methods, Detection and Identification Methods

Strategies for the Manufacture of Contaminant-Free Product
- Controlling Materials, Equipment, Utilities and Environment

Methods for Removing and Inactivating Contaminants
- Product Purification
  - (Ion Exchange, HIC, Metal-Chelate, Affinity, SEC, and RP Chromatography; Filtration; "Open" Column Chromatography vs. HPLC)
- Virus Inactivation
- CIP, SIP and Depyrogenation of Equipment

Prevention of Contaminant Entry into Product and Process
- Qualification and Testing of Materials and Components
- Design and Validation of Equipment
- Design and Validation of Facility
- Training and Qualification of Personnel

Routine Monitoring for Contaminants
- QC Testing of Materials and Product Purity
- Monitoring of Equipment Cleanliness
- Environmental Monitoring
- Monitoring the Cleanliness and Health of Personnel
- Troubleshooting and Trend Analysis
- Handling of Out-of-Specification Results

Course Faculty:

Frieder K. Hofmann, Ph.D. is Principal Consultant of ProCon International, an internationally operating consulting firm that provides comprehensive technical, regulatory and managerial advice in all areas associated with GMP-conforming pharmaceutical and biopharmaceutical manufacturing, product and process development, process engineering, validation, and facility design. For the past nine years Frieder has worked as a technical, regulatory and quality systems consultant for both small start-up pharmaceutical and biopharmaceutical companies and multinational pharmaceutical concerns in the U.S., Europe and Japan.

Until 1990 he was for seven years Technical Director for BioTechnetics, San Diego, CA where his responsibilities included molecular and cell biology, process development and GMP-conforming production scaleup of numerous cell-expressed proteins. Previous positions included European applications manager for a membrane manufacturer where he invented and developed a patented automated upstream integrity tester for filters and three years of work in applied physics for the German pharmaceutical concern Hoechst A.G.

Frieder earned his M.S. and Ph.D. degrees in microbiology and biochemistry at J.W. Goethe University in Frankfurt, Germany. Among others, he is a member of the American Institute of Chemical Engineers, the European Society for Animal Cell Technology, the American Society for Quality Control, the Regulatory Affairs Professional Society and the PDA. He was presented the Parenteral Science and Technology Journal Award 1985 by PDA and was awarded six patents.

His previous employer received the prestigious Kirkpatrick Chemical Engineering Achievement Honor Award in 1989 for Frieder's bioproduction technology. Frieder published numerous articles and authored two book chapters on biopharmaceutical development. He is a frequent speaker and chairperson at national and international pharmaceutical and biotechnology conferences.

Carl J. Wilson is an independent consultant working internationally and providing services in the areas of Quality Assurance, Quality Control and Validation. For the past three years Carl has assisted biotechnology, medical device and international pharmaceutical companies operating in the United States, Hong Kong, Japan and Europe to develop Quality Systems to satisfy GMP, QSR and ISO requirements.

Areas of expertise include development of raw material and product specifications and corresponding analytical and microbiological testing programs, stability programs, calibration and maintenance programs and monitoring programs for water systems, cleanrooms and utilities. He also has extensive experience auditing manufacturing/fill/finish facilities, product testing laboratories and distribution operations.

Prior to 1995, Carl managed Quality Control departments at Cytel Corporation and Invitrogen in San Diego. At Cytel, his responsibilities included development of programs for raw materials qualification, analytical methods transfer and validation and oversight of animal and microbiological safety testing for sterile injectable therapeutic antibodies, carbohydrates and peptides. At Invitrogen he was responsible for developing systems for qualification and stability testing of critical raw materials and kits developed to assist researchers in the field of molecular biology.

Carl received his B.A. and M.A. degrees in biology and microbiology at California State University. In 1984 his graduate research project placed first in the Southern California Graduate Student Colloquium sponsored by the American Society for Microbiology. He is currently a member of the American Society for Microbiology, PDA and ISPE.

You will profit from this course, if you belong to

Quality Assurance/Control, Process Development, Manufacturing; Facility Design or GMP Compliance or if you are involved in CMC submissions to regulatory authorities.

Venue:

To be announced

When making your hotel reservation, please mention the **Center for Continuous Education** to receive the **special group rate!**

Course Schedule:

Each Course Day:
8:00 a.m. to 4:00 p.m.

Fee Schedule:

$1,695 for early payment
$1,795 for payment received by closing date
$1,895 for payment received after closing date

To assure your participation, REGISTER EARLY!

For Registration…

we only need your **name**, **affiliation**, **postal address**, and **phone** and **fax numbers** together with the **course title.** You can **call, fax** or **e-mail** us the information or you can register through our **web site**.

Center for Continuous Education
Providing High-Quality Professional Advancement Courses
1773 Kings Road
Vista, CA 92084-3640, USA
1-760-941-2040 or 1-800-698-2040
1-760-631-3893 (Fax)
www.cce-us.com registrar@cce-us.com

The Unavoidable Small Print!

The course fee includes a **comprehensive course book** containing the complete presentation material. It also covers **continental breakfast** and **refreshments** served in the course room and **lunch** on course days. Course participants will receive a **certificate** confirming 1.8 CEU's.

Course acceptance is based on a **first come, first served basis**. To hold your place as a confirmed participant, CCE must receive your **payment made with check or major credit card by the course closing date.** CCE must have received your payment at the latest 5 business days prior to course start.

90% of the paid fee is refundable, if participant cancels before the course closing date. 50% of the paid fee is refundable for cancellation received no6t later than two weeks prior to course start. **No refund** can be made for cancellation after that date. However, **confirmed participants may send a substitute participant at any time**.

CCE reserves the right to cancel the course or to replace faculty at any time. In case CCE needs to cancel the course, participants will receive a full refund of fees paid to CCE. CCE will not be responsible for any other costs incurred due to course cancellation.

Course participants and their companies agree to these terms by making their payment to CCE.

Please visit
www.cce-us.com
for comprehensive information on all CCE-courses