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Quality Critical Cleaning and Cleaning Validation Processes

October 16-18, 2017 | New Brunswick, NJ

Directed by: **Barbara Kanegsberg,** President, BFK Solutions, LLC and
Ed Kanegsberg, PhD, Vice President , BFK Solutions, LLC

Course Topics Include:

- Critical cleaning, contamination, contamination control basics
- Regulations (e.g. FDA) and compliance guidance
- Utilizing standards effectively
- Rational, risk-based acceptance levels
- Cleaning verification and process validation
- Managing the supply chain
- Effective use of cleanrooms/controlled environments
- Data management

course description

This 3-day accredited course teaches principles and practice of critical cleaning and cleaning validation in life-science applications. The emphasis is on medical devices (single use and reusable) and pharmaceutical applications. Critical product cleaning is distinct from sterilization. Failure to clean properly can pose risks in such applications as pharmaceuticals, medical devices, and food processing.

The program provides approaches to cGMPs for critical cleaning processes that integrate the factors of chemistry, equipment and process methods, and that also consider regulatory and economic issues. A successful cleaning process utilizes the 4Ds: define, develop, document, and defend. The course also addresses challenges and standards/guidance development for applications where residues are adherent or are difficult to access or detect. We encourage interaction during the course; and participants are encouraged to provide examples of "pain points" and nagging problems.

suggested reading

"Handbook for Critical Cleaning," 2nd edition, two volume set, B. Kanegsberg and E. Kanegsberg, ed, CRC Press, 2011, ISBN 9781439828267

This course offers the Virtual Attendee Option

SAVE $200-Register & Pay by September 4,

www.cfpa.com

who should attend

The course is intended for professionals in the development and manufacture of medical devices, pharmaceuticals, food products, and related fields. Disciplines include:

- Research and development
- Design/process engineering
- Safety/environmental
- Final assembly
- Contract manufacturing
- QA/validation

learning objectives

Upon completion of this course, you will be able to:

- Apply the principles of cleaning and contamination control to the product
- Appreciate the approaches to determine risk-based acceptable residue levels
- Describe when and how to employ controlled environments such as a cleanroom
- Anticipate and avoid cleaning failures
- Design reliable, consistent, defendable cleaning processes that can be readily validated
- Monitor and maintain the cleaning process
- Discuss regulatory (e.g. FDA) requirements, guidance, and expectations
- Set up, maintain, and monitor reliable supply chain relationships
- Properly implement industry standards (e.g. ASTM, ISO, AAMI)
- Select and monitor appropriate direct and extractive methods to detect contamination
- Select meaningful analytical techniques and work effectively with the analytical laboratory

course outline

First Day

8:00 a.m.: Registration/Continental Breakfast

8:30–9:00 a.m.:
Introductions
Course overview and objectives

9:00–10:00 a.m.: Expectations and regulatory issues
- What is cleaning?
- How is cleaning different from sterilization and disinfection?
- Regulatory concerns with cleaning

10:20–12:00 noon:
Basics of Critical Cleaning, Part 1
- Chemistry and physics of cleaning
- What makes residue stick?
- Solvent chemistries
- Aqueous chemistries
- Non liquid cleaning processes

1:00–4:00 p.m.: Basics of Critical Cleaning, Part 2, cleaning equipment & technology
- Cleaning is a Process
- Clean In Place (CIP), Clean Out of Place (COP)
- Immersion, spray, flow
- Ultrasonics
- Vapor degreasing
- Point of use cleaning
- Automation

4:00–4:30 p.m.: Cleaning process development
- Participant open discussion of concerns, real-life issues

Second Day

8:30–9:15 a.m.: Cleanrooms, contamination control
- Product cleaning before the cleanroom
- Using controlled environment real estate productively
- Training

9:15-10:00 a.m.: Process development
- Process development
- ADS-Actually Do Something

10:20–11:30 a.m.: How clean is clean enough?
- How Clean is Clean?
- Compatibility
- Risk assessment and residue limits

11:30–12:00 noon: Measure residue, monitor the process
- Choosing techniques for cleaning, validation, and monitoring
- Workhouse techniques
- Analytical techniques; speciation
- Working with the lab

1:00–2:00 p.m.: Measure residue, monitor the process, Continued

2:00-3:00 p.m.: The supply chain
- Selecting contract manufacturers
- Auditing
- Realistic requirements
- Problem resolution
- Effective contracts, partnering

3:20–4:30 p.m.: Discussion:
- Open discussion of participant concerns

Third Day

8:30–10:00 a.m.: Standards
- Standards overview
- Interpreting standards and guidance documents
- Clarifying standards with suppliers
- Internal standards, documenting your interpretation

10:20–12:00 noon: Cleaning validation without tears
- 4D's of validation
- Select the right experts

1:00–1:45 p.m.: Cleaning validation (continued) and life cycle management
- Pre-validate
- Data management
- Continuous process verification

1:45–2:30 p.m.: Challenges
- When does a modification become a new device?
- Challenges with additive manufacturing, complex and combination devices
- Reusable devices

2:30–3:00 p.m.:
Q&A, discussion

3:20–4:00 p.m.:
Assessment opportunity

course co-directors

Barbara Kanegsberg, President of BFK Solutions, LLC, is a recognized expert in critical/industrial cleaning and contamination control. Her education and professional background includes biology, clinical chemistry and aerospace. She develops critical cleaning processes, conducts validations, and resolves product-related regulatory issues. As a member of the ASTM medical device Cleanliness Testing Task Force, she takes an active role in development of standards and guidance documents including "Guide for Validating Cleaning Processes for Medical Devices" (F3127-2016). Ms. Kanegsberg is an appointed United States Expert to ISO/TC 209 WG 12: "Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications." She has a master degree in biological chemistry.

Ed Kanegsberg, PhD, Vice President of BFK Solutions, is a chemical physicist and engineer who troubleshoots and solves manufacturing production problems. He is a recognized advisor and consultant in industrial cleaning process design and process performance. He expedites projects in medical device development and in other high-value product. He has decades of experience in physics and engineering, specializing in the transition of products from prototype to production. He moderated a session at the 2014 FDA workshop on Additive Manufacturing of Medical Devices. Mr. Kanegsberg has a doctorate in physics.

The Kanegsbergs are the industry leaders in critical cleaning. As independent consultants, they work with manufacturers of high-value product, including medical device manufacturers and their suppliers. They publish extensively, lecture at the post-graduate level, and teach practicing engineers and manufacturers. They are co-editors of and contributors to the two-volume "Handbook For Critical Cleaning," second edition, CRC Press, 2011.

course location

This course will be held in the New Brunswick, New Jersey area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee. We recommend that travel/hotel arrangements not be made until final confirmation package is received.

- Easy access to Manhattan, Trenton, NJ and Philadelphia, all less than 40 minutes

accreditations/recertifications for this course

The Center for Professional Advancement (CfPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 11130 Sunrise Valley Drive, Suite 350, Reston, VA 20190. In obtaining this approval, CfPA has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. CfPA is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. This course offers a total of 18 contact hours, or 1.8 CEUs.

The American Society for Quality (ASQ)Recertification Opportunities

The following information was provided courtesy of ASQ, and is not meant as an endorsement of CfPA products. It serves only as an informational guide about the certifications offered by ASQ. Many CfPA courses offer training that may be helpful in obtaining required ASQ's recertification education units. To view a list of recommended courses that may be appropriate please visit **www.cfpa.com** For more information about ASQ, contact them at: help@asq.org

virtual attendee training option

Though attending in person at one of our courses is highly recommended, attending virtually is the next best thing when you can't be there. We will provide you with access to the complete live in person course via an internet connection and phone/audio speakers.

For complete information and FAQs visit: **www.cfpa.com/virtualattendee**

tuition

Early Bird–Save $200–(Must register and pay by September 4, 2017)	$2510
Regular Tuition	$2710
Virtual Live	$2168

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration. Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.
Note: Payment is due 2 weeks prior to course or at time of registration.

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how to register

- Online: www.cfpa.com enter Course ID# into Search. Click Register Now button. Group Rates Available: Save 10% on 2 or more attendees.
- Call Customer Service at 732-613-4500 or email: info@cfpa.com
- Fill out the registration form and email it to: info@cfpa.com

registration form

Quality Critical Cleaning and Cleaning Validation Processes course id# 1867 /course offering# 171016NJ1867

instructions:

Please complete Registrant Information, Course Information and Payment Sections. Submit one form per individual registrant.

☐ Check here if group discount applies (two or more enrollments for the same course, from the same company)

All fields MUST be completed in order for registration to be accepted.

registrant information

Registration Type: ☐ In Person Attendee ☐ Virtual Attendee

Prefix: ☐ Ms ☐ Miss ☐ Mrs ☐ Mr ☐ Dr ☐ Prof

First Name_____ Last Name_____Designation (i.e.Phd, Jr)_____

Email Address _____ Alternate Email (copy sent here as well) _____

Title_____

Your position in the organization is (please check one)

☐ Corporate ☐ Line Operational ☐ Managerial/Supervisory ☐ Staff ☐ Consultant

Your primary job function is (please check one)

☐ Clinical Practice ☐ Project Management ☐ Design Engineering ☐ Quality Control Assurance

☐ Environmental Safety ☐ Research & Development ☐ Legal or Regulatory Affairs ☐ Technical Information Services

☐ Manufacturing & Operations ☐ Training and/or Education ☐ Marketing or Sales ☐ Other _____

*Primary industry that best describes your area of interest (select maximum of 2)

☐ Analytical Chemistry
☐ Biopharmaceuticals/ Biotechnology
☐ Chemical/ Process Engineering
☐ Clinical/ Non-Clinical
☐ Cosmetics/ Personal Care/ Household Products
☐ Environmental and Safety Technology
☐ Food Technology
☐ Mechanical/ Design Engineering
☐ Medical Devices/ Diagnostics
☐ Packaging Technology
☐ Petroleum Technology
☐ Pharmaceutical Technology
☐ Technical/ Project Management

contact information

Company Name _____

Address _____

Zip/Postal Code_____ City_____ Country_____

Phone _____ Fax _____

course information

Course Title_____

Course ID#/Offering#_____

Tuition

Tuition_____

*How did you hear about us? ☐ Email ☐ Postcard ☐ Colleague ☐ Google Search ☐ Social Media

☐ Trade Show ☐ Advertisement ☐ Course Director ☐ Course Brochure ☐ Other _____

discount code

Discount Code _____

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☐ Credit Card

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Card #: _____ Exp. Date: _____ Security Code: _____

Cardholder Name: _____ Signature: _____

Billling Addess (if different from above)

Address _____

Zip/Postal Code_____ City_____ Country_____

☐ Wire Transfer ☐ Purchase order (PO# if applicable _____)

☐ Send Invoice ☐ Check: Payable in US funds to: **The Center for Professional Advancement**

terms and conditions

Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration or upon receipt of invoice. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Bird tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. The Virtual Attendee Option does not qualify for Early Bird pricing. If choosing invoice/wire transfer, payment must be received prior to expiration of early registration tuition or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Please note: Group Rate Discount cannot be combined with any other discount. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: ALL cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit less cancellation fee that can be used towards a future course up to one year from the date of issuance. If you do not cancel and do not attend you are still responsible for the full payment. If for any reason, CfPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice. Substitutions are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

Confirmation Letters: Before each course begins, all registrants will receive written Final confirmation including detailed information regarding course location – VIA EMAIL. We recommend that travel/hotel arrangements not be made until final confirmation package is received. If confirmation is not received two weeks prior to the course please contact Customer Service at info@cfpa.com.

Course photography / video: By registering and attending a CfPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CfPA using these photos and/or videos for marketing or any other CfPA Course and/or promotional purposes. You agree to release CfPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Please note: English will be used in all lectures and course notes. For questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com.

☐ I have read and agree to CfPA's Terms and Conditions