



# APE<sub>x</sub> ASEPTIC TRAINING PROGRAM

## *Compounding Sterile Preparations*

Clinical IQ, LLC and Controlled Environment Consulting in cooperation with the Contamination Control Institute (C<sup>2</sup>I) is proud to offer our *ACPE Accredited Aseptic Training Program*—based on the requirements of USP <797> and the NIOSH Alert. This unique program is a 3-day HANDS-ON intensive course designed specifically for pharmacists and technicians who are working toward compliance with USP Chapter <797>.

USP <797> has redefined the practice of sterile product preparation in all practice settings (hospital, retail, institutional, home infusion). Many states have developed new regulations and have already begun to inspect pharmacies for compliance with <797>.

The APE<sub>x</sub> Aseptic Training Program is intended to aid in all aspects of your Pharmacy's <797> compliance including floor plan design/redesign and facility requirements (**please feel free to bring plans with you for informal review and comment by instructors**); SOP templates and sample SOPs for Environmental Monitoring, Aseptic Media Fill, Cleaning; and introducing participants to hands-on usage of every type of engineering control.

### A partial listing of the topics covered during the training are:

- Understanding the importance of and demonstrate proper hand washing and gowning requirements
- Proper movement and workflow of products and people in anteroom and cleanroom areas
- Basic concepts of proper aseptic technique and psychomotor skills
- Practicing aseptic technique in **ACTUAL** LAFWs, cleanrooms, and barrier isolators
- Proper documentation of media fill challenge results and actions recommended when positive growth is detected
- Best and worst practices of aseptic technique
- Facility and environmental requirements for compounding sterile preparations for each of the 3 risk levels outlined in USP <797>
- Basic principles of microbiology as related to environmental monitoring
- Methods to document training and process validation methods
- NIOSH Alert for Compounding Hazardous Medications vs. USP Chapter <797>



### *Hands-On Sterile Preparation Training*

#### SEMINAR DATES:

4-6 April 2006  
13-15 June 2006

#### COST:

\$1895 per person

#### CLASS LOCATION:

Micro-Clean, Inc.  
177 North Commerce Way  
Bethlehem, Pa 18045



ControlledEnvironmentConsulting

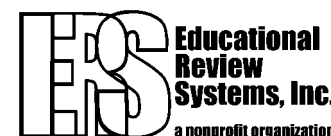
2067 Hilltop Rd.  
Bethlehem, Pa 18015  
Phone (610)868-4646  
FAX: (610)868-4774  
e-mail: jimwagner@fast.net



184 Columbia Turnpike, #282  
Florham Park, NJ 07932  
Phone: (973) 765-9393  
FAX: (973) 966-8720  
e-mail: ekastango@clinicaliq.com

Educational Review Systems is approved by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmaceutical education. Individuals may obtain up to 21.25 hours of credit or 2.125 Continuing Education Units (CEUs). Statement of credit will be awarded to attendees who attend the entire program and complete an evaluation form. Statement of credit will be mailed via first class mail to attendees within 6 weeks of the program end date.

ACPE # 761-999-05-094-L04 to 761-999-05-107-L04



## APEX ASEPTIC TRAINING PROGRAM INSTRUCTOR QUALIFICATIONS

### **ERIC S. KASTANGO, MBA, RPH, FASHP PRESIDENT, CLINICAL IQ, LLC**

Mr. Kastango received his Bachelor of Science in Pharmacy degree from the Massachusetts College of Pharmacy and Allied Health Sciences and a MBA from the University of Phoenix. Since 1980, he has practiced pharmacy in a number of practice settings (including hospitals, community, and home care) in

a number of different of roles, including the Corporate Vice President of Pharmacy Services for Coram Healthcare Corporation, which has 72 pharmacies in 44 states. Mr. Kastango is the founder and President of the consulting company, Clinical IQ, LLC based in Florham Park, New Jersey, started in 1999.

Mr. Kastango is author of the ASHP Discussion Guide on Sterile Preparation: Summary and Implementation of USP Chapter <797>, the ASHP Sterile Product Preparation CD-ROM: A Multimedia Learning Tool, the ASHP web-based 797 Compliance Advisor Gap Analysis Tool for USP Chapter <797>.

### **JAMES T. WAGNER PRESIDENT, CONTROLLED ENVIRONMENT CONSULTING**

Mr. Wagner has over 25 years experience assuring the performance of critical environments. He serves on many standards writing committees including NSF International for Biological Safety Cabinets, the Institute of Environmental Sciences and Technologies for Cleanrooms and HEPA filters, and has been elected to serve on the USP Sterile Compounding Committee council of experts for

2005-2010. Mr. Wagner has authored several papers and presented at numerous professional seminars and symposium on engineering control related issues. He is one of the principal authors for the CETA applications guide for the use of barrier isolators in compounding sterile preparations in healthcare facilities. He conducts training classes internationally for the Eagleson Institute on

matters relating to engineering controls for containment and aseptic processing. While managing Micro-Clean, Mr. Wagner was responsible for development of Cleanroom, Biological Safety Cabinet, and Laminar flow certification as well as Air Balancing, Calibration, Decontamination, Validation, and Environmental monitoring programs for the Pharmaceutical and Healthcare related fields.

### **HOLLY SIMMONS, RPH PRESIDENT, IMPACT SOLUTIONS GROUP**

Ms. Simmons, a pharmacist, is a 1988 graduate of the Medical College of Virginia / Virginia Commonwealth University School of Pharmacy. Ms. Simmons has a varied background in management, sales, training, and business development, having worked in the home care industry since 1992.

She is the founder of Impact Solutions Group, Inc., located in Norfolk, VA, providing innovative healthcare consulting in the areas of USP Chapter <797> compliance and aseptic compounding (via collaboration with Clinical IQ, LLC), staff training, accreditation survey preparation, software

evaluation and selection, as well as general pharmacy operations consulting. Ms. Simmons is currently a Pharmacy Surveyor for the Accreditation Commission for Health Care (ACHC) and maintains membership in several professional pharmacy organizations.

### **KATE DOUGLASS, MS, RN, APN,C, CRNI PRESIDENT, PERFORMANCE STRATEGIES, LLC**

Ms. Douglass has over 25 years in the home health industry in both clinical and executive management positions. Past positions include Senior Vice President of Clinical Operations for Coram Healthcare where she was responsible for all aspects of clinical services nationally. Most recently Kate was the Chief Operating Officer of SoluNet where she personally supervised

the design, engineering and build of four pharmacy compounding complexes that meet/exceed USP <797> facility requirements. She is a past Chair of the National Home Infusion Association's Education Committee and serves on the Editorial Review Board for the Journal of Infusion Nursing. Kate was a reviewer for ASHP's Sterile Product Preparation CD-ROM: A

Multimedia Learning Tool, 1<sup>st</sup> and 2<sup>nd</sup> editions and has authored several articles on aseptic compounding quality and outsourcing. Currently Kate is the President of Performance Strategies, LLC, a healthcare consulting firm. She is working on several articles on competency, training, and other aspects of USP <797> as they relate to pharmacy, nursing and physician practice.

### **KYM FAYLOR QA MANAGER, MICROBIOLOGICAL ENVIRONMENTS**

Ms. Faylor, with 11 years of clinical and non-clinical lab experience, designs & implements environmental monitoring (EM) programs for pharmaceutical, medical device and biotechnology facilities. She designs custom trending and data management programs for these industries. Kym provides consulting ser-

VICES to resolve contamination issues in the cleanroom, and recommends products and practices for EM. Ms. Faylor conducts cGMP compliant training for clients onsite in EM, gowning, and proper cleanroom behavior. She writes protocols and SOPs for EM, gowning, and other USP-compliant testing.

Ms. Faylor is a member of the American Society of Microbiology, Pharmaceutical Microbiology Forum, Parenteral Drug Association, Biopharmaceutical Education & Training Association, Regulatory Affairs Professionals Society, and the American Society for Quality.



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## COURSE REGISTRATION

### Personal Information

Name: \_\_\_\_\_ Phone: \_\_\_\_\_  
Company/Hospital: \_\_\_\_\_ Fax: \_\_\_\_\_  
Address: \_\_\_\_\_ Email: \_\_\_\_\_  
\_\_\_\_\_  
Nickname for Badge: \_\_\_\_\_  
\_\_\_\_\_

### Emergency Contact Information

Name: \_\_\_\_\_ Daytime Phone: \_\_\_\_\_  
Evening Phone: \_\_\_\_\_

### Payment Information

***\$1895 Tuition must be paid PRIOR to class start date (Airfare and Hotel are not included)***

#### Course Date (choose one):

- 4-6 April 2006
- 13-15 June 2006

#### Check (Payable to "Clinical IQ")

#### Credit Card

- Visa
- Mastercard
- American Express

Cardholder Name: \_\_\_\_\_

Card # \_\_\_\_\_

CVV2# (on back of Card): \_\_\_\_\_

Expiration Date: \_\_\_\_\_

Billing Address: \_\_\_\_\_  
\_\_\_\_\_  
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