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PROFESSIONAL EXPERIENCE

CLINICALIQ, LLC and CriticalPoint, LLC

Principal, Florham Park, New Jersey
December 1999 – Present

Initiated and developed all aspects of company operations whose mission is to become leading provider of quality aseptic process and business development strategies for the pharmaceutical, medical device and healthcare industry. Areas of expertise include aseptic processing (pharmacy (USP Chapters <795> and <797> and pharmaceutical industry-based), medical device manufacturing, regulatory and accreditation compliance auditing, and the development and implementation of evidence-based quality systems. Client portfolio includes:

Baxter Healthcare (US, Australia, Canada, China, Ireland, Japan, New Zealand and Puerto Rico)	US Department of Veterans Affairs, VISN 3, VISN 6
Express Scripts, Inc.	Partners Healthcare (Massachusetts)
CVS Health	Home Healthcare Laboratory of America
Dana Faber Cancer Center	Tyco/Mallinckrodt, Inc.
MedStar Health System	American Society of Health-System Pharmacists
Walgreens Specialty/Infusion and Respiratory Svcs	PharMEDium, LLC
B. Braun/CAPS and Manufacturing Division	CareFusion, Inc.
Express-Scripts	Equashield, LLC
APP Pharma/Kabi Fresenius	Baxa Corporation
Scripps Healthcare	The Cleveland Clinic
NABP & State Boards of Pharmacy	University of Texas, MD Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center	Seattle Children's Regional Hospital and Medical Center

CORAM HEALTHCARE CORPORATION

Vice President, Pharmacy Services, Whippany, New Jersey
January 1999 – December 1999

- Responsible for all aspects of clinical services, policy and procedures, clinical initiatives, staff training, field support of 88 branches in 44 states. Responsible for implementing standardized clean room operating guidelines through Computer-Based Training Modules (Good Compounding Practices), physical plant design requirements and policy and procedures. Implemented Home Healthcare Laboratory of America Clinical Laboratory Service Model, Primary Care Management Model with Vice President of Nursing Services, Aminoglycoside Patient Assessment Tool and Process and Calcium Phosphate TPN Stability Process.

COGNITIVE DESIGN ASSOCIATES, Inc

Principal, Upper Saddle River, New Jersey
April 1997 – January 2004

- Initiated and developed all aspects of company operations whose mission is to become leading provider of customized educational strategies for performance improvement in the healthcare industry. CDA facilitates the achievement of identified organizational goals through a performance consulting methodology. Responsible for the development, implementation, and support of customized Interactive Computer-Assisted Learning Modules (ICALMs) for employee competency validation. Additional service offerings include process design, service model revision, clinical and operational policy/procedure development, competency tool development, and instructional design for the hospital and homecare markets.

MILLERS HOMECARE SERVICES, Inc.

Executive Vice-President, Hawthorne, New Jersey
August 1996 – May 1997

- Responsible for all aspects of business operations for Millers Homecare Services, which included the following divisions: Home Medical Equipment and Respiratory, Rehabilitation Technology Services and Infusion and Clinical Services. Annual sales for 1996 were 8.5 million dollars. Responsible for closing a one million dollar supply management contract with the Visiting Nurse Association of Northern New Jersey that provided nursing and patient surgical/medical supplies. Position eliminated due to a potential acquisition.

BAXTER COMPASS, a business unit of Baxter Healthcare Corporation, IV Systems Division.

Compass Facility Manager, Edison, New Jersey
January 1994-August 1996

- Responsible for the start-up and day-to-day operation of a US Food and Drug Administration registered parenteral nutrition and cardioplegia solution manufacturing operation. Operations supported six area hospitals. Areas of responsibilities included compliance with cGMPs, staff development and supervision, purchasing and inventory management, budget and finance management and all aspects of Quality System Management. Facility underwent two FDA site audits without the issuance of any 483's.

HMSS, Inc.

Branch Operations Manager, Wayne, New Jersey
September 1993-January 1994

- Responsible for the day-to-day operation of a home infusion therapy facility. Areas of responsibilities included: development and supervision of three department managers, budget and finance management. Coram, Inc purchased company in March 1994. Position was to be eliminated.

CAREMARK, Inc.

Staff Pharmacist, March 1984-August 1985
Manager of Pharmacy Services, August 1985-September 1986 and January 1990 -January 1993,
Branch Manager, January 1993-August 1993

- Participated in the team management of a branch staff of eighty (80) encompassing pharmacy, nursing and patient services in Totowa, New Jersey. Branch generated sales of forty-one (41) millions dollars and a profit of eleven (11) million dollars in 1992.
- Responsible for the management of the Manhattan Clinical Service Center that provided home infusion and nursing services for over one hundred and fifty (150) HIV patients in New York and New Jersey. The center employed twenty-two (22) clinical and service specialists.
- Responsible for the development and implementation of a clinical pharmacy-training program for the Women's Health Initiative, and trained one hundred and fifteen (115) clinical pharmacists in tocolytic therapy.
- Co-authored and edited a physician sponsored Investigational New Drug Application (IND) for L-glutamine and its use in the home TPN patients. The Food and Drug Administration approved IND 37,331 in May 1991. A paper was published in the Journal of Parenteral and Enteral Nutrition.

TOKOS MEDICAL CORPORATION

Area Clinical Pharmacist, Edison, New Jersey
January 1989-January 1990

- Responsible for managing all women's health (tocolytic and home infusion) patients out of four regional centers from Maine to New Jersey and out to Ohio.
- Responsible for establishing local provider relationships with independent home infusion operations in order to serve infusion patients.
- Designed a trifold-marketing brochure detailing the home infusion services provided by Tokos Medical Corporation. Brochure was implemented nationwide in 1989.

NEW ENGLAND CRITICAL CARE, Inc

Manager of Pharmacy Services, January 1987-September 1987
Branch Operations Manager, September 1987-January 1989

- Responsible for the day-to-day management of an operation that experienced a two hundred percent (200%) increase in patient census with an associated increase in gross sales from six million to eleven million dollars in 1988
- Responsible for obtaining outpatient licensure for the first homecare blood bank/transfusion service in New Jersey
- Participated in several corporate groups that focused on enhancements to clinical operating policy and procedures, computerized pharmacy operating systems and employee incentive programs

ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL

Staff Pharmacist, September 1986-December 1986

OVERLOOK MEDICAL CENTER

Staff Pharmacist, April 1983-March 1984

EDUCATION

Massachusetts College of Pharmacy and Allied Health Sciences Boston, Massachusetts	Bachelor of Science, Pharmacy March 1983
University of Phoenix Phoenix, Arizona	Masters, Business Administration March 2001 (Honors)
University of Tennessee, Department of Pharmaceutical Sciences Memphis, Tennessee <i>The Comprehensive Industrial Course in the Preparation of Parenteral Products</i>	Certificate Program March 2007
BD Six Sigma Program, Certified Green Belt	Certification in Process July and September 2008
Purdue University, West Lafayette, Indiana	65 hours live training Certification in Nuclear Pharmacy May 2009

LICENSURE

Registered Pharmacist, State of New Jersey
Registered Pharmacist, State of New York (Inactive)

APPOINTMENTS

The United States Pharmacopoeia, Council of Experts

Elected member of the Sterile Compounding Committee (USP Chapter <797>), 2005-2010
Elected member of Compounding Expert Committee (USP Chapters <795>, <797>, <1163>), 2010-2013

- Chairman of USP Chapter <797> Subcommittee, 2010-2013
- Member of Hazardous Drug Expert Panel, 2010-2015, 2015-2020

The Commonwealth of Massachusetts Special Commission on Compounding Pharmacies

Appointed member by Governor Duval Patrick, Nov 2012-December 2012

The Commonwealth of Massachusetts Board of Registration in Pharmacy

Appointed member of the Board of Pharmacy's Advisory Committee, December 2014-Present

Pharmacy Purchasing and Products Magazine

Editorial Board 2004-present

International Journal of Pharmaceutical Compounding

Sterile-Product Preparation Section Editor, 2000-2005

Contributing Author

American Society of Health-System Pharmacists

-Vice Chairman, Council of Educational Affairs, 2002-2003

-Member, Committee for the Home, Ambulatory, and Chronic Care Practitioners, 2002-present

-Member, Council on Educational Affairs, 2001-2002

-Chair, Committee on Communications, 2000-2001

FACULTY

Instructor, National Association of Boards of Pharmacy: <ul style="list-style-type: none">• Sterile Compounding Inspector Training	October 2013-present
Instructor, CriticalPoint Sterile Compounding Boot Camp, Totowa, NJ	September 2012-present
Instructor, Baxa Star Center, Englewood, CO	September 2006-September 2012
Instructor, APEx Sterile Training Program, Bethlehem, PA	June 2005-April 2006

AWARDS

ISMP Cheers Award	December 2015
NABP Henry Cade Memorial Award	May 2014
Outstanding Service Award, Massachusetts Society of Health-System Pharmacists	May 2013
Award for Outstanding Contribution to the USP Standards-Setting Process	May 2013
Fellow, American Society of Health-System Pharmacists	March 2001
Eagle Scout, Boys Scouts of America	June 1977

PROFESSIONAL ASSOCIATIONS/MEMBERSHIPS

American Society of Health-System Pharmacists	May 1983-Present
PDA	December 1999-Present
Institute for Environmental Sciences and Technology	December 1999 -Present
Association for Professionals in Infection Control and Epidemiology	November 2007-Present

JOURNAL PUBLICATIONS

- Douglass K, Kastango ES, Cantor, PA. Are USP <898> Compliance Rates Good Enough. *Pharmacy Purchasing and Products Magazine*. October 2015: Cleanrooms & Compounding - Vol. 12 No. 10, 2-5.
- Hirst DVL, Mead KR, Power L, Kastango ES, et. al., A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs. NIOSH Docket Number 288, CDC-2015-0075, Federal Register, 2015 Sept.8.
- Kastango ES, Douglass K, Patel K, et. al., Safer Sterile Compounding: Choosing and Using Disinfectants for the Cleanroom. *Int J Pharm Compd*. 2015; Vol 19 No.4:268-278.
- Kastango ES. Impact of the US Drug Quality and Security Act. *Pharmacy Purchasing and Products Magazine*. November 2014: State of Pharmacy Compounding - Vol. 11 No. 11, 20-24.
- Douglass K, Kastango ES. Let This Be Your Wake-up Call. *Pharmacy Purchasing and Products Magazine*. October 2014: State of Pharmacy Compounding - Vol. 11 No. 10, 2-5.
- Gupta N, Hocevar SN, Moulton-Meissner HA, Stevens KM, McIntyre MG, Jensen B, Kuhar DT, Noble-Wang JA, Schnatz RG, Becker SC, Kastango ES, Shehab N, Kallen AJ. Outbreak of *Serratia marcescens* Bloodstream Infections in Patients Receiving Parenteral Nutrition Prepared by a Compounding Pharmacy. *Clin Infect Dis*. 2014 Jul 1; 59(1):1-8.
- Power LA, Kastango ES, Douglass K and Kienle, PC. Understanding the New Proposed USP Chapter <800>. *Pharmacy Purchasing and Products Magazine*. June 2014: State of Pharmacy Compounding - Vol. 11 No. 6, 6.
- Kastango ES. Compounding in the United States: A Retrospective, *PDA Letter*; January 2014. PDA, Bethesda, MD
- Douglass K, Kastango ES. The 2013 USP <797> Compliance Survey. *Pharmacy Purchasing and Products Magazine*. October 2013: State of Pharmacy Compounding - Vol. 10 No. 10, 1
- Douglass K, Kastango ES. Requirements and Best Practices for Sanitizing Engineering Controls. *Pharmacy Purchasing and Products Magazine*. October 2013: State of Pharmacy Compounding - Vol. 10 No. 9, 16
- Douglass, K, Kastango, ES, Cantor, P. State Regulations Impact USP <797> Compliance. *Pharmacy Purchasing and Products Magazine*. April 2012: State of Pharmacy Compounding - Vol. 9 No. 4, 8
- Kastango, ES. Compounding USP <797>: Inspection, Regulation, and Oversight of Sterile Compounding Pharmacies. *JPEN* Mar 2012; 36(2 Suppl):38S-39S
- Douglass K, and Kastango E. and Cantor P. The 2011 United States Pharmacopeia Chapter <797> Compliance Study: Discussion of Findings and Strategies for Improvement in the Alternate-Site Setting. *Infusion* 2012; 18(3):38-44.
- Douglass K, Kastango ES, and Cantor P. Sterile Compounding and USP <797> Compliance: Where Does the Alternate-Site Pharmacy Setting Stand? *Infusion* 2012; 18(2):21-28.
- Kastango ES. Challenging our aseptic skills using more-rigorous media-fill tests. *Am J Health Syst Pharm*. July 15, 2012 69:1197
- Kastango, ES. How Should CSPs Be Prepared for Patients with a Latex Allergy? *Pharmacy Purchasing and Products Magazine*. April 2012: State of Pharmacy Compounding - Vol. 9 No. 4, 46
- Tribble DA, Kastango ES. Key Considerations in Pharmacy Outsourcing: Understanding Risks and Managing Liability. *Hosp Pharm*—2012; 47(2):112–117
- Douglass K, Kastango ES, Cantor P, Shevitz M. The 2011 USP <797> Compliance Study: Additional Results. *Pharmacy Purchasing and Products Magazine*. November 2011 - Vol. 8 No. 11, 90
- Douglass K, Kastango ES, Cantor P, Shevitz M. The 2011 USP <797> Compliance Study. *Pharmacy Purchasing and Products Magazine*. October 2011: Cleanrooms & Compounding - Vol. 8 No. 10 - Page #8

JOURNAL PUBLICATIONS, continued

- Kastango, ES, Power LA. What are the considerations for decontaminating a CACI? *Pharmacy Purchasing and Products Magazine*. January 2011; 14-15.
- Kastango, ES. Managing Engineering Controls Outside of the Cleanroom. *Pharmacy Purchasing and Products Magazine*. December 2010; 32-33.
- Kastango, ES, Weatherman, KD. Addressing <797> Requirements for Radiopharmaceuticals. *Pharmacy Purchasing and Products Magazine*. September 2010; 24-27.
- Kastango, ES. Blueprint for a Robust Sterile Compounding Training Program. *Pharmacy Purchasing and Products Magazine*. March 2010; 2-4.
- Kastango, ES. The Top Ten Gaps in USP Chapter <797> Compliance. *Pharmacy Purchasing and Products Magazine*. October 2009; 2-7.
- Kastango E and Kramer N. The Top 10 Things You Need to Know About USP <797>. *Infusion* 2009;15(3);43-8.
- Kastango ES. Spread the Word: Aseptic Technique Prevents Infection. *Pharmacy Purchasing and Products Magazine*. April 2009; 6-9.
- Okeke CC, Newton DW, Kastango ES, and Allen LV. Basics of Compounding: United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding-Sterile Preparations, Part 10: First Revision: The Main Changes, Events and Rationale. *Int J Pharm Compd*. 2008; 12:530-536.
- Kastango, ES. Compounded Sterile Preparations Continue to Harm or Kill Patients. *Journal of Pharmacy Practice and Research*. 2008; 3:173-174.
- Kastango, ES, Wagner JT, Kastango KB, Kastango NE, and Wagner TJ. Generation of particulate matter during handling of needle and syringe packaging. *Am J Health-Syst Pharm*. 2008; 65:1443-50.
- Kastango, ES. USP Chapter <797> and Environmental Monitoring. *Clinical Microbiology Newsletter*.30:14, 2008
- Kastango, ES. Microbial Air-Sampling Equipment, Part 1: Meeting United States Pharmacopeia Chapter <797> Standard. *Int J Pharm Compd*. 2008; 12:216-268.
- Kastango ES. The revised USP Chapter <797> in review. *Cleanrooms Magazine*, April 2008.
- Kastango ES. The updated <797> in Review: How the Changes to USP Chapter Impact Your Practice. *Pharmacy Purchasing and Products Magazine*. February 2008; 18-22
- Kastango ES. USP <797>: The First Step to Compliance. *Pharmacy Purchasing and Products Magazine*. July 2007, 10-11.
- Kastango, ES. Quality Assurance and <797> Compliance: Fact versus Fiction-Which are your environmental monitoring and sterility testing programs based on? *Pharmacy Purchasing and Products Magazine*. May 2007, 20-24.
- Kastango ES. So What Have You Done Today to Improve Patient Safety? *Pharmacy Purchasing and Products Magazine*. Special Issue: Cleanrooms & Compounding 2006; 1
- Kastango ES. A Review of USP's Updates to <797>: Don't Just Know About It. *Pharmacy Purchasing and Products Magazine*. Special Issue: Cleanrooms & Compounding 2006; 3:8-10.
- Kastango E. USP chapter <797>: The next phase. *Infusion* 2006. 12(4):25-9.
- Kastango ES. Putting the Science back into the "Art and Science" of Compounding. *Int J Pharm Compd*. 2006; 10:263-268.
- Trissel LA, Zhang Y, Douglass K and Kastango ES. Extended Stability of Oxytocin in Common Infusion Solutions. *Int J Pharm Compd*. 2006; 10:156-158.

JOURNAL PUBLICATIONS, continued

- Kastango ES. Pharmacy Compounding Urban Legends. *Int J Pharm Compd.* 2006; 10:28-31.
- Kastango ES, Faylor, K. The Importance of Environmental Monitoring, Part II: Surface Testing. *Pharmacy Purchasing and Products Magazine.* 2005; 2: 24-26.
- Kastango ES. USP <797>: Making the case for improving environmental controls in pharmaceutical compounding. Supplement to *Infusion.* 2005; 11(4):S1-S12
- Kastango ES. A Blueprint for Implementing USP Chapter <797>, Pharmaceutical Considerations: Sterile Preparations, *Am J Health-Syst Pharm.* 2005; 62:1271-88.
- Kastango ES. The Importance of Environmental Monitoring, Part I: Air Quality. *Pharmacy Purchasing and Products Magazine.* 2005; 4:4-5.
- Kastango ES. A Practical Guide to Aseptic Technique Verification: Policies and Procedures that Meet USP Chapter <797> Requirements. *Pharmacy Purchasing and Products Magazine,* 2005; 3:16-18.
- Wagner J, Kastango ES. Understanding Cleanroom Design. *Pharmacy Purchasing and Products Magazine.* 2005; 2: 21-27.
- Kastango ES. Using Automated Compounding Devices (ACDs) in the Practice of Pharmacy, *Int J Pharm Compd.* 2005; 9:15-21.
- Kastango ES. Using Equipment and Products to Successfully Meet USP Chapter <797> Standards. *Pharmacy Purchasing and Products Magazine.* 2004; 1: 12-17.
- Kastango ES, Bradshaw BD. USP Chapter 797: Establishing a practice standard for the profession of pharmacy. *Am J Health-Syst Pharm.* 2004; 61:1928-38
- Kastango ES. Quality-Control Analytical Methods: USP Chapter <797>Compounded Sterile Preparations Sterility Requirements and Their Relationship to Beyond-Use Dating. *Int J Pharm Compd.* 2004; 8: 393-397.
- Kastango ES. The ASHP Discussion Guide for Compounding Sterile Preparations: Summary and Implementation of USP Chapter 797. Published by ASHP in collaboration with Baxter Healthcare. April 2004.
- Kastango ES, Trissel LA, Bradshaw B. An Ounce of Prevention: Controlling Hazards in Extemporaneous Compounding Practices. *Int J Pharm Compd.* 2003; 5: 401-416
- Kastango ES, Bradshaw B. Sterile Product Compounding: Developing Quality-Based Standards for Pharmacy Practice. *Infusion.* 2002; 8: 23-27
- Kastango, ES. The Cost of Quality for Sterile Products, *Int J Pharm Compd.* 2002; 6: 404-407
- Stranz M, Kastango ES. A Review of pH and Osmolarity. *Int J Pharm Compd.* 2002; 6: 216-220
- Kastango ES, Hadaway, L. New Perspectives on Vancomycin Use in Homecare, Part 2. *Int J Pharm Compd.* 2002; 6: 55-57
- Kastango ES, Hadaway L. New Perspectives on Vancomycin Use in Homecare, Part 1. *Int J Pharm Compd.* 2001; 5: 465-469
- Kastango ES. Compounding Containment Devices: Buyer Be Aware. *Int J Pharm Compd.* 2001; 5: 384-388
- Kastango ES, Douglass K. Quality Assurance for Sterile Products. *Int J Pharm Compd.* 2001; 5: 246-253
- Kastango, ES, DeMarco S. Pharmacy Cleanroom Project Management Considerations: An Experience-Based Perspective. *Int J Pharm Compd.* 2001; 5: 221-225
- Douglass K, Kastango ES. Consolidation of Pharmacy Compounding Services: An Alternative to Outsourcing. *Int J Pharm Compd.* 2001; 5: 140-144
- Kastango ES. Sterile-Product Preparations: Mix or Buy? *Int J Pharm Compd.* 2001; 5:59-63

JOURNAL PUBLICATIONS, continued

Kastango ES, Douglass, K. Improving the Management, Operations and Cost Effectiveness of Sterile-Product Compounding – Improve the ability to predict employee efficiency, cost of service and product wastage while simultaneously improving quality. *Int J Pharm Compd.* 1999; 3:253-258

Kastango ES. Circadian Rhythm Chemotherapy for Renal Cell Cancer. *Alternative Site Care Case Study, CADD-Plus Ambulatory Infusion Pumps*, Number 11, July 1993, Pharmacia Deltec Inc., St. Paul, Minnesota.

REFERENCES AND BOOKS

Kastango ES, Kienle, P, St. John KH. (2014) Chapter 110-Pharmacy Services. The APIC Text of Infection Control and Epidemiology. 4th ed. Washington, DC.

Kastango ES, St. John KH, Weber, DJ. (2009) Chapter 61-Pharmacy Services. The APIC Text of Infection Control and Epidemiology. 3rd ed. Washington, DC.

Kastango ES. (2008). Chapter 14- Finished Preparation Release Checks and Tests. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 3rd edition. Bethesda, MD. ASHP.

Kastango ES. (2008). Chapter 24- Environmental Quality and Control. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 3rd edition. Bethesda, MD. ASHP.

Kastango ES. (2008). Chapter 26- Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 3rd edition. Bethesda, MD. ASHP.

Kastango ES. (2008). Chapter 13- Verification of Compounding Accuracy and Sterility. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 3rd edition. Bethesda, MD. ASHP.

Kastango ES. (2004). Chapter 21- End-Preparation Evaluation. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 2nd edition. Bethesda, MD. ASHP.

Kastango ES. (2004). Chapter 20- Process Validation. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 2nd edition. Bethesda, MD. ASHP.

Kastango ES. (2004). Chapter 18- Environmental Monitoring. In E. Clyde Buchanan & Philip J. Schneider (Eds.), Compounding Sterile Preparations, 2nd edition. Bethesda, MD. ASHP.

ELECTRONICS PUBLICATIONS

Outsourcing Sterile Products Preparation: Contractor Assessment Tool. ASHP Research & Education Foundations. Available online: <http://outsourcingassessment.org> September 2015

Insourcing Sterile IV Compounding Services. Readiness Assessment Tool. ASHP. Available online: <http://cspinsourcing.org>.

Kastango, ES, Douglass KH. Quality Standards for Large-Scale Sterile Compounding Facilities. The Pew Charitable Trusts, May 21, 2014. <http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/05/21/ensuring-the-safety-of-compounded-drugs>

CriticalPoint Virtual Compounder™, 2007-2012

Editor and Author of three (3) lessons in CriticalPoint's ACPE approved Compounding eLearning Modules, 2007-2015.

Clinical IQ, LLC (www.clinicaliq.com) and CriticalPoint (www.criticalpoint.info) websites

Kastango, ES. (2005). Compounding Sterile Preparation, 2nd ed: A Multimedia Learning Tool CD-ROM. American Society of Health-System Pharmacists, Bethesda, MD.

Kastango ES (2004). The Comprehensive Sterile Compounding Compliance Gap Analysis and Risk Assessment Tool. Available online: www.797complianceadvisor.com. American Society of Health-System Pharmacists, Bethesda, MD.

Kastango, ES. (2002). Sterile Product Preparation: A Multimedia Learning Tool CD-ROM. American Society of Health-System Pharmacists, Bethesda, MD.

Critical Issues in Homecare Compounding. Training Video, Clintec Nutrition Division, Baxter Healthcare, Inc., Deerfield, Illinois. 1997.

INTERNATIONAL PRESENTATIONS

“The Current State of Compounding Standards: What Happens Next” and “USP <800>: Strategies for Compliance. 1st Annual IVPN Summit. Abu Dhabi, United Arab Emirates, November 21, 2015

“Empowering Your Staff to be the Front Line of Defense in Ensuring Sterile Compounding Safety.” I International Congress on Patient Safety ISMP Brazil and V International Forum on Patient Safety: Medication Errors. Ouro Preto, Minas Gerais state, Brazil. April 2014.

“Adecuación de medicamentos biotecnológicos.” ASOCIACION COLOMBIANA DE QUIMICOS FARMACEUTICOS HOSPITALARIOS ACQFH. VIII National Hospital Pharmacy Congress, Cali, Colombia. March 2014.

“Radiopharmaceuticals: Quality-Safety-GMP Requirements-USP, the US Point of View.” ECA Academy, Vienna, Austria. February 2014.

“The Evolution of the USP Chapter 797 Guidelines and the Important of Quality Control.” A.P.E.S Symposium on Sterile Pharmacy Preparation. Trois-Rivieres, QC, Canada. February 2014.

“Commissioning”. Barts Health NHS Trust Radiopharmacy Design Symposium. St Bartholomew’s Hospital, London, United Kingdom, October 2013.

“Safe Handling of Biotechnology Drugs” and “Cuidados en la Manipulación en las Centrales de preparaciones.” ASOCIACION COLOMBIANA DE QUIMICOS FARMACEUTICOS HOSPITALARIOS ACQFH, Bogota, CO, July 2013

“The Importance of Achieving and Maintaining an Operational State of Control as it relates to Sterile Compounding.” 1st International Nutrition Support and IV Therapy Symposium & Workshops. Tabuk, Saudi Arabia, 25th & 26th June 2013,

“Compounding Conundrums: Outsourcing, Shortage, Clean Room Design, and Hazardous Drugs. 2013 CSHP Clinical Meeting, Toronto, Canada, February 2013.

“Staying the Course with Chapter <797>: Empowering Staff to be the Front Line of Defense to Ensure Sterile Compounding Safety.” Quality and Safe Hospital Pharmacy Practice Symposium, Saudi Arabia, June, 2012.

“Safe Compounding of Parenteral Nutrition (PN).” 2010 Medical Nutrition Therapy Conference, Jeddah, Saudi Arabia, July 25, 2010.

Keynote speaker and presenter at “Updates in Sterile Compounding and Parenteral Nutrition” International Symposium, King Fahad Medical City (KFMC), Riyadh, Saudi Arabia, June 21-22, 2008.

International 7 City Speaking Tour in Japan, China, and Australia to inform/educate Key Healthcare and Political agencies/Pharmacists on the current US USP 797 experience and sterile compounding regulations”, Baxter Healthcare, April 4-18, 2008.

Keynote speaker and “Regulation of Aseptic Dispensing in Hospital Pharmacies: Federal, State, or...?” Society of Hospital Pharmacist of Australia (SHPA) 28th Federal Conference 2007, Sydney, NSW.

“Applying Aseptic Compounding Standards to protect patients and employee: Advances in Targeted Therapies: Where Next & How?” 5th Annual Hospital Pharmacists’ Association, Ireland (HPAI) meeting, Dublin, Ireland, January 18, 2007.

International 3 City Tour in Ireland to discuss current hospital aseptic compounding practices in the Republic of Ireland. Baxter Healthcare Ltd, January 15-20, 2007

“Practices and Requirements for the Compounding of Sterile Pharmaceuticals (CSPs)” Cleanrooms Europe 2006, Brno, Czech Republic, October 26, 2006

INTERNATIONAL PRESENTATIONS, continued

“USP Chapter <797>: A Compounding Patient Safety Roadmap Achieving Compliance”. Colegio de Farmaceuticos 2006 Convencion, Rio Grande, PR, August 25, 2006.

International 6 City Speaking Tour in Australia and New Zealand to inform/educate Key Healthcare and Political agencies/people on the current US USP 797 experience, Baxter Healthcare ANZ, August 7-14, 2006.

NATIONAL AND LOCAL PRESENTATIONS

“Ensuring the Safety of Pharmacy Personnel Compounding Hazardous Drugs: Personal Protective Equipment, Engineering Controls, and Transfer Devices” ASHP Midyear Clinical Meeting, New Orleans, LA., December 2015

“Hazardous Drugs: USP, NIOSH, and OSHA-Oh, My!” ASHP Midyear Clinical Meeting, New Orleans, LA., December 2015

“Moving Targets: An Update on Legislation and Standards Aimed at Ensuring the Quality of Compounded Drug Products in the United States”. 2015 Leadership Forum, ASHP Midyear Clinical Meeting, New Orleans, LA., December 2015

“Understanding the Changes to the USP Chapter 797 Revision and Their Impact on Current Operations” Pharmacy OneSource Webinar, October 16, 2015

“USP <800>: Strategies for Compliance” 2015 ASHP Summer Meeting, Denver, CO, June 2015.

“Understanding the New Federal Framework for Oversight of Sterile Compounding.” 2014 ASHP Midyear Clinical Meeting, Anaheim, CA, December 2014.

“Hazardous drugs: What’s Really Happening Out There?” 2014 ASHP Midyear Clinical Meeting, Anaheim, CA, December 2014.

“Compounding: Surprising Places where Compounding Occurs”. SHEA Spring 2014 Conference, Denver, CO. April 2014.

“Understanding the “Whys” of USP Chapters on Compounding USP 795 and USP 797.” North Dakota Pharmacists Association. Fargo, ND. April 2014.

“Creating a Culture of Safety: Practical Approaches to Ensuring the Integrity of I.V. Products in the Health System”. 2013 ASHP Midyear Clinical Meeting, Orlando, FL December 2013.

“USP Chapter <797> Shock and Awe-What is it going to take?” 2013 ASHP Midyear Clinical Meeting, Orlando, FL December 2013.

“Headline News: USP and NIOSH Guidance in the Face of Compounding Tragedy”. 2013 ASHP Midyear Clinical Meeting, Orlando, FL December 2013.

“Outbreaks Related to Compounded Sterile Preparations: Lessons Learned.” The 5th Annual Fleming Infection Prevention and Infectious Disease Symposium. September 2013. Allentown, PA

“What has the Compounding Tragedy Taught Us?” 2013 ASHP Summer Meeting, Minneapolis, MN, June 2013.

“Multi-State Outbreak of Fungal Meningitis and Other Infections Associated with Contaminated Steroid Medication, 2012–2013.” 40th Annual Conference, APIC 2013, Ft. Lauderdale, FL, June 2013

“Lessons Learned from the NECC 483.” Various professional organizations, 2013.

“Pharmacy Sterile Compounding Summit presentation.” The Pew Charitable Trust Headquarters, Washington, DC, February 2013.

“Compounding Conundrums: Outsourcing, Shortage, Clean Room Design, and Hazardous Drugs.” 2012 ASHP Midyear Clinical Meeting, Las Vegas, NV, December 2012.

“ASPEN Parenteral Nutrition Safety Summit-Parenteral Nutrition: Preparation, Products, and Safety.” ASPEN webinar, March 2012.

“Staying the Course with Chapter <797>: Empowering Staff to be the Front Line of Defense to Ensure Sterile Compounding Safety” 2010 ASHP Midyear Clinical Meeting, New Orleans, LA, December 2011.

“The 5 W’s of Isolators.” Pharmacy OneSource Webinar, October, 2011

NATIONAL AND LOCAL PRESENTATIONS, continued

“Compounding USP <797>: Inspection and regulation of pharmacies-State regulations and oversight.” ISMP IV Safety Summit, Horsham, PA, October 2011.

“USP: Overview for Nuclear Pharmacy Operations: Monitoring a Compounding Facility for Compliance with USP 797.” APhA2011, Seattle, WA, March 28, 2011.

“Watch Your Step: IV Room Flow with USP 797”. Pharmacy OneSource Webinar, January 19, 2011

“Better Patient Care and Safer Staff with IV Compounding Automation.” 2010 ASHP Midyear Clinical Meeting, Pasadena, CA, December 6, 2010.

“10 Tips for a More Efficient USP 797 Compliant Cleanroom.” Pharmacy OneSource Webinar, October 7, 2010

“Understanding USP 71 Sterility Tests and Extended BUD.” Pharmacy OneSource Webinar, August 4, 2010

“Hazardous Drugs: Managing them from Cradle to Grave.” Pharmacy OneSource Webinar, May 5, 2010

“When Going Lean, Waste is the Enemy.” Pharmacy OneSource Webinar, May 5, 2010

“Clarifying Training Requirement of USP 797.” Pharmacy OneSource Webinar, February 3, 2010

“The Hospital Pharmacy Guide to Radiopharmaceuticals.” 2010 ASHP Midyear Clinical Meeting, Las Vegas, NV, December 6, 2009.

“USP 797: De-mystifying Beyond-Use Dating.” Pharmacy OneSource Webinar, November 18, 2009

“The Top 10 Gaps in USP 797 Compliance” Pharmacy OneSource Webinar, September 2, 2009

“Understanding the Environmental Sampling Requirements of USP <797>.” 28th Annual Meeting, Southwest Association of Clinical Microbiology, Ft. Worth, TX, September 3, 2009

“USP <797> Update 2009.” 2009 ASHP Summer Meeting, Rosemont, IL, June 17, 2009.

“Seven Deadly Myths of USP Chapter 797” Pharmacy OneSource Webinar, March, 2009

“USP <797>: Overcoming Challenges on the Road to Compliance.” 2009 NHIA Annual Conference & Exposition, Baltimore, MD, March 1, 2009.

“USP <797> Update 2008.” 2007 ASHP Summer Meeting, San Francisco, CA, June 10, 2008.

“Practical Application of USP to Pharmaceutical Compounding and Dispensing.” The United States Pharmacopeia Chapter <797> Workshops, Bethesda, MD, March and May 2008.

“USP <797>: New Requirements for Compounding Sterile Preparations.” NHIA 2008 Annual Conference, Phoenix, AZ, March 12, 2008.

“Understanding Pharmaceutical Compounding-USP Chapter <797>.” Virginia Association of Hematologists and Oncologists. Irvington, VA, March 7, 2008.

“USP 797 Basics.” BD Medical Surgical, National Sales Training Program, Charlotte, NC and Salt Lake City, UT, February and March 2008.

“Understanding the USP process and the recent changes to USP Chapter.” 2007 ASHP Midyear Clinical Meeting, Las Vegas, NV, December 5, 2007.

“USP <797> Update 2007.” 2007 ASHP Summer Meeting, San Francisco, CA, June 27, 2007.

“A Practical and Evidence-based approach to Surveying Pharmacies for Compliance to USP <795> and <797>.” NABP 103rd Annual Meeting, Portland, OR, May 19, 2007.

“USP <797> Update” ESTECH 2007 Conference, Institute of Environmental Sciences and Technology, Bloomingdale, IL, May 1, 2007.

“USP <797>: Understanding the past, present, and future of sterile compounding regulations”. Texas Society of Health-System Pharmacists’ 59th Annual Seminar, San Antonio, TX, April 22, 2007.

NATIONAL AND LOCAL PRESENTATIONS, continued

- “Achieving USP 797 Compliance”. American Pharmacists Association 2007 Conference, Atlanta, GA, March 2007.
- “Handling Hazardous Drugs: Implementation Strategies for a Safer Work Environment: Short-term and long-term compliance activities for USP 797 and the NIOSH Alert.” 2006 ASHP Midyear Clinical Meeting, Anaheim, CA, December 6, 2006.
- “USP <797> Updates” California Society of Health-System Pharmacists Seminar, Sacramento, CA,
- “Tuning UP Your Plan for USP 797, Parts I and II” 2006 ASHP Summer Meeting, Orlando, FL, June 28, 2006.
- “USP <797>: Understanding the Air, Surface and Personnel Sampling Monitoring Requirements.” 2006 ASHP Midyear Clinical Meeting, Anaheim, CA, December 5, 2006.
- “USP Chapter <797>: Surveying for Sterile Compounding Compliance”. NABP 102nd Annual Meeting Compliance Officer Programming, San Francisco, CA, April 11, 2006
- “Extemporaneous Sterile Compounding for Preparing Clinical Supplies Roundtable: Environmental Controls Required During Extemporaneous Sterile Pharmaceutical Compounding.” 2006 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, San Antonio, TX. November 1, 2006
- “Tuning up your plan for USP 797, Part I and Part II” 2006 ASHP Annual Meeting, Orlando, FL June 28, 2005.
- “USP 797 Webinar” USP sponsored web-based conference, Bethesda, MD, June 7, 2006.
- “USP 797 Update: Next Steps” Tenet Healthcare 2006 Quality Summit. Dallas TX. February 1, 2006.
- “Automating the Compounding of Sterile Products - A USP <797> Perspective” ForHealth Technology ASHP 39th MCM Exhibitor’s Theater. Las Vegas, NV December 6, 2005
- “What’s Next for USP <797> Compliance” Baxa ASHP 39th MCM Exhibitor’s Theater. Las Vegas, NV December 5, 2005
- “USP Chapter <797>: Steps to Compliance in 2006” 40th ASHP Midyear Clinical Meeting, Las Vegas, NV, December 4, 2005
- “USP Chapter <797> and Infection Control”. Northern Chapter Monthly Meeting, Association for Professionals in Infection Control and Epidemiology, Montclair, NJ, October 26, 2005.
- “Implementing Your USP 797 Plan 6: Issues Around Outsourcing” 2005 ASHP Annual Meeting, Boston, MA June 15, 2005
- “Implementing Your USP 797 Plan 1: Environmental Monitoring, Infection Control, and Process Validation of Media Fills” 2005 ASHP Annual Meeting, Boston, MA, June 13, 2005
- “Using USP 797 to Improve Patient Care and Healthcare Processes”. 2005 INS Annual Meeting, Ft. Lauderdale, FL, May 14, 2005.
- “USP Chapter <797>: Reducing Sterile Compounding Risk”. 2005 NHIA Meeting,
- “Meeting USP <797>: Buyer Beware: Avoid costly mistakes in complying with the requirements of USP Chapter” Baxa ASHP MCM Exhibitor’s Theater. Orlando, FL, December 7, 2004
- “USP Chapter <797> Standards: An Expert Panel Offers Practical Strategies for Implementation” 39th ASHP Midyear Clinical Meeting. Orlando, FL, December 6, 2004.
- “USP Chapter <797>, The New Standard of Practice for Compounding Sterile Preparations VHA Gulf States Pharmacy Directors Meeting. Cranbury, NJ, November 18, 2004
- “USP <797> Pharmaceutical Compounding-Sterile Preparations: What is it and what does it mean to pharmacy practice?”. 2004 NABP/AACP District II Meeting, Chester, WV October 22, 2004

NATIONAL AND LOCAL PRESENTATIONS, continued

“Practical Strategies in meeting the requirements of Chapter USP <797>” The United States Pharmacopeia Chapter <797> Workshop, Bethesda, MD, August, November 2004 and May and August 2005.

“Quality Assurance and Compounded Prescriptions” The Ohio Northern University’s Raabe College of Pharmacy 14th Symposia, Ada, Ohio, July 2004.

“Your homecare practice and meeting the new USP Guidelines, The New Standard of Practice for Compounding Sterile Preparations.” Annual Education Conference, Pharmacy Society of Wisconsin, Madison, Wisconsin, April 2004.

“Understanding USP Chapter <797> Standards for Compounded Sterile Preparations.” Greater New York Hospital Association Pharmacy Directors Meeting, Flushing, NY, April 2004.

“USP Chapter <797>, Meeting the Challenges in Homecare.” Child Health Corporation of America, Homecare Directors Forum Meeting, Phoenix, AZ, April 2004.

“USP Chapter <797>, Meeting the Challenges in Hospitals.” Child Health Corporation of America, Hospital Pharmacy Directors Forum Meeting, San Antonio, TX. April 2004.

“USP <797> Pharmaceutical Compounding-Sterile Preparations: What is it and what does it mean to hospital pharmacy practice?” New Jersey Society of Health-System Pharmacists Spring Meeting, East Rutherford, NJ. April 2004.

“Sterile Preparations: A Full Day Workshop on Meeting New USP Guidelines, Regulations, and Standards of Practice for Compounding Sterile Preparations”, NHIA 13th Annual Conference, Las Vegas, Nevada. March 2004.

“Meeting the Future Challenges in Sterile Product Compounding, an overview of USP Chapter <797>”, NHIA Audio-teleconference: October 2003

“NHIA Pharmacy Compounding Conference, Regulatory Issue Focus: Sterile Product Preparation” NHIA 12th Annual Conference, San Antonio, Texas. February 2003.

“Designing Robust Sterile Compounding Conditions” NHIA Regional Conference: Quality and Compounding-Meeting the New Challenge in California, Sacramento, California. September 2002.

“Sterile Product Preparations-Mix or Buy?” Maryland Society of Health-System Pharmacist, March Meeting. Columbia, Maryland. March 2002.

“Impact of Accreditation: ACHC” NHIA Clinical Track Conference Program: NHIA 11th Annual Conference, Las Vegas, Nevada. February 2002.

“Pharmacy Compounding Errors: Learn the Lessons Before They Occur.” Expert Panel Presentation. International Academy of Compounding Pharmacists. IACP National Meeting, Houston, Texas, October 2001.

“Nursing and Pharmacy Collaboration in Alternate Care Setting” NHIA Clinical Track Conference Program: NHIA 9th Annual Conference, Cincinnati, Ohio. May 2000.

“1999 National Clinical Meeting, Maximizing Divisional Synergies: The Clinical Approach to Customer Service”. Phoenix, Arizona, Coram Healthcare Corporation. Program Organizer, Director, and Presenter. October 1999.

“Pharmacologic Management of Preterm Labor.” Various conferences nationwide. (1994-1998)

“Infusion Pharmacy Services: Improving Management, Operations, and Cost-Effectiveness.” NHIA Pre-Conference Program: NHIA 7th Annual Conference, Pittsburgh, Pennsylvania. May 1998