

Kate Douglass, MS, RN
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EDUCATION

American Society of Training and Development	Advanced eLearning Instructional Design Certificate
Seton Hall University	Clinical Pharmacology: post graduate level
Rutgers, The State University of New Jersey Graduate Program Newark, New Jersey	Master of Science, Nursing; GPA: 4.0 of 4.0
Villanova University College of Nursing Villanova, Pennsylvania	Bachelor of Science, Nursing

PROFESSIONAL EXPERIENCE

Consultant to Industry	Contec Healthcare a division of Contec Inc.	December 2020-present
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Provide regulatory interpretation of USP nonsterile and sterile compounding standards as well as best practices in sterile compounding and contamination control. Provide guidance to sales team, specialty dealer representatives, company clinical support, marketing and administrative teams. Established and leads the Contec Clinical Advisory Committee consisting of; Patricia Kienle, RPh, MPA, BCSCP, FASHP; Melissa A. McDiarmid, MD, MPH, DABT and MiKaela Olen DNP, APRN-CNS, AOCNS, FAAN and others.

Vice President and Chief Learning Officer	CriticalPoint, LLC d/b/a Performance Strategies, LLC	November 2010-September 2020
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Joined CriticalPoint, LLC full-time after long consulting history. Together with staff developed and maintained the Sterile Compounding Boot Camp curriculum held at the CriticalPoint Center for Training and Research in Totowa, NJ as well as all of CriticalPoint's extensive eLearning offerings. Coordinated the building of this 4M center with state of the art classroom, two ISO 4 buffer rooms, large ISO 8 anteroom and Containment Segregated Compounding Area. During tenure trained approximately 1000 pharmacists and technicians from all states and Canadian territories. Developed Sterile Compounding Inspector Training, partially sponsored by the National Association of Boards of Pharmacy which provided training and competency verification of pharmacy compounding inspectors from all states. Developed and maintained the CriticalPoint Peer Network.

President	Cognitive Design Associates, LLC d/b/a Performance Strategies, LLC	December 2005-October 2010 May 2002-December 2002
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Healthcare consulting firm that assisted providers, laboratories, manufacturers and other healthcare related businesses to develop new product lines or implement initiatives to achieve simultaneous quality and cost performance improvement using strategic business integration methodology. Consultative expertise and evaluation of current clinical and administrative SOPs, staff education and performance as they relate to the current standard of care. Consultative expert to healthcare attorneys representing clients in infusion related nursing and pharmacy practice.

Vice President Operations/Sales Chief Operating Officer	SoluNet LLC 11B Commerce Way Totowa, NJ 07512-1154	January 2003-September 2004 October 2004-November 2005
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Rejoined Coram Healthcare to serve as VP of this Coram affiliate formed on the basis of the original business model brought to Coram by Cognitive Design Associates in 1999. SoluNet provided compounded sterile preparations to hospitals through both pharmacy and FDA manufacturing models and was acquired by B. Braun CAPS in 2006. Responsible for all aspects of company operations, profitability, sales, marketing and product line development. Successfully built and opened 4 USP <797> compliant pharmacy compounding outsourcing facilities in highly competitive markets (Boston, MA; Hartford, CT; Greater NY/NJ market and Dunbar, WV). Opened FDA manufacturing operation in Totowa, NJ providing non-patient specific

compounded preparations to hospital clients. Developed all policy, procedures, performance improvement, marketing, employee training and sales/marketing materials.

**Senior Vice President
Clinical Operations**

**Coram Healthcare
11H Commerce Way
Totowa, NJ 07512**

February 1999-April 2002

Entered company as VP, Nursing. Promoted to Senior VP of Clinical Operations after 1 year with responsibility for 72 facilities in 44 states. Designed and implemented new service model (Primary Case Management Model) resulting \$47/patient clinical cost reduction (\$1.3M annually); 9% increase patient satisfaction relating to education of side effects of drug therapy; reduction in catheter related complications (5.6% to 4.4% damage/occlusion); and increased pharmacist involvement in clinical management. Responsible for developing, implementing and overseeing enterprise-wide clinical operations components as it relates to the delivery of patient care and to maximizing overall company profitability. Re-engineered performance improvement program; initiated Clinical Activity Matrices and patient care mapping as well as on line activity and patient outcome reports to measure the ongoing delivery of care and achievement of desired therapeutic patient outcomes through continuous refinement of clinical and operational processes that resulted in maximally cost effective use of organizational resources. Initiated unannounced accreditation surveys at all locations through ACHC. Responsible for drug and supply formulary changes that resulted in achievement of \$1.9M cost savings and \$2M margin enhancement over 1 year.

President

Cognitive Design Associates, LLC

May 1997-February 1999

Initiated and developed all aspects of company operations with mission to become leading provider of customized educational strategies for performance improvement in the healthcare industry. CDA facilitated the achievement of identified organizational goals through a performance consulting methodology. Developed customized Interactive Computer-Assisted Learning Modules (ICALMs) for employee education competency verification. Assisted clients in new product line development and launch; process design; service model revision, clinical and operational SOP development; competency tool development; and instructional design for the hospital and homecare markets. Negotiated and completed sales of significant company assets to Coram Healthcare.

Executive Vice-President

Millers Homecare Services, Inc.

December 1995-May 1997

Rejoined Millers and was responsible for all aspects of business operations for Millers Homecare Services, Inc. including Home Medical Equipment and Respiratory Therapy, Rehabilitation Technology, Infusion and Nursing Agency Supply divisions. During tenure increased sales 28%, managed care and direct marketing components added, new facility licensed and opened, reorganized entire corporate structure to gain efficiencies, gained ability to draft all contracts in house through attorney mentorship, created new product lines, and instituted new clinical/reimbursement software. Position eliminated due to potential acquisition.

Healthcare Consultant

July 1994-December 1995

Independent consultant to health care organizations, assisting to develop strategies for achievement of excellence in IV and Oncology care; development of inservice and continuing education programs; instruction and preception of PICC certification courses; consultation to devise efficient billing mechanisms to decrease DSO; expansion or internal audits in preparation for survey by accrediting bodies and regulatory agencies; develop continuous performance improvement mechanisms; medical-legal consultation; assist with the development and delivery of corporate presentations. Collected \$1.5M for one client through submission of unbilled claims.

Regional Clinical Manager

**Infu-Tech, Inc.
145 W. Commercial Avenue
Moonachie, NJ**

April 1994-July 1994

Nurse Manager

**Quantum Health Resources
11 Commerce Way; Totowa, NJ**

January 1994-April 1994

Director, Millers Home Infusion

**Millers of Wyckoff, Inc.
678 Wyckoff Avenue; Wyckoff, NJ**

September 1990-January 1994

Clinical Nurse Specialist

**Visiting Health Services of New Jersey, Inc.
678 Riverview Drive; Totowa, NJ**

May 1989-May 1990

Oncology Administrative Coordinator	Newark Beth Israel Medical Center 201 Lyons Avenue; Newark, NJ	August 1987-January 1989
Hospice Director	Tri-Hospital Home Health Program Beth Israel Hospital Passaic, NJ	July 1985-June 1987
Data Management Consultant		April 1985-May 1986
Research Assistant	Concurrent with Graduate School	January 1985-June 1985
Oncology Public Health Nurse	Community Nursing Service of Delaware County	October 1982-July 1983
Primary Nurse-Oncology	Thomas Jefferson University Hospital Philadelphia, PA	July 1979-October 1982

APPOINTMENTS/ACTIVITIES

- Member Editorial Review Board; Journal of Infusion Nursing; 1998 to 2016.
- Faculty APEx Aseptic Compounding Training Course offered by ClinicalIQ and Controlled Environmental Consulting; ongoing.
- Beta tester and reviewer for the American Society of Health Systems Pharmacist product "797 Compliance Advisor"
- Beta tester and manuscript reviewer for 1st (2002) and 2nd (2005) editions of the American Society of Health Systems Pharmacists product "Sterile Product Preparation: A Multimedia Learning Tool"
- Member Advisory Board; National Home Infusion Association; Home Infusion Pharmacy Certificate Program; 2002-2003
- Chair, Education Committee; National Home Infusion Association 2002-2003; Vice-Chair, Education Committee 2001-2002; Member Education Committee 1997-2002.
- Resource Person, Intravenous Nursing Society Nursing Network. 1997-1998.
- Expert field reviewer for the Oncology Nursing Society's "Access Device Guidelines: Recommendations for Nursing Practice and Education. Dawn Camp-Sorrell Editor. Oncology Nursing Press: Pittsburgh, PA, October, 1996.
- Member of the DMERC Advisory Committee, 1996-1997.
- Member of the Expert Witness Program sponsored by the New Jersey State Nurse's Association for the specialty areas of Oncology, Chemotherapy, and Pain Management. 1990-2000.
- Expert reviewer for manuscript entitled *Prostate Cancer for Nurses*, to be published by Jones and Bartlett Publishers in 1999.
- Nursing Practice Consultant with the New Jersey State Board of Nursing; December, 1989-December, 1992; Reinvited December, 1992- December, 1996.
- National and founding Coordinator of the Oncology Nursing Society, Patient Education Special Interest Group, May, 1991.
- Appointed to task force developing statewide cancer plan by Department of Health, Commissioner of Health, November, 1990.
- Co-Chair of the Bereavement Committee, Newark Beth Israel Medical Center; September, 1988.
- Mentor for the Guest Relations Program; Newark Beth Israel Medical Center; 1988-89.
- President of the Graduate Nurse's Alliance, Rutgers University; August, 1984-May, 1985.

PAPERS/PUBLICATIONS

- Douglass K & Roth A. Part 3 of 3. [Answers to Common Cleaning Questions](#). Pharmacy Purchasing & Products Magazine. Vol 17. No 9. September 2020.

- Douglass K & Roth A. Part 2 of 3. [Practices to Drive Effective Cleaning](#). Pharmacy Purchasing & Products Magazine. Vol 17. No 6. June 2020.
- Douglass K & Roth A. Part 2 of 3. [Principles that Drive Effective Cleaning](#). Pharmacy Purchasing & Products Magazine. Vol 17. No 3. March 2020.
- Kienle P and Douglass K. [Perform an Assessment of Risk to Comply with USP <800>](#). Pharmacy Purchasing & Products Magazine. Vol 14 No 3. March 2017
- Douglass K, Richter A, Dorey M and Rizvi I. [Refining PPE Usage for HD Compounding: Part 1](#). PPPMag. Vol 14, No. 2; February 2017.
- Douglass K. [Compliant Garbing Practices for Sterile Compounding](#). PPPMag. Vol 14; No 1, January 2017.
- Kastango E, Douglas K. The 2017 USP <800> Compliance Study: A National Study of Hazardous Drug Compounding Practices Gap Analysis Tool. CriticalPoint, LLC.
- Kastango E, Douglas K. The 2017 USP <800> Compliance Study: A National Study of Hazardous Drug Compounding Practices Gap Analysis Tool. CriticalPoint, LLC.
- Douglass K. [Best Practices for Cleanroom Cleaning Documentation](#). PPPMag. October 2014. Vol 11. No. 10.
- Kastango ES, Douglass K, Patel K et al. [Safer Sterile Compounding: Choosing and Using Disinfectants for the Cleanroom](#). International Journal of Pharmaceutical Compounding. Vol 19 No 4; July 2015.
- Kastango, ES and Douglass K. [Quality Standards for Large Scale Sterile Compounding Facilities](#). Paper commissioned by the Pew Charitable Trust. May 2014.
- Cantor P, Douglass K, Kastango ES. [Let this Be your Wake-Up Call](#). PPPMag. Vol 11, No 10. October 2014.
- Cantor P, Douglass K, Kastango ES. PPPMag. [The 2014 USP Chapter <797> Compliance Survey](#). Vol 11, No 10. October 2014
- Douglass K, Kastango ES, Kienle PC, Power LA. [Understanding the New Proposed USP Chapter <800>](#). PPPMag. Vol 11, No 6. June 2014.
- Douglass K, Kastango ES. [Requirements and Best Practices for Sanitizing Engineering Controls](#). PPPMag. Vol 10. No 9; September 2013.
- Douglass K. [Top 10 Effective Cleaning Practices](#). PPPMag. Vol 10. No 1. January 2013.
- Douglass K, Kastango ES, Cantor P. [The 2012 USP <797> Compliance Survey: Measuring Progress](#). Originally published in Pharmacy Purchasing and Products Magazine. October 2012.
- Douglass K. [Support Patient Safety with a Robust Cleaning Program](#). PPPMag. Vol 9. No 9. September 2012.
- Douglass K. [Environmental Monitoring and Sampling: Expanding on Facility and Personnel Related Performance Metrics](#). PPPmag. Vol 6. No 10. October 2009
- Douglass K. [Cleanrooms and Compounding: Staff Training](#). PPPMag. Vol 4, No 10. October 2007.
- Douglass, K. [Facilitating a Quality Culture Through Effective Staff Training and Competency Assessment](#). Pharmacy Purchasing and Products Magazine. 2007. 4S(10): 1-4.
- Douglass K. [Design Your Cleanroom to Ensure Easier Use, Cleaning and Maintenance Part 2](#). PPPMag. Vol 3, No 3, April 2006.
- Douglass K. [Design Your Cleanroom to Ensure Easier Use, Cleaning and Maintenance Part 1](#). PPPMag. Vol3, No 2. March 2006.
- Douglass, K. Effective Strategies for Cleanroom Budget Approval. Pharmacy Purchasing and Products Magazine. 2006. 3(4): 8-10.
- Douglass, K. [Training and Competency Considerations for Pharmacies providing compounded sterile preparations](#). *Int J Pharm Compd*. 2006. 10(4): 253-261.
- Trissel, LA, Zhang, Y, Douglass, K, and Kastango, E. [Extended Stability of Oxytocin in Common Infusion Solutions](#). *Int J Pharm Compd*. 2006. 10(2): 156-158.
- Douglass, K. Cleaning Your Cleanroom: Three Time Cleaning and Cleaning in the Event of a Power Outage. Pharmacy Purchasing and Products Magazine. 2005. 2(7): 4, 6-7.
- Douglass, K. [Establishing Sound Practices for Cleaning Your Cleanroom: Cleaning Products and Procedures for USP <797> Compliance](#). Pharmacy Purchasing and Products Magazine. September 2005. 2(5): 16-19.
- Douglass K, Kastango, ES. [Quality Assurance for Sterile Products](#). *Int J Pharm Compd*. 2001. 5(4): 246-253.
- Kastango, ES and Douglass, K. [Consolidation of Pharmacy Compounding Services: An Alternative to Outsourcing](#). *Int J Pharm Compd*. 2001. 5(2): 140-144.

- Kastango, ES. and Douglass, K. [Improving the Management, Operations, and Cost Effectiveness of Sterile Product Compounding](#). 1999. 3(4): 253-258.
- Douglass, K. It's time to stop treating adults like children: Re-engineering the traditional approach to education. INFUSION. 1998. 4(6): 22-27.
- Author of "Cookbook for Caring and Comfort" and "Managing your Pain at Home: A Guide for patients and their families" which includes 18 symptom management teaching tools related to chemotherapy side-effects; Copyright, 1991.
- Revised the Learned Helplessness Scale (Quinless, 1983) and piloted the tool to obtain further reliability and validity data via Alpha Coefficients, Pearson Correlation, and Factor Analysis. Scale stability data obtained Fall, 1985.
- Douglass, K. The Paradox of Pain. Straight Talk: A publication of the Council on Nursing Practice. Newark Beth Israel Medical Center. Winter, 1988.

PRESENTATIONS

- "Implementing USP <797>: Facility, Equipment and Strategizing for USP <797> Compliance Budget Approval" at the American Society of Health Systems Pharmacists Summer Meeting; Boston, MA, June 13, 2005.
- "Nursing and Pharmacy: Visions for New Service Models that Achieve True Collaboration" at the National Home Infusion Association Dinner Symposium held at the Infusion Nursing Society Annual Conference; Nashville, TN; May 30, 2003.
- "Creative Staffing for Home Infusion Organizations" NHIA Regional Conferences; Atlanta, GA March 21, 2003 and Chicago, IL; May 2, 2003.
- "Nursing Cost Management" at the National Home Infusion Association Executive Preconference (Enhanced Costing Strategies for Sustainable Third Party Contracting); San Antonio, TX; February 2, 2003.
- "Working with Home Health Agencies: Changing the Paradigm" at the National Home Infusion Society Annual Conference; San Antonio, TX; February 5, 2003.
- "Beyond Staffing Models: Practical Considerations for Managing Nursing Costs in Home Infusion" at the Infusion Nursing Society Annual Meeting; Phoenix, AZ; May 8, 2002.
- "Maximizing Home Infusion Operations: Strategic Integration of Clinical, Operation, Sales, and Finance" at the National Home Infusion Association 11th Annual Conference; Las Vegas, NV; Feb 8, 2002,
- "Nursing and Pharmacy Collaboration in Alternate Site Settings" at the National Home Infusion Association 9th Annual Conference; Cincinnati, OH; May 18, 2000.
- "Caring for Patients with AIDS" Visiting Nurse and Health Services, Elizabeth, NJ December, 1989.
- "Facilitating Patient/Family/Staff Self-determination: The Implementation of a Self-Care Oncology Unit." Roundtable, ONS Congress, San Francisco, CA; May 18, 1989.
- "Hospice Care: The right to die" at Beth Shalom Reform Temple; Clifton, NJ November 2, 1986.

AWARDS/HONORS/CERTIFICATIONS

- 2013-2014 Co-Recipient (other recipient Eric S. Kastango) of the Henry Cade Memorial Award given by the National Association of Boards of Pharmacies Executive Committee in recognition of her support of the goals and objectives of the NABP and the state Boards of Pharmacy.
- Achieved QP503A certification in 2014 and maintained through 2019.
- CRNI certification by the Intravenous Nurses Certification Corporation in November, 1991; maintained continuous recertification through 2010
- AOCN (Advanced Oncology Certification) from the Oncology Nursing Certification Corporation; May, 1996.
- Attained OCN certification from the Oncology Nursing Certification Corporation; December, 1988-2000
- Recipient of the Award for Academic Excellence, The Graduate School of Rutgers University, Newark, NJ, May, 1985.
- Federal Nurse Traineeship Grant Recipient, January-June, 1984.
- ANA certification in Medical Surgical Nursing; October, 1982.

NURSING REGISTRATIONS

New Jersey: Advanced Practice Nurse; License 26NC05722900; inactive
New York: 422934-1

REFERENCES

Furnished upon request.