Pennylee Truax Bellows
17 Mar 15

PENNYLEE (LEE) TRUAX-BELLOWS, MS, FNP, CCRA, RQAP-GCP
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WORK EXPERIENCE

Norwich Clinical Research Associates Ltd. 1994 – Present

President (2001 – current / CEO (2003 – current)
Duties include: overall management of all NCRA business and personnel, personnel training, marketing, contract budgeting and all tasks specific to clinical research conduct for pharmaceuticals, medical devices and nutraceuticals, and duties consistent with company presidency and chairmanship of the BOD.
Chairperson for Board of Directors (2003 – current)
Auditor (1999 – Current) SQA Registered in 2007
Duties include: GCP and Corporate auditing and reporting.
Project Manager (1994 – Current)
Duties include: Project Management for regulated device and drug trials.
Director, Clinical Operations (1996 – current)
Duties include: GCP Auditing, overall management of Clinical Research Assistants (CRAs) and Data Management personnel (DMAs), CRA and DMA training, marketing, contract budgeting, SOP formulation, review, and updates, all tasks specific to clinical research conduct.
Previous Monitor (1994 – 1996)
Duties included: all on-site and remote monitoring activities
Previous Vice Chairperson of Board of Directors (1997 – 2003)
Previous Vice-President Company ((1998 – 2001))
Duties included: co-author of study protocols, designing study case report forms/patient diaries, budgeting, coding of data for entry into database, establishment and maintenance of project timeline as part of a team, set up of clinical sites which included recruiting, contract negotiation, site-staff training, start-up, monitoring, and close-down of sites, site payments, and adverse event evaluation and reporting to in-house Regulatory and Medical Surveillance.

NOTE: Experience includes pharmaceutical products for Attention Deficit Hyperactivity Disorder (ADHD), diabetes, cardiovascular, muscular dystrophy, oncology, rosacea, auto-immune thrombocytopenia purpura (ITP), cystic fibrosis, mixed and stress incontinence, wound healing/scaring (including athrofibrosis), influenza, chronic kidney disease, herpes virus, schizophrenia, sickle-cell anemia, hypertension and diabetes for dietary supplements/nutraceutical products and for device products imaging, thermography, cardiovascular angioplasty, AAA stents, endobronchial valve therapy, Lasik, Minimal Invasive Surgery (MIS), trocar-cannula systems, PTCA wires and atherectomy systems, VSD/VSA/PFO closures, muscle stimulators, back brace, neuro-stimulator, meniscus replacements, stress incontinence, hyperthermia systems, non-invasive blood pressure monitoring (NIBP), Opto-acoustics, thermometry, spirometry and ECG. Encompassed drug, device and nutritional products for function health

claims, 510[k]/PMAs, QSR clinical validation, IDE and IND Phase 1-III studies, registry studies and post-marketing research. Extensive experience assisting companies under both company and study-specific integrity holds.

State University of NY, Binghamton, NY 2000

Adjunct Professor
Course preparation and teaching of a 3 Credit, Graduate/Doctoral level course, titled *The Conduct of Regulated Clinical Research from the Monitoring & Data Management Perspective.*

Bassett Research HealthCare, Cooperstown, NY 1995

Public Health Nurse Researcher
Duties included: collation and analysis of data specific to Otsego county for submission of the bi-yearly Community Health Assessment to the New York State Department of Health (NYSDOH), collation of data and co-author and submission of grant application for rural school-based clinic to the NYSDOH, co-author and submission of grant to the NYSDOH for a health care professional training program on HIV/AIDS, formulation and co-teaching of seminar for school health teachers on sexuality and drug abuse under the Scientific Educational Partnership Award program.

Procter & Gamble Pharmaceuticals, Inc. 1990 – 1994

Clinical Research Associate
Duties included: co-author of study protocols, designing study case report forms/patient diaries, budgeting, coding of data for entry into database, establishment and maintenance of project timeline as part of a team, set up of clinical sites which included recruiting, contract negotiation, site-staff training, start-up, monitoring, and close-down of sites, site payments, and adverse event evaluation and reporting to in-house Regulatory and Medical Surveillance.

NOTE: Products included cardiac, nutritional and encompassed Phase I, II and IV studies.

Associate Scientist in Medical Communications
Duties included: researching and constructing Medical Communication letters for outside health care professionals concerning marketed products, ad copy review, assigned research and review of specific adverse event trends, formulation of department policy and procedures, continuous literature review pertinent to assigned products, first contact for adverse events reported by consumers and health care professionals, responding to health care professionals' questions on marketed products and disease process related to the products, preparation of standard responses for new product launches, review of pertinent computer software for applicability to department.

NOTE: Products included respiratory, gastrointestinal, urinary antibiotic, and bone focus.

State of NY, Broome Developmental Center, Oneonta, NY 1984 – 1989

Registered Nurse Level I

Fox Memorial Hospital, Oneonta, NY 1981 – 1984

Relief Charge Nurse and Staff Nurse

Genesee Nursing Home, Utica, NY 1975 – 1980

Nursing Supervisor

PROFESSIONAL EDUCATION

Society of Quality Assurance (SQA)
Registered Quality Assurance Professional in Good Clinical Practices Auditing Certification Since 2007 - ongoing

Association of Clinical Research Professionals
Clinical Research Assistant Certification Since 1998 - ongoing

Binghamton State University of New York, Binghamton, NY 1994 – 2002
M.S., majoring in Nursing Administration
M.S., majoring in Family Nurse Practitioner (Advanced Nursing)

Hartwick College, Oneonta, NY 1987 – 1990
B.S. majoring in Nursing

Mohawk Valley Community College, Utica NY 1973 – 1975
A.D.S., RN

PUBLICATIONS

- Ferdous Al-Faruque, *Interview With Lee Truax-Bellows, Don't Play Catch-Up With FDA Inspections, Avoid Form 483s*, Clinical Trial Advisor Newsletter Aug. 15, 2013
- Lee Truax-Bellows, *Surviving the Aftermath of an FDA Clinical Trial Inspection (Part 2)*, Journal of Clinical Research Best Practices, June 2013, Vol. 9, No. 6
- Lee Truax-Bellows, *The Relationship Between Humanitarian Use Device (HUD) Designation and Humanitarian Device Exemption (HDE) Approval*, Monitor April 2013, Vol. 27 Issue 2
- Lee Truax-Bellows, *Surviving the Aftermath of an FDA Clinical Trial Inspection (Part 1)*, Journal of Clinical Research Best Practices, March 2013, Vol. 9, No. 3
- Lee Truax-Bellows, *Adverse Event Differences Between Investigational Devices and Drugs: Perceived or Actual?*, Monitor, June 2009, Vol. 25 Issue 1

PRESENTER / TRAINER AT SEMINARS/WEBINARS/WORKSHOPS/COURSES

Ms. Truax-Bellows was awarded Top Speaker Award for the ACRP 2014 Global Conference

- FDA Inspections: Handling the Consequences: MAGI West Conference November 2014
- Quality System Risk Management Tools Workshop: MAGI West Conference November 2014
- FDA/EMA Inspection Lessons Learned: Protocol Deviations –Why They Occur and How to Handle Them, July 2014
- Key Skills For Ensuring Quality Control, ACRP Classroom Course, June 2014
- Building Quality Management Systems (QMS) for Sites and Sponsors, ACRP Classroom Course, June 2014
- What IS the Relationship Between an FDA HDE (Humanitarian Device Exemption) & HUD (Humanitarian Use Device) or are They the Same?, AudioEducator Webinar May 21014
- Implementing Effective Corrective and Preventive Action Processes in Clinical Trials Workshop, ACRP April 2014
- Key Concepts in IRB Review of Medical Device Studies, ACRP Annual Conference April 2014
- Comparing ICH E6 With ISO 14155 Medical Device GCPs, ACRP Annual Conference April 2014
- GCP: Beyond the Basics Workshop, SQA Spring Quality College, April 2014
- Advanced GCP Workshop, MedTech March 2014
- FDA/EMA Inspection Lessons Learned: How Adequate Monitoring Can Reduce or Avoid Findings, ACRP Webinar March 2014
- IRB Responsibilities: Investigator Qualifications, Adequacy of Sites, & IND/IDE Requirement Determination Per the August 2013 FDA Guidance, ACRP Webinar January 2014
- Declaration of Helsinki Updates and the Impact on You, ACRP Webinar, December 2013
- Medical Device Regulations: MAGI October 2013
- Corrective and Preventive Action (CAPA) Plans: MAGI October 2013
- Good Clinical Practice: Beyond the Basics Workshop: SQA Spring Quality College September 2013
- Good Clinical Practice: Beyond the Basics Workshop: SQA Spring Quality College May 2013
- Using Requests for Proposal as the First Step in Setting Quality Expectations with Potential Vendors: SQA Annual Conference April 2013
- The Future of Clinical Trial Conduct Demands a Quality System Approach: Are You Ready? Workshop: ACRP Global Conference April 2013
- Advanced GCP Workshop: MedTech Institute March 2013
- Budgeting For Device Studies, ACRP Webinar October 2012
- GCP: Beyond the Basics Workshop: SQA Fall Quality College October 2012
- FDA Inspections: Handling the Consequences: MAGI East Conference May 2012
- GCP: Beyond the Basics Workshop: SQA Spring Quality College April 2012
- Utilizing a Risk-based Approach to Meet Sponsor Monitoring Obligations: SQA Annual Meeting April 2012
- Comparative Effectiveness Research: Has the Time Come? : ACRP Global Meeting April 2012

PRESENTER / TRAINER AT SEMINARS/WORKSHOPS/COURSES (CONTINUED)

- Overview of Device Clinical Trial Risk Management Models, Including a Six Sigma Case History: ACRP Global Meeting April 2012
- Advanced GCP Workshop: MedTech Institute March 2012
- Advanced Competency for Device Professionals: ACRP Alexandria November 2011
- Advanced Competency for Device Professionals: ACRP Minneapolis October 2011
- Advanced Competency for Device Professionals: ACRP San Francisco September 2011
- FDA Inspections: Handling the Consequences & Challenges in Conducting Medical Device Trials: MAGI West Conference October 2011
- GCP: Beyond the Basics Workshop: SQA Fall Quality College Meeting September 2011
- Advanced Competency for Device Professionals: ACRP San Diego June 2011
- Risk Management in Clinical Trials Workshop: ACRP Global Conference April 2011
- Advanced Competency for Device Professionals: ACRP Seattle April 2011
- GCP: Beyond the Basics Workshop: SQA Annual Meeting April 2011
- Advanced GCP: MedTech Institute April 2011
- FDA Inspections: Handling the Consequences – Dealing With the Aftermath of an FDA Inspection at a Sponsor or Site: MAGI West Conference October 2010
- Advanced Topics in GCP: A Global GCP QA Workshop: SQA Spring Quality College April 2010
- Risk Management in Clinical Studies: SQA Spring Quality College April 2010
- Site Quality System Approach for Meeting Investigator Supervisory Responsibilities Workshop: ACRP Global Meeting April 2010
- Comparing and Contrasting Safety Reporting in Drug and Device Trials: ACRP Metropolitan Chapter Education Session November 2009
- Current Topics in GCP: Risk Management in Clinical Studies: SQA Quality College Workshop September 2009
- Advanced Topics in Good Clinical Practice: MedTech June 2009
- Applying a Quality Systems Approach to Clinical Device Research: ACRP Global Meeting April 2009
- Comparing and Contrasting Safety Reporting in Drug and Device Trials: ACRP Global Meeting April 2009
- Advanced Topics in GCP: A Global GCP QA Workshop and Seminar: Risk Management in Clinical Studies: SQA Annual Meeting April 2009
- Errors in GCPs – Preventing Nightmares: How Proper Institution of GCPs Principals Assures Meeting of FDA Regulations: ACRP October 2008
- Application of GCPs to 510(k) Device Studies: SQA, Fall Training, September 2008
- Application of GCPs to 510(k) Device Studies: SQA April 2008
- Errors in GCPs – Preventing Nightmares: How Proper Institution of GCPs Principals Assures Meeting of FDA Regulations: ACRP April 2008
- Practical Issues in Medical Device Clinical Trials: Quality Systems Roundtable Discussion: AdvaMed April 2008
- Conducting Studies to Meet Good Clinical Practice Requirements Workshop: MedTech March 2008
- GCP in Medical Device Clinical Trials: Interactive Workshop in Conducting, Monitoring, Financing and Inspecting Device Studies: RxTrials July 2007

PRESENTER / TRAINER AT SEMINARS/WORKSHOPS/COURSES (CONTINUED)

- Monitoring Medical Device Trials Tele-seminar: RxTrials/FDANews May 2007
- What Is Device Risk Management and Why Should I Care Workshop: ACRP NA Annual Meeting April 2007
- Successful Collaborations in the Good Clinical Practice (GCP) Conduct of Clinical Research: MedTech, April 2006
- Good Clinical Practices Throughout the Life-cycle of a Medical Device: ACRP Tele-seminar, November 2006
- Good Clinical Practices Throughout the Life-cycle of a Medical Device: ACRP NA Annual Meeting May 2006
- Regulated Clinical Research: Is It For You?: IEEE/EMBS Speaker Series Binghamton NY State University, April 2005
- Adverse Event/Complication Capture in Device Trials: Are We Capturing What We Should Be?: ACRP NA Annual Meeting April 2005
- Clinical Studies in Medical Devices versus Pharmaceuticals: An Overview: ACRP Western NY Chapter, October 2004
- Clinical Studies in Medical Devices versus Pharmaceuticals: An Overview: ACRP CNY Chapter, September 2004
- Clinical Studies in Medical Devices versus Pharmaceuticals: An Overview: State University of New York, Syracuse, NY, September 2004
- Clinical Studies in Medical Devices versus Pharmaceuticals: An Overview: ACRP New England Chapter, September 2004
- Research with Medical Devices and Drugs – What is the Difference: ACRP Atlanta Chapter, September 2004
- Consultation and Administration in the Advanced Nurse Practitioner Role: Binghamton Univ., Binghamton, New York, February 2001
- Emerging Roles for Nurses in the Conduct of Regulated Clinical Trials: Hartwick College, Oneonta, New York, April 2000 Emerging Roles for Nurses in the Conduct of Clinical Trials: Univ. of Tennessee, August 1999

RELEVANT TRAINING

Continuing education and training are required to support both of my professional certifications and meet regulatory obligations. Relevant training records are supplied upon request.

GRANTS

Implementation Grant for School Based Health Centers in the "Making the Grade" Program. Dr. E. Lewin, Dr. A. Gadomski, Dr. C. Lewis, PL Truax-Bellows, R.N., B. McLaud R.N., T. Colletti, P.A., and D. Franklon.

Grant for HealthCare Professional HIV/AID Educational Program. Dr. C. Lewis and PL Truax-Bellows, R.N.

PROFESSIONAL MEMBERSHIPS/COMMITTEES

Association of Clinical Research Professionals (ACRP)
- Device Interest Group Steering Committee
- Global Conference Planning Committee
- ACRP Academy Board CRA Working Group

Society of Quality Assurance (SQA)
- Clinical Specialty Section
  - Electronic Medical Records Whitepaper Sub-committee Chair