

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

WORK EXPERIENCE

Norwich Clinical Research Associates Ltd. 1994 – Present

President (Since 2001) current / CEO (since 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 (since 2003) current

Auditor (6 years) Registered in 2007

Duties include: GCP and Corporate auditing and reporting.

Project Manager (12 years)

Duties include: Project Management for regulated device and drug trials.

Previous Vice Chairperson of Board of Directors (5 years)

Previous Vice-President Company (3 years)

Director, Clinical Operations and Data Management (11 years)

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 and duties consistent with vice-presidency.

Clinical Research Associate (4 years)

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), nutritional metabolic (diabetes), cardiac (anti-arrhythmic and heart failure), oncology, rosacea, auto-immune thrombocytopenia purpura (ITP), cystic fibrosis and for device products thermography, cardiovascular angioplasty, AAA stents, Minimal Invasive Surgery [MIS] trocar-cannula systems, PTCA wires, VSD/VSA/PFO closures, muscle stimulators, back brace, ventricular septal defect closures, meniscus replacements, stress incontinence, hyperthermia systems, NIBP, thermometry, spirometry and ECG. Encompassed drug, device and nutritional products for pre- (510[k], QSR clinical validation, IDE and NDA Phase I-III studies, and post-marketing research.

State University of NY, Binghamton, NY 2000

Adjunct Professor

Duties included: 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

RN I

Fox Memorial Hospital, Oneonta, NY 1981 – 1984

3-11 Relief Charge Nurse and Staff Nurse

Genesee Nursing Home, Utica, NY 1975 – 1980

3-11 Supervisor

PROFESSIONAL EDUCATION

Society of Quality Assurance

Registered Quality Assurance Professional in Good Clinical Practices Auditing Certification ongoing

Association of Clinical Research Professionals

Clinical Research Assistant Certification ongoing

Binghamton State University of New York, Binghamton, NY 1994 – 2002

M.S., majoring in Nursing Administration

M.S., majoring in Family Nurse Practitioner

Hartwick College, Oneonta, NY 1987 – 1990

B.S. majoring in Nursing

Mohawk Valley Community College, Utica NY 1973 – 1975

A.D.S., RN

RELEVANT ADDITIONAL TRAINING

Advanced Training: Good Clinical Practice, Society of Quality Assurance, May 2007

ACRP 2007 Annual Global Meeting (9 total credits), April 2007

Skills for Presenters and Trainers, ACRP CNY Chapter Seminar, April 2006

FDA Auditing of Computerized Systems and Part 11, EduQuest, Inc., December 2006

Introduction to Systematic Risk Management, EduQuest, Inc., December 2006

Corrective and Preventative Action (CAPA) System, EduQuest, Inc., December 2006

Patient Recruitment Strategies for the Sponsor and Site, ACRP CNY, October 2006

Basic Training: Good Laboratory Practice (included auditing training), Society of Quality Assurance, September 2006

Advanced Training: Good Laboratory Practice (included auditing training), Society of Quality Assurance, September 2006

Introduction to the Principles of Computer Validation (included auditing training), Society of Quality Assurance, September 2006

Advance Concepts in Computer Validation (included auditing training), Society of Quality Assurance, September 2006

Disaster Preparedness, CNY MedTech, September 2006

Regulation and Guidelines for Device Clinical Research, SoCRA, June 2006

GCP Quality Assurance Auditing, ACRP CNY Chapter Seminar, June 2006

AAMI Training and Certification on Quality System Requirements & Industry Practice, CNY Med Tech, September 2005

Time Management for Clinical Research Professionals, ACRP CNY Chapter Seminar, June 2005

Reimbursement: How it Can Impact Device Studies, ACRP CNY Chapter Seminar, March 2005

How to Write Certification Exam Questions, ACRP, May 2004

Informed Consent: The Art of Respect, ACRP CNY Chapter Seminar, April 2004

Budgets: Know Your Costs, ACRP CNY Chapter Seminar, December 2003

Access 2000 – Level 1 New Horizons, Inc., October 2003

Good Clinical Practice: Are We There Yet? David LePay, FDA, ACRP CNY Chapter Seminar, October 2003

Wage and Hour Law Compliance, Rockhurst University, August 2003

Labor Law Update and Wrongful Discharge, JSEC Inc., June 2003

RELEVANT ADDITIONAL TRAINING CONTINUED

Legal Accountability Process and Protections in Clinical Research, ACRP CNY Chapter Seminar, June 2003

HIPAA 101, ACRP CNY Chapter Seminar, March 2003

Countdown to HIPAA Research Compliance: Practical Tools for Complying with the Privacy Rule and Managing Sponsor Investigator Relationships, Health Information Privacy Alert, March 2003

MS Project 200 Software Training Level I, New Horizons, Inc. December 2002

Update HIPAA Seminar, ACRP, October, 2002

Project 2000 Software Training Level 1, New Horizons, Inc., December 2002

Project Management in the Pharmaceutical Industry, Barnett International, October 2002.

Gold Mine Software Training, May 2002

Computer System in Validation in FDA-regulated Industries, Validation Associates, Inc., November 2001

Adult/Child CPR Training, American Red Cross, September 2000

Activity Based Costing: To Fixed Unit Priced Contracts for Clinical Trials, Institute for International Research (IIR), August 2000

Corporate Growth-Control or Chaos, Association for Clinical Research Professionals (ACRP), May 2000

Protecting Human Research Subjects: An NIH Sponsored Regional Conference, SUNY Health Science Center, Syracuse, NY, April 2000

Basic Type II Diabetes Mellitus, Dr. Au, NCRA, April, 2000

Managing Problem Employees and Difficult Supervisory Situations, National Business Bureau, April 2000

Medical Devices and Diagnostics 510(k)s, PMAs and IDEs, IIR, November 1999

GoldMine Training: Basic, Greystone Computer Training Center, Nov. 1999

Clinical Trial Strategies for Medical Device & Diagnostics, IIR, Sept. 1999

The New Device Tutorial, Drug Information Association (DIA), June 1999

Alzheimer's 1999: A Conference for Health Care Professionals and Caregivers SUNY Health Science Center, Syracuse, NY, June 1999

Marketing Strategies: A dialog Between CROs, Sponsors, Investigators & FDA, DIA, June 1999

An Overview of New EU GCP Guidelines: Emerging Issues for Global Clinical Trials, DIA, June 1999

Sources of Agreement and Disagreement about Source Documents: 4 Perspectives, DIA June 1999

Measuring Clinical Trial Performance at Pharmaceutical Companies, CROs & Sites, DIA, June 1999

DataFax™ Training: Basic, NCRA, May 1999

How to Screen for Major Cancer Killers, SUNY Health Science Center, Syracuse, NY, April 1998

Monitoring Medical Device Studies: Basic, Barnett, May 1998

Good Clinical Practices Training, Burch Consulting Services February 1997

Understanding the ICH GCP Guideline: The Inside Story, DIA, February 1997

Reference Manager, Computer Software Training, July 1993

Current Contents on Disk, Computer Software Training, June 1993
Implementing Total Quality, November 1991
Project Management, October 1991

PROFICIENCY IN COMPUTER SOFTWARE PACKAGES

MS Word
MS Excel
MS Power Point
QuickBooks
GoldMine
MS Project Manager
Lotus Approach

GRANTS

Implementation Grant for School Based Health Centers in the “Making the Grade” Program.
Dr. E. Lewin, Dr. A. Gadowski, Dr. C. Lewis, PL Truax-Bellows, R.N., B. McLaud R.N.,
T. Colletti, P.A., and D. Franklon.
Grant for HealthCare Professional HIV/AIDS Educational Program.
Dr. C. Lewis and PL Truax-Bellows, R.N.

PRESENTATIONS

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, Nov
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

PROFESSIONAL MEMBERSHIPS/COMMITTEES

Association of Clinical Research Professionals (ACRP)
ACRP CNY President
ACRP Device Forum Steering Committee
ACRP CCRA Exam Committee
Society of Quality Assurance (SQA)
Society for Clinical Research Associates (SoCRA)

HONORS

Honorary Nursing Society of Hartwick College
Sigma Theta Tau International Nursing Society