

GLEND A M. GUEST, BS, CCRA, RQAP-GCP

WORK EXPERIENCE

1998 – present

Norwich Clinical Research Associates Ltd.

2001 –present Vice-President

2004 – present Vice-Chair of the Board of Directors

Duties include: assist with the overall management of NCRA business and personnel, marketing, personnel training, contract budgeting and all tasks specific to clinical research conduct for pharmaceutical, medical device and nutraceutical products. Responsible for development, review and updating of NCRA SOPs. Additional duties consistent with company vice-presidency and vice-chair of the BOD.

2001 – present Project Manager

Duties include: clinical trial project management, including identification, management and oversight of projects' schedules, budgets & resources with direct accountability to management; establishment and maintenance of project timelines; and project management reporting, including written and presentation reports.

2000 – present Director of Marketing

Duties include: oversight of all marketing activities and personnel, maintenance/updates to marketing materials such as letters, brochures, NCRA's web page and marketing presentations to potential clients, maintenance of profile and database listings for the company, manage marketing contacts and oversight of follow-up activities related to marketing for all NCRA personnel, attendance at annual trade shows/exhibitions, manage department budget.

2002 – present Auditor (SQA Registered Auditor as of 4/2007)

Duties include: GCP auditing and reporting, corrective action recommendations. Have participated in independent third party pre-IND and pre-PMA audits to assist in preparation for FDA audit of clinical sites. Have also provided site staff training relative to correcting site audit deficiencies.

1998 – present Clinical Research Associate (ACRP Certified since 4/2002)

Duties include: protocol development and review; informed consent and CRF development; Sponsor's liaison with IRBs; conduct Qualification, Initiation, Interim and Close-Out Monitoring visits; establishment and maintenance of project timeline as part of a team, Adverse Event evaluation and reporting to in-house Regulatory and Medical Affairs personnel; maintenance of Study Master Files; and all tasks specific to clinical research conduct and duties consistent with CRA role. Additional duties have included oversight and training of junior CRAs, programming and database development, conducting subject interviews and data collection, coding of data for entry into study databases, data entry and clean-up activities. Have assisted biopharmaceutical client to develop clinical SOPs. Have assisted with Regulatory submissions (Final Study Reports, IND and 510[k]).

NOTE: Experience involves devices (i.e., validation, IDE and post-marketing clinical studies), pharmaceutical products, biological agents and nutritional supplements.

Diagnostic, surgical and implantable device experience includes: NIBP, ECG, spirometry, thermometry, radio-frequency ablation, breast cancer diagnostic, minimal access surgical cutting trocars, PFO implant repair devices and stents. Disease areas involve breast cancer, chondromalacia and meniscal injury of the knee, abdominal aortic aneurysm, hypertension, patent foramen ovale and coronary artery occlusion.

Pharmaceutical experience encompasses Phase II, III and IV studies. Pharmaceutical product disease areas include cystic fibrosis, Type II diabetes (nutritional product), pediatric attention deficit/hyperactivity disorder, autism, autoimmune thrombocytopenic purpura, obsessive compulsive disorders, schizophrenia, and rosacea.

1982 – 1998

State of New York, Broome Developmental Services

Habilitation Specialist (5 years)

Community Residence Director (4 years)

Community Residence Assistant Director (3 years)

Developmental Assistant (2 years)

Community Residence Aide (2 years)

1981-1982

Upper Delaware County Alternative Living

- Community Residence Aide

PROFESSIONAL EDUCATION:

Society of Quality Assurance

Registered Quality Assurance Professional – Good Clinical Practices (RQAP-GCP) ongoing since 4/2007

Association of Clinical Research Professionals

Certified Clinical Research Associate (CCRA) ongoing since 4/2002

SUNY, Oneonta NY

Bachelor of Science (BS) in Psychology

SUNY Ag. and Tech., Cobleskill NY

Associate of Arts (AA) in Liberal Arts

Stamford Central School, Stamford NY

Regents Diploma

PROFICIENCY IN COMPUTER SOFTWARE PACKAGES

MS Excel

MS Word

Power Point

Lotus Approach

MS Access

SPSS Data Entry Builder

DBMS Copy

DBMS Compare

GoldMine

RELEVANT ADDITIONAL TRAINING

- Clindex Trial Management and Data Management Software CX-901 EDC Study Development training, Fortress Medical Systems, October 25, 2007
- Clindex Trial Management and Data Management Software CX-101 Development I training, Fortress Medical Systems, October 23-24, 2007
- Contemporary Issues in Clinical Research, Low Country Chapter of ACRP, September 29, 2007, **6 CEUs**
- Regulatory Affairs Professionals Society (RAPS) Annual Conference, September 23-26, 2007
- Copyright and Intellectual Property Rights – An Overview, CNY ACRP, September 19, 2007, **2 CEUs**
- MedTech 2007: Quality Product Development in a Regulated Environment, September 17-18, 2007, SoCRA, **8.25 CEUs**
- SQA Annual Meeting and GCP Item Writer's Workshop, Austin, TX, April 29 – May 4, 2007
- ACRP Global Meeting and Exhibition, April 2007, Seattle WA, **8 CEUs**
- Skills for Presenters and Trainers, CNY ACRP, April 17, 2007, **2 CEUs**

- Successful Collaborations in the Good Clinical Practice (GCP) of Clinical Research, SoCRA, April 12, 2007, **2 CEUs**
- Washington Update: What's Ahead for the Medical Device Industry in 2007?, MedTech, Mark Leahy, Director of Medical Device Manufacturer's Association, February 27, 2007.
- Preparation and Conduct of an FDA Inspection at a CRO, L. Truax-Bellows, NCRA, February 6, 2007
- Patient Recruitment Strategies for the Sponsor and Site, Web Seminar hosted by the Philadelphia Chapter of ACRP, October 2, 2006, **2 CEUs**
- Advanced Training: Good Laboratory Practice (included auditing training), Society Of Quality Assurance, September 28, 2006
- Basic Training: Good Laboratory Practice (included auditing training), Society Of Quality Assurance, September 27, 2006
- Advance Concepts in Computer Validation (included auditing training), Society Of Quality Assurance, September 26, 2006
- Introduction to the Principles of Computer Validation for the QA Professional (included auditing training), Society Of Quality Assurance, September 25, 2006
- Device Research Conference: Regulations and Guidelines for Device Clinical Research, June 20-21, 2006, SoCRA, **13.9 Contact Hours**
- GCP Quality Assurance Auditing, June 8, 2006, CNY ACRP, **1.25 CEUs**
- ACRP Global Meeting and Exhibition, April 28 – May 2, 2006 in Phoenix AZ, **12 CEUs.**
- Auditing Techniques for Clinical Research Professionals, November 16-17, 2005, Barnett International **15 Contact Hours**
- Seventh Annual Fall Symposium of the Research Triangle Park Chapter of ACRP, November 5, 2005, RTP ACRP, **6 CEUs**
- American Association for the Advancement of Medical Instrumentation AAMI / Quality System Regulation Requirements and Industry Practice (August 29 – September 2, 2005), CNY MedTech
- Time Management for the Clinical Research Professional, June 2005, CNY ACRP, **1.5 CEUs**
- Certified Clinical Research Associate Certification Test Item Writers Workshop and attend sessions at ACRP Annual Meeting, April 2005, **13 CEUs**
- Reimbursement Issues for Medical Devices, March 2005, CNY ACRP **1.25 CEUs**
- Ethical Challenges in Clinical Research, December 2004, CNY ACRP **1.25 CEUs**
- Drugs vs. Devices: An Overview, September 2004, CNY ACRP **2.25 CEUs**
- ACRP Annual Meeting, May 2004, **6 CEUs**
- Informed Consent: The Art of Respect, April 2004, CNY ACRP. **1.25 CEUs**
- Collaborative IRB Training Initiative/Human Subjects Research Training/SUNY UMU web site "CITI course", December 2003
- Budgets: Know Your Costs, December 2003, CNY ACRP, **1.25 CEUs**

- GCP and FDA Audits, October 2003, CNY ACRP, David LePay, FDA **1.25 CEUs**
- Microsoft Access 2000 Level 1, 2-day software training course at New Horizons Learning Centers, October 27 & 28, 2003
- Legal Accountability Process and Protections in Clinical Research, **1 CEU**, CNY ACRP
- HIPAA 101, **1 CEU**, March 2003, CNY ACRP
- SPSS Base Software training, 6 hours, May 2003, Robert Ploutz-Snyder, Ph.D., SUNY Upstate Medical Center, Syracuse, New York.
- Medical Devices: Basic Elements and Special Circumstances, **1.5 CEUs**, ACRP Annual Meeting, Jean Toth-Allen, FDA
- Countdown to HIPAA Research Compliance: Practical Tools for Complying with the Privacy Rule and Managing Sponsor Investigator Relationships, Health Information Privacy Alert, March 2003
- MicroSoft Project 2000 Level 1, 2-day software training course at New Horizons Learning Centers, December 5 & 6 2002
- “HIPAA Update: Managing your research and research subjects. What you should be doing now to be ready for the compliance date.” ACRP Virtual Seminar, September 21, 2002. **1.5 CEUs**
- “PowerPoint Level 1”, software training course at New Horizons Learning Centers, October 3, 2002
- “Clinical Project Management in the Pharmaceutical Industry”, Barnett International, September 30 – October 1, 2002 **1.5 CEUs**
- DIA Annual Meeting: “Regulatory Plenary Session: Update on the Industry Coalition: 21 CFR Part 11”, June 2002
- “Computer System Validation in FDA Regulated Industries”, 2 day seminar, November 2001
- ACRP Annual Meeting (“Building and Maintaining Effective Client/Consultant Relationships”, “Fear and Loathing on the Electronic Highway: Life Without Paper”), April 2001
- FDA Guidance for Industry “Computerized Systems used in Clinical Trials”, April 2001
- NCRA NTServer maintenance tasks training, January 2001
- BOCES: Introduction to EXCEL, November, 2000
- Clinical Trial Strategies for Medical Devices & Diagnostics, Institute for International Research, Medical Device Division, (“Clinical Trials for Medical Devices: An FDA Perspective” (Dan Schultz, ODE/CDRH/FDA), “Designing Medical Device Clinical Trials and Interacting With the FDA”, “Understanding the Challenges of Conducting European Clinical Trials”, “Ensuring Success in your Clinical Trial Through Site and Patient Training”, “Clinical Investigator Responsibilities for Financial Disclosure Requirements”, “FDA Bioresearch Monitoring: Sponsor, Clinical Investigator and IRB Responsibilities Before, During and After the Device Study Audit”, “Accelerating Clinical Trials for Devices and Diagnostics”, “Maintaining Data Quality for Efficient Medical Device Trials: In-House and Remote Data Entry Applications”, “FDA

Regulations for Medical Devices: What You Should Know to Succeed”, September, 25-27, 2000.

- Adult, Child, Infant CPR, American Red Cross, September, 2000.
- SUNY Binghamton (3 credit graduate course) “Clinical Trials: The Conduct of Regulated Clinical Research from the Monitoring and Data Management Perspective”, June 2000
- DIA Annual Meeting (“Analysis of Statements of Nutritional Support”, “State Laws and Clinical Research”, “Nutraceuticals Update-NREA”, “Dietary Supplement Regulation: Update 2000”, and “Electronic Data Capture”), June 2000
- Advancing Medical Device Research in a Changing Global and Regulatory Environment, Robin Zehr-Newman, MedTrials, Inc., June, 2000
- ACRP Annual meeting (“Top 10 Reasons for Medical Device Clinical Study Delays” and “How to Put Zip Into Your Training”) May, 2000
- Device Dynamics: Successful Management of the Medical Device Trial, Robin Zehr-Newman, MedTrials, Inc., May, 2000
- Certification by the American Nutraceutical Association for Dietary Supplement Health and Education Act: Labeling, May 2000
- Basic Type 2 Diabetes Mellitus, NCRA, William Y. W. Au, MD, April, 2000
- Leadership Trends: The Dynamics of an Empowered Workplace, International Association of Administrative Professionals, April 2000
- GoldMine Introductory Training, Greystone Computer Training Center, November, 1999
- Clinical Trial Strategies for Medical Devices & Diagnostics, Institute for International Research, Medical Device Division, (“Exploring the Benefits of Statistical Designs in the Conduct of Effective Medical Device Trials”, “Using the Internet to Conduct Efficient Medical Device Trials”, “FDA Bioresearch Monitoring Audits: How to Prepare and Succeed”, “Presenting the Best Case Before the IRB: Maximizing Relationships between Sponsors, IRBs, Institutions and Investigators”, “Understanding FDA Expectations for Medical Device Trials”, “The Investigations Device Exemption Process: New Opportunities and New Challenges”, “Expediting Time to Market: Strategic Use of Pre-Clinical Meetings and the PMA Modular Review Process”, “Impact of IDE Changes on Clinical Development”, “Management of the Medical Device Trial: Strategies for Success”, “Putting the Pieces Together for a Successful Clinical Trial: Protocol and Consent Form Development”) September 27-29, 1999
- DIA Annual Meeting 1999 (“Moving Beyond Patient Recruitment to Retention”, “Update From CDRH – A Medical Devices Primer: What You Need to Know About the Regulation of Medical Devices”, “Sources of Agreement and Disagreement About Source Documents: 4 Perspectives”, “Worldview-Botanical Medicine Overview: Update 1999”, “US View: The Nutraceutical Revolution”), June 1999
- DataFax™ Training (basic data entry and validation levels), Robbin Abbott, DMC, NCRA, April, 1999
- Master File training – September 1998

- NCRA Supervised Field Training:
Site Initiation Visit – July 1998
Interim Monitoring Visit – July 1998
Close-Out Monitoring Visit – June 1998
- NCRA ICH GCP Training, July, 1998

PRESENTATIONS

- Clinical Studies in Medical Devices Versus Pharmaceuticals: An Overview: Charleston, SC “Low Country Chapter of ACRP”, September 2007
- Preparation for and Conduct of an FDA Inspection at an Investigational Site: Greater Pittsburgh Chapter of ACRP, September 2007
- Overview of the Drug/Device Development Process: ACRP National Meeting, Phoenix AZ, April 2006
- Understanding Medical Devices: A Practical Overview: Research Triangle Park Chapter of ACRP, November 2005
- An Overview of Human Subject Protections: Roswell Park Cancer Institute, Western NY Chapter of ACRP, October 2005
- Understanding Medical Devices: A Practical Overview: ACRP National Meeting, Orlando FL, April 2005
- Clinical Studies in Medical Devices Versus Pharmaceuticals: An Overview: Roswell Park Cancer Institute, Western NY Chapter of ACRP, October 2004
- Clinical Studies in Medical Devices Versus Pharmaceuticals: An Overview: Central NY Chapter of ACRP, September 2004
- Clinical Studies in Medical Devices Versus Pharmaceuticals: An Overview: State University of New York, Upstate Medical University, Syracuse, NY, September 2004
- Clinical Studies in Medical Devices Versus Pharmaceuticals: An Overview: Tufts Medical Center, New England Chapter of ACRP, September 2004

CERTIFICATIONS

- April 2002: Association of Clinical Research Professionals (ACRP)
Certified Clinical Research Associate (CCRA)
- April 2007: Society of Quality Assurance (SQA)
Registered Quality Assurance Professional in Good Clinical Practices (RQAP-GCP)

PROFESSIONAL MEMBERSHIPS/COMMITTEES

- Society of Quality Assurance 2006 to present
- Society of Clinical Research Associates (SoCRA) 2006 to present

- Association of Clinical Research Professionals (ACRP) 1999 to present
 - ACRP 2008 Global Conference Program Planning Committee
March 2007 to present
 - ACRP 2007 Global Conference Program Planning Committee
March 2006 to April 2007
 - ACRP Device Forum Steering Committee Chair
April 2006 to present
 - ACRP Device Forum Vice Chair for Web Site Development
June 2003 to present
 - CNY ACRP Chapter President 2003-2006, ongoing active charter member
- Drug Information Association (DIA) 1999-2005