GLENDA M. GUEST, BS, CCRA, RQAP-GCP, TIACR

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Glenda Guest
17 July 15

WORK EXPERIENCE

Norwich Clinical Research Associates Ltd. 1998 – present

Clinical Research Associate	1998 – present
Director of Marketing	2000 – present
Project Manager	2001 – present
Vice-President	2001 – present
Auditor	2002 – present
Data Management Coordinator	2002 – present
Trainer	2004 – present
Vice-Chair of the Board of Directors	2004 – present
Trainer	2001-2015
Director of Data Management	2013 – present
Sr. Trainer	2015 – present

Sr. Trainer 2004 - present

TIACR Certified via the International Association of Clinical Research since March 2015.
Duties include learning needs assessments, course development and delivery for a wide variety of topics and audiences, such as NCRA staff, clients, research sites, professional organizations and contracted training organizations (Center for Professional Innovation in Education, Barnett International).

Director of Data Management 2013 - present

Duties include oversight of all personnel in the Data Management department, supporting the business and conducting clinical research utilizing applicable Good Clinical Practice (GCP) guidelines and regulations. Oversight of all policies and procedures (including Standard Operating Procedures and Quality Manual Policy & Procedures) that pertain to Data Management services and management of the department.

Auditor 2002 – present

Registered Quality Assurance Professional – Good Clinical Practices (RQAP-GCP attained and maintained since 4/2007.
Duties include: GCP auditing and reporting, third party pre-IND and pre-PMA audits, Japanese GCP preparation audits, corrective action recommendations. Also provide SOP development assistance and staff training relative to correcting site audit deficiencies.

Data Management Coordinator 2002-present

Duties include: create CRFs and aCRFs, data management plans, coding/entry guides; code CRF data, data verification and query generation/resolution, SOP development and consulting. Database experience included MS Access (with Part 11 toolkit installed), SPSS, Excel, Clindex

Project Manager 2001 – present

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.

Director of Marketing 2000 – present
Duties include: assist with the overall management of NCRA business and personnel, marketing, contract budgeting and all tasks specific to clinical research conduct for pharmaceutical, medical device and nutraceutical products.

Clinical Research Associate 1998 – present
ACRP Certified Clinical Research Associate since 4/2002
Duties include: protocol development; informed consent and CRF development; conduct Qualification, Initiation, Interim and Close-Out Monitoring visits; establishment and maintenance of project timeline, Adverse Event evaluation and reporting to in-house Regulatory and Medical Affairs personnel; 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. Assisted biopharmaceutical client to develop clinical SOPs. 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: LASIK, 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 thrombocytopenia purpura, herpes, influenza, obsessive compulsive disorders, schizophrenia, rosacea, urinary incontinence and immunology (vaccines).

Barnett International (December 2014-present)
Duties include: Preparation and delivery of Course Materials several times each year (see below)

- Adverse Events: Managing and Reporting for Medical Devices

The Center for Professional Innovation and Education (CfPIE) March 2012-present

Course Director
Duties include: Preparation and delivery of Course Materials several times each year (see below)

- Comprehensive Overview of FDA Regulatory Compliance for Medical Devices (two day in-person course) for those who are involved with ensuring regulatory compliance for medical devices

- Clinical Trial Design for Medical Devices (two day in-person course) for those involved with clinical study development for medical devices
- Comprehensive Overview of FDA Regulatory Compliance for Drug and Biotech Products

State of New York, Broome Developmental Services 1982 – 1998
Habilitation Specialist (5 years)
Community Residence Director (4 years)
Community Residence Assistant Director (3 years)
Developmental Assistant (2 years)
Community Residence Aide (2 years)

Upper Delaware County Alternative Living 1981-1982

- Community Residence Aide

PROFESSIONAL EDUCATION:

International Association of Clinical Research
Certified Trainer TIACR ongoing since March 2015
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

COMPUTER SOFTWARE PROFICIENCY

CLINDEX and *ClindexLIVE Data* Management and Trial Management
Microsoft Products: Excel, Word, Power Point, Project, Access
GoldMine
SPSS Data Entry Builder
DBMS Copy
DBMS Compare

RELEVANT ADDITIONAL TRAINING

Relevant training records are supplied upon request.

PROFESSIONAL CERTIFICATIONS

- March 2015 – present: International Association of Clinical Research (IAoCR) Certified Trainer (TIACR designation)
- April 2007 - present: Society of Quality Assurance (SQA)

Registered Quality Assurance Professional in Good Clinical Practices (**RQAP-GCP**)

- April 2002 - present: Association of Clinical Research Professionals (ACRP) Certified Clinical Research Associate (**CCRA**)

PUBLICATIONS

- **Guest, GM, (2014).** FDA Recommended Strategies for Sponsors and Investigators to Build Quality into Clinical Research. ***Clinical Researcher*** 10.14524/CR-14-0013 (1), 20-22.
- **Guest, GM, (2014).** *Is the GUDID a GOOD Idea? Can Unique Device Identification (UDI) and Global UDI Database (GUDID) Improve Medical Device Development and Surveillance?* ***Clinical Researcher***. 28 (6), 12-15.
- **Guest, G. (2014).** *How can we effectively identify and report clinical research misconduct*? **Clinical Investigation**, 4(12), 1057–1059. doi:10.4155/cli.14.92
- **Guest, GM,** *Are we O(k) with the 510(k)?.* **The Monitor**: Journal of the Association of Clinical Research Professionals 26(1) 59-60 (December 2012)
- **Guest, GM,** *De Novo Classification: How Does it Fit in the US Medical Device Classification System*. **The Monitor**: Journal of the Association of Clinical Research Professionals 26(2): 66-68 (April, 2012)
- **Guest GM,** *Investigator Responsibilities Revisited by FDA*, **Next Generation Pharmaceuticals**, February 2010, Issue 18

AWARDS

- **ACRP 2015 Global Conference Top Speaker award**

  The ACRP 2015 Global Conference Top Speaker award is in recognition of your excellent content score, speaker score, overall score and attendee interest as represented by the number who attended and rated your session.

PRESENTATIONS/COURSES/WORKSHOPS (AS PRESENTER/TRAINER)

- Advanced Topics in Medical Devices, MAGI East, May 2015
- *Master Class: Risk Management for Sponsors, Sites and CROs,* MAGI East, May 2015
- *FDA Inspections: Handling the Consequences, Exploratory Learning Session,* ACRP Annual Conference, April 2015
- GCP Auditing Techniques, full day workshop ACRP Annual Conference, April 2015
- *Quality by Design: The Value of CRF Mapping, SQA Spring Quality College, April 2015*
- *GCP Beyond the Basics Workshop: Best Practices in Vendor Management, SQA Spring Quality College, April 2015*
- *Quality Control versus Quality Assurance: The Role of Quality in Management of Clinical Trials,* Allegheny – Singer Research Institute, Dec 2014
- FDA/EMA Inspection Lessons Learned: Ineligible Subject Enrollment ACRP Webinar 1.5 hr, September 2014
- *FDA Inspections: Handling the Consequences, MAGI East Conference May 2014*
- *Master Class: Good Clinical Practices, full day workshop, MAGI East Conference, May 2014*
- *Best Practices for Transitioning to Risk-based Monitoring, ½ day workshop, ACRP Annual Conference, April 2014*
- *Identification and Ethical Reporting of Suspected Fraud or Misconduct, ACRP Annual Conference April 2014*
- *Evolving Ethics of Animal Use Within the Clinical Research Enterprise, ACRP Annual Conference April 2014*
- *Building Quality Management Systems (QMS) for Sites and Sponsors, ACRP Classroom Course, 2014-2015*
- *Key Skills for Ensuring Quality Control, ACRP Classroom Course, 2014-2015*
- *Overview of FDA Regulatory Requirements for Medical Device Combination Product Development, SQA Annual Conference March 2014*
- *GCP Beyond the Basics Workshop, SQA Spring Quality College, April 2014*
- *Advanced GCP Workshop, MedTech March 2014*
- New Skills for Risk Based Monitoring, ACRP Webinar 1.5 hr, November 13, 2013
- Foundation Class: Good Clinical Practice Essentials, full day workshop, MAGI Clinical Research Conference, October 26, 2013
- Good Clinical Practice: Beyond the Basics Workshop presenter and attendee, Society for Quality Assurance (SQA), Sep 26, 2013
- Exploring the FDA's Refuse to Accept Policy for 510(k)s, ACRP 1.5 hr webinar, June 12, 2013

- Risk-Based & Remote Site Monitoring, MAGI Clinical Research Conference, May 5-8, 2013
- The Forensic Site Monitor, MAGI Clinical Research Conference, May 5-8, 2013
- Using Requests for Proposal as the First Step in Setting Quality Expectations with Potential Vendors, Society for Quality Assurance (SQA), May 3, 2013
- Good Clinical Practice: Beyond the Basics Workshop, Society for Quality Assurance (SQA), May 3, 2013
- An FDA Inspection of a Clinical Research Site, ACRP Global Conference & Exhibition, April 16, 2013
- New Skills for Risk-based Monitoring of Investigational Studies, ACRP ½ day workshop, April 12, 2013
- GCP Update: FDA Guidance A Risk-Based Approach to Monitoring, MedTech Advanced GCP Workshop, March 12, 20132
- The 510(k) Route to Market for Medical Devices, What's All the Fuss About? , ACRP 1.5 hr webinar, January 16, 2013
- *Applying Quality System Concepts to Clinical Research Activities*, Webinar, Compliance Online, October 11, 2012
- *Applying Quality Systems and Risk Management Techniques to Improve Clinical Research*, ACRP RTP Chapter Symposium, October 5, 2012
- *US Pharmaceutical vs Device Clinical Development: Similarities and Differences Explored*, Webinar for Compliance 2 Go group, June 28, 2012
- *Applying Vendor Management Practices to Clinical Research Sites*, Barnett International's Clinical Trial Oversight Summit, Vendor Management in Clinical Trials June 6, 2012
- *Preparing for FDA Inspection and Handling the Consequences*, Webinar for Compliance 2 Go group, May 31, 2012
- *Practical 21 CFR Part 11 Risk Mitigation Strategies for Electronic Records in Clinical Trials*, MAGI Conference, May 22, 2012
- *Utilizing a Risk-based Approach to Meet Sponsor Monitoring Obligations*, Society for Quality Assurance Annual Meeting, April 25, 2012
- *Comparative Effectiveness Research: Has the Time Come?*, ACRP Global Conference, April 17, 2012
- The Investigator Agreement: How and When to Complete FDA Form 1572, Webinar for Compliance 2 Go group, March 8 2012
- Device and Drug Clinical Development: Similarities and Differences Explored; Webinar for Compliance 2 Go group, January 11, 2012
- Incorporating Centralized Monitoring into your Quality System Approach to Clinical Research; Webinar for Compliance 2 Go group, December 1, 2011
- Advanced Competency for Device Professionals; 2 Day Professional Development Course, Alexandria, VA, ACRP November 10-11, 2011

- Compliance and the Digital Age: Basic 21 CFR Part 11 Considerations for Electronic Medical Records in Clinical Trials; NY Metropolitan Chapter of ACRP Fall Symposium, November 16, 2011
- Device and Drug Development: Similarities and Differences Explored; Research Triangle Park Chapter of ACRP Fall Symposium, November 4, 2011
- Electronic Health Records (EHRs) and Clinical Research; MAGI Conference, October 25, 2011
- Advanced Competency for Device Professionals; 2 Day Professional Development Course, San Diego, CA, ACRP October 13-14, 2011
- Advanced Competency for Device Professionals; 2 Day Professional Development Course, San Francisco, CA, ACRP September 22-23, 2011
- Clinical Quality Assurance: Roles and Responsibilities for Auditors and Managers; 2 Day Course for FDA News, August 30-31, 2011
- Preparation for and Conduct of an FDA Inspection at an Investigational Site; Webinar provided for My Webinars group August 25, 2011
- Using FDA Warning Letters as a Tool to Evaluate and Improve Your Research Activities at Clinical Sites, Webinar provided for My Webinars group, July 27, 2011
- Applying a Quality System Approach to Device Clinical Research, Webinar provided for My Webinars group, July 13, 2011,
- Advanced Competency for Device Professionals; 2 Day Professional Development Course, San Diego, CA, ACRP June 23-24, 2011
- In Light Of This Event Should This Study Continue?; ACRP Global Conference May 3, 2011
- Strategies To Build Quality Into Device Research; ACRP Global Conference, May 2, 2011
- Advanced Competency for Device Professionals; 2 Day Professional Development Course, Seattle, WA, ACRP April 27-28, 2011
- Clinical Development Under the Cloud of FDA Uncertainty; Frost & Sullivan Medical Devices Summit, March 14th, 2011
- Basic 21 CFR Part 11 Considerations for Electronic Medical Records in Clinical Trials, ACRP Suncoast Chapter Expert Online Webinar, December 1, 2010
- Clinical Research in China, the EU and the US: A Device Perspective, ACRP Global Conference, April 24, 2010
- Clinical Value in the Eyes of Your Customer: Preparing to Meet the Challenges Imposed by Healthcare Reform Initiatives, Frost & Sullivan Medical Devices Summit, March 15th, 2010
- Device and Drug Development: Similarities and Differences Explored, ACRP Webinar, February 18, 2010
- Electronic Medical Records: What Sites and Sponsors/Monitors Should Understand about Basic Part 11 Implications, National Meeting, Denver CO, April 27, 2009
- Device and Drug Development: Similarities and Differences Explored, ACRP National Meeting, Denver CO, April 27, 2009

- Using FDA Warning Letters as a Tool to Evaluate and Improve Your Research Activities at Clinical Sites, ACRP National Meeting, Denver CO, April 26, 2009
- Outsourcing to Contract Research Organizations for Innovation & Efficiencies in Today's Economic Climate, San Francisco, CA, Frost & Sullivan Mind Exchange, March 2009
- Everything You Need to Know About FDA Warning Letters, ACRP National Meeting, Boston, MA, April 27, 2008
- FDA Inspections: What to Expect and How to Respond to Warning Letters, ACRP National Meeting, Boston, MA, April 28, 2008
- 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

PROFESSIONAL MEMBERSHIPS/COMMITTEES

- GCP Expert Advisory Panel member for Cambridge Health Institute (CHI) Barnett International for the 2012 Edition of the GCP Question and Answer Guide publication.
- Society of Quality Assurance 2006 to present
- Association of Clinical Research Professionals (ACRP) 1999 to present
  - ACRP Academy Board of Trustees Liaison (appointed) 2015-[resent
  - ACRP Association Board of Trustees (elected member) 2015-present
  - ACRP Regulatory Affairs Committee Chair (RAC) March 2014-present
  - ACRP Device Interest Group (DIG) Steering Committee Chair April 2013 to 2014

- ACRP Device Interest Group Steering Committee (Device Forum changed to Device Special Interest Group and then to Device Interest Group in 2012)
  My membership in the device steering committees for ACRP has been continuous since April 2005
- ACRP Regulatory Affairs Committee (RAC)
  March 2012-present
- ACRP Global Conference Program Planning Committee
  June 2003 – March 2011
- ACRP Device Forum Steering Committee Chair
  April 2006 to 2008, April 2013 to present
- ACRP Device Forum Vice Chair for Web Site Development
  June 2003 to 2008
- ACRP Device Forum Steering Committee (renamed Special Interest Group)
  April 2005 to 2012
- CNY ACRP Chapter President 2003-2006, ongoing active charter member