



CURRICULUM VITAE
Linda (Lin) M. Rhea, BS, CCRC
Phone/Fax 727-733-4699
Cell 727-430-0934
Email: lmrhea@verizon.net

Professional Experience:

I have been professionally involved in Pharmaceutical and Medical Device clinical research for over twenty-five years, with more than ten years of GCP compliance auditing.

Oct2003 – present

Vice President

Principal Consultant GCP Compliance Auditor

Achieve Quality, Inc.

602 Riverside Drive

Tarpon Springs, FL 34689

- ◆ Conduct Routine and Directed GCP audits, Scientific Misconduct and Pre-Qualification evaluations, according to FDA and local regulations, as well as ICH and ISO Guidelines of:
 - Clinical Investigator sites
 - Institutional Review Boards
 - Vendors and CROs
 - Sponsor systems and processes (including Monitoring, Project Management, IVRS/IWRS, EDC, Drug Safety/Pharmacovigilance, CTMF, Data Management, Biostatistics, Medical Affairs, Training and Regulatory Affairs)
 - Database and Data Management audits
- ◆ Conduct Pre-Qualification evaluations
- ◆ Prepare Clinical Investigator sites for FDA inspections
- ◆ Provide GCP training to Investigator sites, Sponsors and CROs
- ◆ GCP Compliance Consultant Auditor for the following organizations:
 - Abbott Vascular
 - Altus Pharmaceuticals
 - Antares Pharm, Inc.
 - ASG
 - Avancen, LLC
 - Boehringer Ingelheim Pharmaceuticals
 - Celator Pharmaceutical
 - ClinAudits
 - Coloplast A/S
 - GCP / GLP Consulting
 - GenVec, Inc.
 - Hisamitsu Pharmaceuticals
 - Innocoll
 - J&J Consumer & Personal Products
 - Janssen AI
 - Javelin Pharmaceuticals
 - M & A Consulting
 - MannKind Corporation
 - Marshall Edwards Proprietary
 - McNeil Nutritionals (Division of J&J)
 - Meda Pharmaceuticals
 - Novartis Vaccines and Diagnostics
 - NovoCure Ltd
 - OmniComm Systems
 - Ortho-McNeil Janssen
 - Perrigo Pharmaceuticals
 - Pharma Compliance Partners
 - Phoenix Regulatory Associates
 - PTC Therapeutics
 - QRx Pharma, Inc.
 - Theravance Pharmaceuticals
 - Vertex Pharmaceuticals

Previous Employment:

Jun2004 – May2005

QA/Regulatory Affairs Consultant

Arthritis Research of Florida, Inc.
3633 U.S. Highway 19 North
Palm Harbor, FL 34684

- ◆ Company representative for all Regulatory Authority inspections and Sponsor/CRO audits
- ◆ Provided training on GCPs and regulations to physicians, nurses and other staff
- ◆ Liaison with central and institutional IRBs
- ◆ Supervised all IRB submissions and interactions
- ◆ Developed/Maintained Standard Operating Procedures for Clinical and Regulatory Affairs

Aug2002 to 2004

Owner/President

Gulf Coast Pharmaceutical Research, Inc.
5622 Marine Parkway, Suite 22
New Port Richey, Florida

- ◆ Start-up clinical research organization
- ◆ Recruited clinical trials from Pharmaceutical and Medical Device Companies
- ◆ Negotiated and managed budgets for each clinical trial
- ◆ Contracted with area physicians as Investigators
- ◆ Provided all training to Investigators, Nurses and other staff on Good Clinical Practices (GCPs) and Protocol requirements
- ◆ Managed all Institutional Review Board (IRB) submissions and correspondence
- ◆ Overall project management for multiple clinical trials

1996 to Aug2002

Director of Regulatory Affairs

Tampa Bay Medical Research, Inc.
3251 McMullen Booth Road
Clearwater, FL 34615

- ◆ Liaison with FDA and Sponsors/CRO during all external inspections/audits
- ◆ Provided training on GCPs to physicians, nurses and other staff
- ◆ Liaison with central and institutional IRBs, as dictated by the clinical trial or Sponsor
- ◆ Supervised all IRB submissions and interactions
- ◆ Developed/Maintained Standard Operating Procedures (SOPs) for Clinical and Regulatory Affairs

1992 to 1996

**Director of Regulatory Compliance
and Quality Assurance**

Tampa Bay Medical Research, Inc.
3251 McMullen Booth Road
Clearwater, FL 34615

- ◆ Completed all regulatory documents and communicated with central and local hospital IRBs
- ◆ Coordinated all communication with Sponsors and Clinical Research Organizations (CROs)
- ◆ Responsible for assuring compliance with FDA regulations and Good Clinical Practices
- ◆ Responsible for developing and implementing visit specific source documents/progress notes
- ◆ Responsible for training/in-service of all new and existing coordinators
- ◆ Developed Quality Assurance program for evaluating CRCs' performance and data integrity
- ◆ Responsible for attending on-site Sponsor/CRO monitoring visits, GCP Audits and Investigator Meetings and coordinating necessary staff training

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Curriculum Vitae

1990 to 1992

Clinical Research Associate and GCP Auditor

Tampa Bay Medical Research, Inc.
3251 McMullen Booth Road
Clearwater, FL 34615

- ◆ Monitored multiple sites' clinical research on a contract basis for Pharmaceutical companies
- ◆ Conducted Pre-study evaluations and Initiation, Interim and Close-out visit activities
- ◆ Audited regulatory documents and submissions
- ◆ Conducted initial, maintenance and final overall drug accountability
- ◆ Co-audited several Investigator sites for GCP compliance

1988 to 1990

Clinical Research Manager

Tampa Bay Medical Research, Inc.
3251 McMullen Booth Road
Clearwater, FL 34615

- ◆ Organization of Coordinators' duties associated with conducting Phase I, II, III, & IV multi-specialty clinical research trials
- ◆ Interaction with patients and physician Investigators
- ◆ Review of subjects' clinical charts to confirm subject enrollment and qualification
- ◆ Provide training on venipuncture, electrocardiograms and clinical lab procedures to Coordinators
- ◆ Communication with Pharmaceutical and Medical Device companies, Laboratories and Monitoring agencies (CRAs or CROs)

1986 to 1988

Senior Clinical Research Coordinator

Tampa Bay Medical Research, Inc.
3251 McMullen Booth Road
Clearwater, FL 34615

- ◆ Coordination of clinical duties associated with conducting Phase I, II, III, & IV multi-specialty clinical research trials
- ◆ Interaction with patients and physician Investigators
- ◆ Review of charts for subject enrollment and qualification
- ◆ Performance of venipuncture, electrocardiograms and clinical lab procedures
- ◆ Communication with Pharmaceutical companies, Laboratories and Monitors/Clinical Research Associates (CRAs)

1979 to 1987

Medical Assistant

Steven Bowman, M.D.
Internal Medicine
Mease Clinic Countryside

- ◆ Provided general office nursing and administration
- ◆ Conducted patient assessment and follow-up
- ◆ Assisted with performance of minor surgical procedures (including GI procedures)
- ◆ Performed ECGs, phlebotomy, Pulmonary Function Testing, injections and Laboratory testing

Education:

2006

Bachelor of Science; Health Care Administration
Alameda University

Memberships:

- 1990 to present** Associates of Clinical Research Professionals (ACRP)
2006 to present Quality Assurance Forum
- 2008 to present** Society of Quality Assurance (SQA)

Certification:

- 1998** Certified Clinical Research Coordinator (ACRP)
- 1993** ADAS Rater Certification

Significant Training:

- 2011** FDA Exception from Informed Consent for Emergency Research
- 2011** Update on EMA and MHRA Requirements
- 2010** Reporting Potential Fraud and Scientific Misconduct to FDA
- 2010** FDA's Updated Process for Issuing Warning Letters
- 2009** Dr. Mengele's Human Experimentation Atrocities in Auschwitz
- 2008** Update on EU Clinical Trial Directive Requirements
- 2008** Detecting Fraud & Misconduct in Clinical Trials
- 2007** Advanced Auditing and Interview Techniques
- 2006** Investigating Scientific Misconduct
- 2006** EU and FDA Pharmacovigilance Auditing
- 2006** Standardized MedDRA Queries; Univ. of South Florida
- 2005** HIPAA Security Regulations
- 2005** New FDA Guidances for Industry; Risk Assessment and Risk Minimization
 - Premarketing Risk Assessment
 - Development and Use of Risk Minimization Action Plans
 - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
- 2003** HIPAA Privacy Regulations
- 2003** FDA Safety Reporting Requirements; FDANews / RxTrials
- 2003** Introduction to Pharmacovigilance; DIA
- 2002** Sponsor / CRO Auditing; Barnett International
- 2002** Advanced GCP Auditing Techniques; Barnett International
- 1999** Comparison of ICH and FDA Regulations, DIA
- 1998** Auditing Clinical Device Trials
- 1998** GCP CCRC 3-day Review course, ACRP
- 1997** ICH GCP Guidelines, DIA
- 1995** FDA Inspections and BIMO Program
- 1991** CRA Training course; Barnett International

Presentations:

- 2014** *A Comparison of FDA vs. European Regulations'* Internal CRO Training, April 2014
'Monitoring v. Auditing v. Inspections: Aren't They All the Same?' ACRP Global Conference, San Antonio, TX,
- 2010** 'Communication Dilemmas among Clinical Sites, Sponsors, and Institutional Review Boards (IRBs): A Case of Regulatory Confusion or Confused Interpretations? How do IRBs Assess Investigator Qualifications and Compliance?' Drug Information Association 46th Annual Meeting, Washington, DC June 2010
- 2009** 'SAEs: Updated Reporting Requirements'
Moffitt Oncology 2nd Annual Clinical Research Conference, June 2009
- 2008** 'Development of an Investigator Site QA System'
ACRP Global Conference, April 2008, Boston, MA
- 2007** 'Regulatory Documents: A to Z'
- ACRP Weekend Workshop, Oct 2007, Baltimore, MD
 - Suncoast Chapter of ACRP, Oct 2007, St. Petersburg, FL
 - ACRP Global Conference, May 2007, Seattle, WA

Auditing Experience

- Two Investigator Site Audits for Oncology trials, 2015**
- Post Capability Audits for Trial Master Files and twenty five Investigators Site Files, 2015**
- CRO Post Capability Audit for Antibiotic Trials, 2014 (Russia)**
- Ten Clinical Investigatory Audits for Psychosis in Parkinson's disease, 2014**
- Two Clinical Investigatory Audits for Oncology trials, 2014**
- For Cause Clinical Investigator Audit for Chronic Idiopathic Constipation, 2014**
- Four Pre-Qualification Full- Service CRO Audits, 2014**
- Two Pre-Qualification Phase I Audits, 2014**
- One Pre-Qualification Microbiology Lab Audit, 2014**
- Three Pre-Qualification Full-Service CRO Audits, 2013**
- CSR review, 2013**
- Vendor Post-Capability Audit of Neurocognitive Rating assessment vendor, 2013**
- For Cause Clinical Investigator Audit, Herpes Labials 2013**
- Five Clinical Investigatory Audits for multiple Oncology trials, 2013**
- CRO Post-Capability Audit for full service Schizophrenia trial, 2013**
- CRO Post-Capability Audit for full services Ophthalmology trial, 2013**
- Central IRB Post-Capability Audit for five different protocols for Hepato-renal syndrome, 2013**

- **Three Comparative Pre-Qualification Full-Service CRO Audits for Oncology trial, 2012**
- **Six Clinical Investigator Audits for multiple Oncology trials, 2012**
- **Mock FDA CDER Audit of Sponsor, 2012**
- **Post Capability Audit of CRO transferred Pharmacovigilance and Regulatory Reporting services in Ireland, 2012**
- **Two Comparative Pre-Qualification Full-Service CRO Audits for Oncology trial, 2012**
- **Six Clinical Investigator Audits in Alzheimer's Disease; 2011**
- **Post-Capability CRO Audit for Oncology trial; 2011**
- **Five Clinical Investigator Audits in Pancreatic Cancer, 2011**
- **Mock MHRA Inspection at Sponsor facility in UK for Cystic Fibrosis trial; 2011**
- **Mock EMA Inspection at Sponsor facility in US for Hepatitis C trial; 2011**
- **Sponsor mock FDA BIMO Inspection in US for two Oncology trials; 2011**
- **Three Pre-Qualification CRO Audits for Oncology trial; 2011**
- **Two CRO Trial Master File Audits; 2011**
- **Two Sponsors and CRO Trial Master Files Audit and 3-Party Reconciliation; 2010**
- **Sponsor Pharmacovigilance / Drug Safety Audit; 2010**
- **Sponsor Mock FDA BIMO Inspection following NDA fast-track submission; 2010**
- **CRO Full Service Pre-qualification Audit; 2010**
- **CRO Full Service Post-Capability Audit; 2010**
- **Three CRO Full Service Pre-qualification Audits; 2010**
- **One For-Cause Investigator Site Audit for the treatment of acne; 2010**
- **Six Investigator Site Audits in US and Canada of Untreated Acute Myeloid Leukemia; 2010**
- **Sponsor Mock FDA BIMO Inspection following NDA submission; 2010**
- **Three Investigator Site Audits of infection prevention following cardiac surgery; 2009**
- **Post Capability CRO Audit of five Cystic Fibrosis and Duchenne Muscular Dystrophy protocols; 2009**
- **Three Investigator Site Audits of two Vaccine protocols in healthy Pediatrics; 2009**
- **Full Service CRO Prequalification Audit for two Post-Op pain clinical trials; 2008**
- **EU CRO and Two Investigator Site Audits for an Oncology trial in the UK and Poland; 2008**
- **UK Investigator Site Audit for an HIV / AIDS clinical trial; 2008**
- **Sponsor Trial Master File Audit for a Phase I clinical trial in normal volunteers; 2008**
- **CRO Prequalification Audit for Dietary Supplement clinical trial; 2008**
- **Phase I Unit Audit for Controlled Drug Narcotic Pain Control clinical trial; 2008**
- **Three domestic Investigator Site Audits for Oncology protocol with InForm eCRF; 2008**

- **Sponsor Trial Master File Audit**, including review of applicable **SOPs** and **training**; 2008
- **Three Vendor/CRO audits** prior to **NDA submission**, with **Pharmacovigilance**, **Central Imaging Management** and **Project Management and Monitoring**; 2008
- **Australian Sponsor Systems and Processes Audit**, including contracted **Vendor study process** evaluations, applicable **Regulatory submissions**; 2008
- **Targeted International and Domestic Clinical Investigator Audits** for **Complicated Skin Infection** clinical trial related to **FDA concerns following NDA submission**; 2008
- **CRO Full Service Audit** for **Medical Device** Clinical trial; 2008
- **Database Audit** prior to FDA submission of NDA for **Diabetes** clinical trial; 2008
- **Five Investigator Team Audits** for **FDA Gap Analysis** of **Oncology** clinical trial; 2008
- **Consultant to Clinical Investigator** for Administrative Hold placed by Sponsor and subsequent Enrollment Suspension of all active trials by IRB, including review and revision of SOPs and assistance with Appeal process; 2008
- **FDA BIMO Inspection preparation** of Clinical Investigator site for two **HTN** trials; 2008
- **Three Investigator Audits** of a **Cystic Fibrosis** trial in adults and children; 2008
- **Ten Investigator Device Team Audits** and **FDA CDRH BIMO Inspection preparation** of Investigator sites for two **Coronary Stent** trials (Two Directed Evaluations); 2007
- **Investigator Device Team Audits** at **five** Investigator Sites for a Phase III **Breast Implant** clinical trial; 2007
- **Directed Investigator Audit** at an Investigator Site to investigate and verify allegations of questionable data for a Pivotal Phase III **Sickle-Cell Anemia** clinical trial; 2007
- **Investigator Team Audits** at three Investigator Sites to evaluate data integrity, regulatory documentation, drug accountability and informed consent process and documentation for a **Parkinson's** clinical trial; 2007
- **Six Full Service CRO Pre-Qualification Team Audits and Comparison Evaluation** of Systems and Processes of Monitoring, Project Management, Pharmacovigilance, Data Management, Investigational Product Distribution, CTMF Management, Training and SOPs; 2007
- **In-House 3-week Data Management / Database Team Audit** for a **Diabetes Mellitus** multi-center clinical trial conducted at 22-sites in Russia; 2007
- **CRO Team Audit** at an International CRO to evaluate Processes and Documentation for Drug Safety, AE Coding, Project Management, Monitoring, Data Entry, Data Management, CTMF and SOPs; 2006
- **Investigator Device Team Audits** at five Investigator sites for an **Orthopedic** trial; 2006
- **CRO Team Audit** to evaluate Project Management, Monitoring, CTMF, Drug Safety records, SOPs and processes; 2006
- **Investigator Audits** at three Investigator Sites to conduct data verification, assess regulatory documentation, drug accountability and informed consent process and documentation for a **Female Menopause** clinical trial; 2006

- **Four CRO Pre-Qualification Team Audits and Comparison** of Systems and Processes of Monitoring, Project Management, Pharmacovigilance, Data Management, Drug Distribution, CTMF Management, Training and SOPs; 2006
- **Investigator Audits** at six Investigator Sites to conduct data verification, assess regulatory documentation, drug accountability and informed consent process and documentation for two pivotal **CNS** clinical trials; 2006
- **CRO Team Audit** of Systems and Processes for Drug Safety, Monitoring, Training, SOPs and CTMF; 2006
- **Central Independent Review Board Audit** to evaluate SOPs, processes, documentation, membership and Investigator notification; 2006
- **CRO Audit** of Systems and Processes for Drug Safety, Monitoring, Project Management, Staff Training records, SOPs and CTMF; 2005
- **Team Investigator Audits** at four Investigator Sites to conduct data verification, assess regulatory documentation, drug accountability and informed consent process and documentation for a **COPD** clinical trial; 2005
- **Investigator Device Team Audits** of eight Investigator sites and Sponsor SOPs, CTMF, and Project Management, Monitoring and Safety Reporting; 2005
- **Investigator Audits** at three Investigator Sites to conduct data verification, assess regulatory documentation, drug accountability and informed consent process and documentation for a **cardiovascular** clinical trial; 2005
- **Pharmacovigilance System Team Audit** at Major Global CRO, including Safety Database and records comparison and reconciliation; 2005
- **Investigator Site GCP Audits** at **five** investigator sites in the U.S. for a **Postmenopausal** Symptomology clinical trial; 2005
- **CRO Audit** of Systems and Processes to evaluate processes and documentation for Drug Safety, Monitoring, Project Management, CTMF, Training, SOPs and CTMF; 2004
- **Institutional Review Board Audit** to evaluate SOPs, Study records, IRB documentation and processes and compliance with FDA regulations; 2004
- **Investigator Audits** at **five** Investigator Sites to assess data integrity / verification, regulatory submission / documentation, drug accountability and informed consent process / documentation for a **Rheumatoid Arthritis** clinical trial; 2004
- **Hospital IRB Audit** to evaluate SOPs, Study records, IRB documentation and processes and compliance with FDA regulations; 2004
- **Investigator GCP Investigator Team Audits** at seven Investigator sites for an **HIV** trial prior to NDA submission; 2004
- **CRO Audit** of Systems and Processes to evaluate processes and documentation for Drug Safety, Monitoring, Project Management, CTMF, Training, SOPs and CTMF; 2004
- **Investigator Audits** at **three** Investigator Sites to conduct data verification, assess regulatory documentation, drug accountability and informed consent process and documentation for a **cardiovascular** clinical trial; 2003

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Curriculum Vitae

- **CRO Team Audit** to assess Pharmacovigilance, Data Management and Part 11 compliance for a **Diabetes Mellitus** trial; 2003
- **Investigator Team Audits** at **three** Investigator sites to assess data verification, drug accountability, Site regulatory files and site staff training for a **HTN** clinical trial; 2003
- **CRO Device Team Audit** - to include Project Management, Monitoring, Data Management and IDE/PMA report/submission of a **Contact Lens device** trial; 2003
- **Investigator Audits** at **twelve** Investigator Sites to assess data integrity / verification, regulatory submission / documentation, drug accountability and informed consent process / documentation for two pivotal **Multiple Sclerosis** clinical trials; 1991-1992