ACHIEVE QUALITY

Auditing, Consulting, and Training

CURRICLUM VITAE

Linda (Lin) M. Rhea, BS, CCRC

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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 — **Achieve Quality, Inc.**
Vice President — 602 Riverside Drive
Principal Consultant GCP Compliance Auditor — 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.
  - TetraPhase Pharmaceuticals
  - 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/inservice 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

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
Almeda 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, April2008, Boston, MA

2007 'Regulatory Documents: A to Z'

- ACRP Weekend Workshop, Oct2007, Baltimore, MD
- Suncoast Chapter of ACRP, Oct2007, St. Petersburg, FL
- ACRP Global Conference, May2007, 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 Fibrosi**s 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

- **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