CHRISTOPHER G. BOTH

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CURRICULUM VITAE

SUMMARY OF EXPERTISE

Independent Consultant with over 16 years of auditing experience, over 12 years internationally. Extensive training and medical experience during a 20 year military career is the foundation for providing sound value added auditing. Expertise in a wide range of disciplines, including quality assurance, quality control and pharmaceutical training. Skilled in conducting site qualifications, investigator site audits, laboratory audits, vendor assessments and facility audits. Experienced in establishing clinical quality assurance units, including development of standard operating procedures (SOPs) and standardized reporting tools. Working knowledge of clinical trial processes, EMA, EU Directives, ICH guidelines, and FDA regulations. Compliance Audit Partners (CAP) LLC provides a wide range of Quality Assurance services to the pharmaceutical and biotechnology industries.

KEY AREAS OF FOCUS:

- Investigator site and vendor audits globally
- Developing and writing SOPs
- Submission documents and tables listing and graph (TLG) audits
- Pre-inspection visits/training in preparation for a regulatory inspection
- Computer System Validation (CSV)
- Database auditing
- Part 11 Compliance auditing
- Pharmacovigilance auditing
- Trial Master File auditing
- GCP and specialized training
- GLP/GCLP Laboratory audits
- QA support/consultancy
- Medical Device auditing experience
- Risk Management
- Trainer in the areas of: Good Clinical Practices, Good Documentation Practices, Auditing Techniques and any topics related to Quality Assurance

EXPERIENCE

FOUNDER, PRESIDENT AND SENIOR CONSULTANT
COMPLIANCE AUDIT PARTNERS, LLC (CAP) ▪ LINCOLN, NE *2018 – PRESENT*

Owner, project manager and senior consultant for CAP which provides a wide range of services including, but not limited to: one or two person audits, for cause and routine site audits, vendor audits and assessments, data management and database audits, GLP

Laboratory audits. GCLP Laboratory audits, Phase I-unit audits and assessments, document audits and QC, trial master file audits and QC, tables listings and figures audits, systems/process audits, Part 11 audits, CSV audits, mock inspections, pre-inspection readiness training, Quality Assurance consultancy via remote and on location support, SOP writing, gap analysis and training across many areas. CAP LLC has experience with both drug and device audits.

Therapeutic areas including, but not limited to: Cardiovascular, Gastrointestinal, Pain Management, Diabetes, Infectious Disease, Women's Health, Rheumatology and Inflammatory Diseases, Nutrition, Vaccines, Oncology, Consumer Health Products, Urology, Psychiatry, Dermatology, Neurology, etc.

CAP has provided training to Site, Vendor and Sponsor personnel for GCP, Inspection Readiness for FDA and EMA, Part 11 Compliance, Sponsor SOPs and many more areas.

CAP can partner with you to provide services for one or multiple audits, training, mock inspection, SOP development, QA Consultancy. We have experience working with small, medium and large pharmaceutical companies.

MANAGING PARTNER AND SENIOR CONSULTANT
LIFE SCIENCE COMPLIANCE, LLC (LSC) ▪ *PHILADELPHIA, PN* *2014 – 2017*

Responsible for collaboratively managing the company and solely responsible for Good Clinical Practice (GCP) quality assurance division. Duties included prospecting new customer sales and delivery of awarded projects.

Responsible for conducting GCP investigator site audits including: Phase I unit audits, vendor qualification and in-process audits, to include full-service CROs and specialty vendors such data management, GLP Laboratory audits, GCLP Laboratory audits, Statistics, e-CRF vendor, Trial Master File audits, Computer System Validation/Part 11 audits, Risk Evaluation Mitigation Strategy (REMS) audits, Limited Distribution Specialty Pharmacy audits and other contract services used in a clinical trial.

OWNER AND CONSULTANT
B&B GXP CONSULTING *2013 – 2015*

Responsible for providing a wide range of GxP Consulting services to clients nationwide. Clients ranged from small business to large pharmaceutical corporations.
Services included, but were not limited to:

- For cause and routine site audits and vendor audits
- GCP, GLP, GCLP, TMF and CSV audits
- training to Site, Vendor and Sponsor personnel for:
  - GCP
  - Inspection Readiness
  - Part 11 Compliance
  - FDA Perspective in EU

    - Sponsor SOPs
- mock inspection
- SOP development
- QA Consultancy

VICE PRESIDENT OF QUALITY AND COMPLIANCE
PRACS INSTITUTE (FORMERLY CETERO RESEARCH) ▪ FARGO, ND *2012 – 2013*

Oversight of the Quality and Compliance divisions for the company:

- Provided management oversight to all QA programs such as the Corrective and Preventative Action (CAPA), Computer System Validation (CSV) and vendor audit assessments
- Supervised and mentored four QA managers
- Provided expertise in discussion of regulatory issues and provided auditors guidance and mentoring to advance their quality assurance careers
- Facilitated Regulatory and Sponsor inspections and provided guidance for QA managers during these inspections
- Oversight of the Regulatory Affairs department in the submission of Clinical Trial agreements to the Canadian authorities
- Provided training to ten auditors on conducting vendor and investigator site audits.
- Co-audited with trainees to assure compliance with training plan.

GLOBAL DIRECTOR, CLINICAL QUALITY ASSURANCE
CETERO RESEARCH ▪ FARGO, ND *2010-2012*

Actively managed day to day quality assurance operations for 3 divisions: Clinical, Pre-Clinical Laboratory and Scientific Affairs and oversight of QA at 5 other Cetero clinical sites in North America. Facilitated Regulatory and Sponsor inspections and communicates critical findings to senior management. Prepares monthly metrics to illustrate improvement areas for all Cetero sites. Provides expertise in discussion of regulatory issues and provides auditors guidance and mentoring to advance as a quality assurance auditor.

- Implemented Quality Incident Reporting (QIR) and Corrective and Preventative Action Plans (CAPA).
- Acts as facilitator to the CAPA board for the clinical operation group to help them to complete risk management assessment for all QIRs and CAPAs.
- Conducted vendor audits of external vendors to assure the vendors can appropriately supply services to Cetero's needs.
- Instrumental in changing QA procedures for Clinical Study Report (CSR) and Common Technical Document (CTD) review.
- Restructured assignments for clinical QA auditors to follow study from beginning to end to allow for in-process audits to be done on all studies at Cetero Research.

ASSOCIATE DIRECTOR, GCP SERVICES
FALCON CONSULTING GROUP, LLC ▪ EXTON, PA *2008-2010*

Responsibilities included:

- International and Domestic Vendor Assessments and Due Diligence Audits, including: CROs, Phase I Units, Data Management providers, Biostatistical vendors, Clinical Laboratories and Electronic Data Capture vendors
- Global Clinical Investigator Site Audits in therapeutic areas such as oncology, allergy, cardiology, behavioral and infectious disease
- Conducted focused Clinical Investigator audits for four different clients. Provided the clients direct feedback as to the effectiveness that the investigator was gathering the primary and secondary endpoints in this trial
- Pre-FDA preparation visits to clinical investigator sites. Provided review of ICH essential documents and provided training for staff on what is to be expected during a U.S. regulatory inspection and how to respond to interview questions.
- Pre-MHRA preparation visits to CROs in the UK. Provided review of ICH essential documents and provided training for staff on what is to be expected during a UK regulatory inspection and how to respond to interview questions
- Evaluation and Auditing of GCP Quality Process Assessments for various clinical departments, (e.g. Clinical Operations, Clinical Trial Management, Clinical Data Management, Safety Surveillance, Investigational Product management, Study Initiation, and Vendor Selection
- Quality Control review and Audits of Trial Master Files
- Standard Operating Procedure (SOP) and Policies Development custom to the client's needs
- Audits and Quality Control review of documents including: Clinical Study Reports, Tables and Listings
- Management and coordination of large Falcon project incorporating multiple services both domestic and international
- Project Communication/Information Flow, Documentation Compliance
- Project Tasks, Resources Timeline Efficiencies and Budget Management

QUALITY ASSURANCE AUDITOR II
ANGIOTECH ▪ HERNDON, VA *2006-2008*

Responsibilities included:
- Performed quality assurance duties to include GCP audits of clinical investigator sites, CRO qualification audits and vendors such as IVRS, packaging facilities, GLP laboratories, preclinical animal facilities, clinical laboratories, QC release laboratories, trial master file audits and FDA preparatory visits to CROs and investigator sites pending FDA inspections.
- Provided GCP and quality system training to new clinical research personnel.
- Responsible for reporting audit observations for quality analysis and assessment, identified compliance risk and provided feedback and direction for improving quality systems within the company.

CLINICAL QUALITY ASSURANCE ASSOCIATE
PRACS INSTITUTE LTD ▪ EAST GRAND FORKS, MN *2003-2006*

Responsibilities included:

- Performed internal and external audits ensuring compliance with GCP regulatory standards, company policies and procedures.
- Managed observations for quality analysis and assessment, identified compliance risk and provided feedback and direction for improving quality systems.

SUPERVISOR MANAGER, HEALTH PROMOTIONS
GRAND FORKS AIR FORCE BASE ▪ GRAND FORKS, ND *2001-2003*

Responsibilities included:
- Provided educational classes on nutrition, fitness improvement and smoking cessation for over 6,000 Air Force beneficiaries
- Managed the tobacco cessation program and assisted the exercise physiologist with program administration for Air Force fitness program.
- Monitored self-inspection program and ensured compliance with JCAHP standards.

PHYSICIAN TEAM LEADER, FAMILY MEDICINE CLINIC
GRAND FORKS AIR FORCE BASE ▪ GRAND FORKS, ND *1999-2001*

Responsibilities included:
- Managed daily operations for 1 physician and nurse with a workload of 800 patients per month.
- Supervised 3 support staff.
- Managed appointment templates
- Provided medical record maintenance and administrative support.
- Communicated with the HMO and patients daily on behalf of physician
- Coordinated referrals with HMO and ensured patients received appropriate care.
- Active member of the process improvement team; assisted with designing and implementing strategic plan for primary care optimization.
- Provided computer technical support for entire clinic of 9 providers and 30 support staff.

SUPERVISOR MANAGER, WOMEN'S HEALTH CLINIC
GRAND FORKS AIR FORCE BASE ▪ GRAND FORKS, ND *1997-1999*

Responsibilities included:
- Managed operations for 5 physicians that saw 800 patients monthly.
- Supervised and evaluated 8 medical technicians.
- Maintained supply equipment budget of $35,000 annually.
- Trained personnel on all duties in the clinic setting.
- As section safety monitor, ensured all personnel provided care in accordance with set safety standards
- Provided monthly safety briefings to ensure standards were maintained.

EDUCATION

MS Central Michigan University 2002

Human Resources Administration

BS	Park University Management in Healthcare	1999
AS	Community College of the Air Force Allied Health Sciences	1997

PRESENTATIONS AND PUBLICATIONS

Advanced GCP Training- SQA Annual Meeting (National Harbor, MD) – Mar 2017
Developing and Managing a Trial Master File – Life Science Compliance LLC – Oct 2015
Project Management Workshop – Life Science Compliance LLC – May 2015
Root Cause Analysis Across the GxPs Symposium – SQA Fall Training (Denver, CO) – Sept 2014
Basic and Advanced GCP Training – SQA Fall Training (Denver, CO) – Sept 2014
Good Clinical Practices and Good Documentation Training – PRACS Institute – Jan 2013
Quality Assurance: a year in review: a look at trends in the industry – North Dakota Chapter ACRP – Sept 2012
Is it Time to Refocus Our Audit Process? – SQA Annual Meeting (Cincinnati, Ohio) – April 2010
Conflict at the Investigator Site, CRO or Vendor. How do I get past it? – SQA Annual Meeting (San Diego, CA) – Apr 2009
Auditing In vivo Bioequivalence Studies Utilizing the FDA Compliance: *Program Guidance Manual 7348.001I* – SQA Annual Meeting (Phoenix, AZ) – Apr 2006
The Differences Between Drug and Device Studies – Falcon Consulting Group – 2008
Angiotech Pharmaceuticals, Investigator Meetings: Good Clinical Practice, Investigator Obligations during Clinical Trials – 2006-2007
Risk Management in Clinical Research - PRACS Institute – 2005

PROFESSIONAL DISTINCTIONS AND CERTIFICATIONS

Society of Quality Assurance (SQA):	2003 – Present
SQA Board of Directors:	2019 – Present
Chair, Clinical Specialty Section:	2017-2018 2009-2012
Vice Chair, Clinical Specialty Section:	2016– 2017
President, Rocky Mountain Regional Chapter SQA:	2013-2015
Vice President, Rocky Mountain Regional Chapter SQA:	2012-2013
Annual Meeting Program Committee:	2004 - 2009, 2019
Chair, Annual Meeting Program Committee:	2007-2008
Chair, Regulatory Sub-committee:	2004-2008
Chair, ADHOC Committee for RQAP/GCP exam:	2004-2007

Registered Quality Assurance Professional in Good Clinical Practices (RQAP/GCP) Certification: 2007 – Present