CHRISTOPHER BARNEY

Managing Partner
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CURRICULUM VITAE

Summary of Experience

Professional Consultant with greater than 20 years of experience in the pharmaceutical and healthcare industries, with expertise in a wide range of disciplines, including over 15 years of experience in Quality Assurance. Expertise in a wide range of disciplines, including quality assurance, quality control and pharmaceutical training. Skilled in conducting qualification site audits, investigator site audits, vendor assessments and facility audits. Experienced in establishing clinical quality assurance units, including development of SOPs and standardized reporting tools. Working knowledge of clinical trial processes, EMA, EU Directives, ICH guidelines, and FDA regulations.

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
- Project Management activities: Communication/Information Flow, Documentation Compliance, Budgeting, Resourcing, and Timeline Management.
- Training for site staff, CRO Staff, Sponsor Staff and other junior auditors.
- Perform Clinical Trial Management activities: including Investigator Site selection, Regulatory Document review, ICF review, Investigator Meeting preparation, SAE reporting and review.

PROFESSIONAL EXPERIENCE

COMPLIANCE AUDIT PARTNERS, LLC (CAP) **2020 – PRESENT**
MANAGING PARTNER AND SENIOR CONSULTANT

Managing Partner, 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.

Global Clinical Solutions, LLC (a division of CAP) **January, 2020 - Present**
Global Clinical Solutions, LLC CRO **October, 2017 – December, 2019**
MANAGING PARTNER AND PROJECT MANAGER

Responsibilities include:

- Management of international and domestic clinical trials.
- Performing Monitoring Visits including Site Qualification Visits, Site Initiation Visits, Routine Monitoring Visits and Close Out Visits.
- Performing FDA and IRB Submissions.
- Feasibility and Study Start-up.
- Study Team Management.
- Budget and Vendor Management.
- Investigator Meeting Preparation, Coordination and Execution.
- Provide Quality Support for all CRO functions.
- Management of Global Partner CROs.

B&B Consulting Group LLC (located in USA) **August, 2016 – December, 2019**
B&B GxP Consulting (located in Poland) **June, 2011 – July, 2016**
Owner & Consultant

Owner and Consultant for B&B Consulting Group LLC, which provided a wide range of services including: global audits, for cause and routine site audits, vendor audits and assessments, data management and database audits, Phase I unit audits and assessments, document audits and QC, trial master file audits and QC, tables listings and figures audits, pharmacovigilance audits, systems/process audits, mock inspections, pre-inspection readiness training, Quality Assurance consultancy and support, SOP writing and gap analysis and visits and training across many areas.

Experienced in numerous 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, Urology, etc. Additional experience in Medical Device trials.

Provided training to Site, Vendor and Sponsor personnel for GCP, Inspection Readiness, Part 11 Compliance, FDA Perspective in EU, Sponsor SOPs and many more areas.

Provided services for one or multiple audits, training, mock inspection, SOP development, QA Consultancy. Experienced working with small companies and some of the world's largest pharmaceutical companies.

Falcon Consulting Group, Good Clinical Practice Services **2005 – 2011**
Exton, PA, USA
Warsaw, Poland

Associate Director and Senior Consultant, GCP Services

Responsibilities included:

- International and Domestic Vendor Assessments and Due Diligence Audits, including: CROs, Data Management providers, Biostatistical vendors, Clinical Laboratories and Electronic Data Capture vendors.
- Audits and Quality Control review of documents, including: Clinical Study Reports, Clinical Protocols, Informed Consent Forms, Investigator Brochures, Case Report Forms, Clinical Overview, Safety Narratives, Standard Operating Procedures, Summary of Clinical Efficacy and Summary of Clinical Safety documents.
- Management and Auditor of large project (100+ laboratory visits per year) including Laboratory Assessments and Laboratory Monitoring Visits for international and domestic laboratories (central, local and specialty).
- Quality Control review and Audits of Trial Master Files.
- International and Domestic Investigator Site Audits.
- Pre-Inspection Readiness Visits.
- Systems Audits at Sponsors and Vendors, including Inspection Readiness.
- Pharmacovigilance audits (system and study specific)
- Clinical Data Management and Database Audits.

- Tables, Figures and Listings Audits.
- Electronic Repository Quality Review and Clean-up: Inventory and Quality review of Repository file content, study/investigatory-specific and subject specific levels, ensure that each individual document contains all pages as appropriate and ensure that files contain all appropriate documents as required by ICH E3 & E8.0 Essential Documents and other country-specific regulations.
- Provide Subject Matter Expert and Business Analyst support for the implementation of SharePoint.
- Computer System User Specifications gathering.
- Site and vendor audits for medical device trials.
- Served as Lead Clinical Project Manager for, two Phase III and one Phase II, international programs
- Management and coordination of multiple large Falcon projects incorporating multiple services both domestic and international.
- Project Communication/Information Flow, Documentation Compliance.
- Project Tasks, Resources, Timeline Efficiencies and Budget Management.
- Training and mentoring of employees.

AstraZeneca
Wilmington, DE. USA **2002 - 2005**

Study Delivery Operations Specialist
Clinical Data Analyst
IMPACT Specialist

Responsibilities included:
- Author Informed Consent Form and Protocols.
- Perform Clinical Trial Management activities: including Investigator Site selection, Regulatory Document review, ICF review, Investigator Meeting preparation, SAE reporting and review.
- Manage day to day interactions with sites.
- Perform Data Management activities including: data reviews, query generation and resolution and database QC checks.
- Ensure CRF archival for all data in databases.
- Ensure clinical trial data is complete and of high quality.
- Conduct Protocol and CRF reviews.
- Develop working guidelines that adhere to Global SOPs.
- Perform database set up.
- Execute database lock.
- Study, Study Country, Site, Vendor set-up in IMPACT.
- Obtain requirements, design and deliver ad hoc reports from the IMPACT system.
- Develop and deliver various levels of IMPACT training.

Parexel International **2001 – 2002**
Media, PA. USA

Clinical Research Associate

Responsibilities included:
- Responsible for identifying potential Investigator sites, review of essential documents, obtaining Regulatory Affairs Approval and Central IRB set-up, submission and maintenance.
- Maintain contact with Sponsor to provide study and site status.

- Monitoring activities including Pre-Study visits, Site Initiation visits, Interim Monitoring visits and Close-out visits.

DuPont Pharmaceuticals
Wilmington, DE. USA **1998 – 2001**

Clinical Research Assistant

Responsibilities included:
- Responsible for multiple study activities across multiple therapeutic areas.
- Created, maintained and provided training on an Access database that was used world-wide for tracking Clinical Studies.
- Collected and reviewed Regulatory Documents for multiple studies.
- Prepare, negotiate and track Informed Consents and Investigator Agreements.
- Member of the SAE Reporting Team.
- Develop and deliver training for the IMPACT system.

Olsten Health Services **1996 – 1998**
Wilmington, DE. USA

Client Care Coordinator
Accounting Clerk

Responsibilities included:
- Supervision of thirty part time and five full time employees.
- Daily scheduling of patient care workers.
- Maintain contact with patients and managed care providers.
- Assist with training, coaching and hiring.
- Maintain payroll for staff of 100 employees.

EDUCATION

Delaware Technical & Community College. Stanton, DE, USA **2002**
Chemistry Degree

Salesianum Senior High School, Wilmington, DE, USA **1996**

Additional Training

Vendor Assessments – Falcon Consulting Group – September 2005
Laboratory Monitoring Visits – Falcon Consulting Group – October 2005
Laboratory Assessments – Falcon Consulting Group – October 2005
Investigator Site Audits – Falcon Consulting Group – May 2006
Auditing of Clinical Study Reports – Falcon Consulting Group – February 2007
Diversity Training – Falcon Consulting Group – January 2008

Clinical Study Report Training – Falcon Consulting Group - February 2009 (Trainer)
International Audit Training – April, 2009
Tables, Listings and Figures Training – April, 2009 (Trainer)
GCP, ICH, EMEA Training – 2005 – Present (Trainer)
ICH GCP – FDA Perspective in the EU – 2011 – Present (Trainer)
Inspection Readiness Training – 2008 – Present (Trainer)

Auditing Experience in the Following Countries

- United States of America
- Iceland
- The Netherlands
- Switzerland
- Sweden
- Poland
- Romania
- Austria
- Lithuania
- Italy
- Bulgaria
- United Kingdom
- France
- Belgium
- Portugal
- Estonia
- Czech Republic
- Greece
- Bulgaria
- Ukraine
- Serbia
- Canada
- Ireland
- Spain
- Germany
- Denmark
- Latvia
- Slovenia
- Hungary
- Slovakia
- Russia
- Moldova
- South Africa

References available upon request

Signature: _____ **Date:** 13 Jan 2020