Anne Bush

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PROFESSIONAL EXPERIENCE

Bush Consulting Services LLC Home Based   Jan 2023– Current
Independent Biometrics Consultant
- Supporting small to mid-size biotechnology organizations to achieve successful project execution.
- Ensure optimal execution of project deliverables with services including Interviewing and hiring resources, Coordination between interdepartmental stakeholders to ensure the execution of key milestones, Compliance with ICH, FDA, and GCP standards, Streamlining operations and process improvement, Resource planning, ISS/ISE support, CDISC standards adoption, eSubmission support for NDA and BLA filings.
- On-side advocacy for vendor qualification, selection, and ongoing management including RFP Development, Bid Defense Advocacy, Executive oversight and proactive monitoring of vendors, Negotiation and implementation of budgets and budget tools, Evaluation of pricing and discount schema, Expansion into lower-cost regions, Risk management solutions to critical path issues.
- Create methodologies to collaborate and measure success including Implementation of and participation in operational and executive governance, Establishment and implementation of quality metrics, oversight plans, project adoption checklists, communication plans, workflow, process, timeline, resource planning, recruitment, and forecasting tools, SOP/WI creation, and harmonization.

Cytel Home Based   Feb 2022– Jan 2023
Vice President, Strategic Account Management
- In conjunction with business development, oversee the development and implementation of global account plans and customer strategies to meet overall growth and profitability targets across FSP, Project Based Services, Software, RWAA, Strategic Consulting, and Data Monitoring Committee services.
- Lead a team of experienced operational and commercial professionals serving as executives on key accounts, accountable for greater than $215M annual new business awards, representing 20% growth for managed clients year over year and more than half annual NBA for the organization.
- Oversee development and implementation of project strategies and selling propositions, including RFP support and attendance at bid defenses.
- High bid defense meeting success rate with awards ranging from $100K to $50M.
- Competitive hit rate improvement of 14% with involvement from the strategic account management team.
- Expand the global footprint for FSP into emerging regions such as APAC and Eastern Europe.
- Implemented sales dashboards for key accounts for continuous account monitoring.
- Conduct quarterly business reviews of key accounts to ensure profitability and project delivery.
- In conjunction with the financial team, streamline financial reporting mechanisms at a customer level.
- Assess the success of operational delivery and design and implement high-quality, efficient, cost-effective processes tailored to customer needs.
- In concert with clients, design and implement operational and executive governance for effective oversight, continuous improvement, and account expansion.
- Liaise with other senior leaders to improve the effectiveness of strategic partnerships
- Support the development of new business verticals. Work with relevant business leaders to assess emerging areas for business growth and build business plans to expand market share.
- Provide a point of escalation and drive issue resolution internally and externally across all projects and teams in conjunction with relevant business leaders.

Labcorp Drug Development (formerly Covance) Home Based   Sep 2018 – Jan 2021
Director, Statistical Programming

- Establish, oversee, and develop multiple simultaneous key functional service provider accounts as biometrics and CDM lead, with an operational team exceeding 400 FTEs in reporting line.
- Oversee operational delivery of data management, statistical programming, and biostatistics team that achieved successful FDA approval for high-priority oncology drug several months ahead of schedule.
- Institute governance documents for a functional service provider relationship, including the relationship management plan, oversight plan, project adoption checklist, communication plan, and credit/bonus thresholds.
- Ensure coordination with clinical operations, data management, and biostatistics to meet critical study milestones.
- Establish and implement KPIs/rKPIs.
- Manage global teams from four continents.
- Create and Harmonize SOPs.
- Improve staff retention through an emphasis on growth and learning opportunities for staff, organizing training opportunities, encouraging conference presentations, establishing employee recognition programs, and developing relationships with individual staff.
- Develop budget tools for implementation within partnerships.
- Oversee governance at the functional and operational management team level and liaise with the executive oversight team in a relationship management capacity.
- Line manage senior management staff, including performance appraisals and ongoing evaluation of goals.
- Institute quality gates, including formalizing senior statistical review process and better project management to ensure high-quality deliverables.
- Provide a broad range of leadership and team-building capabilities to manage the performance and developmental programming team in order to achieve departmental goals and objectives.
- Communicate with broader management regarding workflow, process, timelines, and resource planning.
- Attend conferences as both a speaker and in a business development capacity.
- Develop budget estimations for biostatistics and programming components of RFPs
- Interface with client teams to drive joint initiatives forward, including deliverable quality tracking, CDISC implementation, escalation pathways, and eTMF compliance.

PPD Home Based   Aug 2017 – Aug 2018
Associate Director, Programming
- Develop budget estimations for biostatistics and programming components of RFPs.
- Interface with client teams to drive joint initiatives forward, including deliverable quality tracking, CDISC implementation, escalation pathways, and eTMF compliance.
- Provide project-level oversight, encompassing budget, timeline, and risk assessment.
- Drive employee engagement initiatives and activities.
- Supervise and mentor manager-level staff.

Chiltern International (formerly Theorem Clinical Research) Home Based   March 2012 – Aug 2017
Director, Statistical Programming (April 2016-Aug 2017)
Associate Director, Statistical Programming (Oct 2015-April 2016)
Manager, Programming (June 2014-Oct 2015)
Senior Analyst/Statistical Programmer (Mar 2012-June 2014)
- Oversee governance of functional management team and operational management team, and liaise with executive oversight team in a relationship management capacity.
- Line Manage Senior Management staff, including performance appraisals and ongoing evaluation of goals progress.
- Institute quality gates, including formalizing senior statistical review process and better project management to ensure high-quality deliverables. Maintained quality through a growth phase.
- Provide a broad range of leadership and team-building capabilities to manage the performance and development of a statistical programming team in order to achieve departmental goals and objectives.
- Manage the recruitment process for new team members, including resume review, screening and panel interviews, and revision of the process to identify fraudulent candidates.

- Evaluate and resolve complex personnel issues.
- Established method of tracking study level metrics through creation and implementation of KPIs/rKPIs.
- Instate project management system to achieve timely deliveries, including establishing the project management team, initiating the Spotfire database to replace the Excel-based system, and Microsoft project tracking.
- Communicate with broader management regarding workflow, process, timelines, and resource planning to leverage department-wide initiatives for the sponsors.
- Attend national and international conferences as both a speaker and in a business development capacity.
- Establish Functional Service Provider Relationships as one of the small groups of programmers to pilot.
- Serve as the lead programmer on pivotal phase III study and subsequent ISS studies for hepatitis C that resulted in the approval of a high-profile drug.
- Institute and provide training to new resources.
- Implement CDISC standards.
- Interview candidates.
- Manage budget and margins in an FTE-based system.
- Utilize and modify complex company-wide macros.

Dataphiles Programming, LLC, Durham, NC   Nov 2009 – March 2012
Senior Programmer (Nov 2011-March 2012)
Statistical Programmer II (Nov 2009-Nov 2011)
- Perform extensive SDTM/ADaM mapping and implementation.
- Establish new client relationships.
- Serve as interim statistical programming project lead, collaborating with project managers, biostatisticians, and other programmers.
- Conduct training sessions for other programmers.
- Create specification documents, program and validate analysis datasets, tables, figures, and listings for Phase I-Phase III oncology studies.
- Utilize and modify complex company-wide macros.

PAREXEL International, Research Triangle Park, NC   Oct 2008 – Oct 2009
Statistical Programmer II
- Programming lead, coordinating an international team of programmers for a large Phase III study. Responsibilities extended to resource management, reporting key metrics to upper management regarding deliverable timelines, and other critical operational duties.
- Function as an interdepartmental liaison, communicating with teams of data managers, statisticians, and medical writers to ensure data quality.
- Program and validate analysis datasets, tables, figures, and listings for Phase I-Phase III studies and ISS.
- Develop programming specifications for datasets and tables.
- Create and maintain thorough study documentation.

StatWorks, Inc., Research Triangle Park, NC   Jul 2006 – Oct 2008
Statistical Programmer II (Apr 2008-Oct 2008)
Statistical Programmer I (Nov 2007-Apr 2008)
Research Associate (Sep 2006-Oct 2007)
Administrative Assistant/QC Support (Jul 2006-Sep 2006)
- Coordinate multiple Phase I studies as a lead programmer with project teams of off-site contractors and junior-level programmers.
- Program and validate analysis datasets, tables, figures, and listings for large Phase III study and ISS submission.
- Communicate directly with clients as a technical liaison for data managers.
- Participate in the design and implementation of new SOPs.
- Develop programming specifications for datasets and tables.

- Provide programming support for data management including reconciliation of external datasets, development of SAS edit checks, generation of database audit listings, data extraction from Oracle into SAS datasets, and preparation of ICH standard datasets.
- Communicate with the project manager, lead biostatistician, and other team members regarding the status and deadlines of programming tasks.
- Maintain tracking documents as a record of validation and study progression.

- Perform validation of tables and listings.
- Write SAS edit checks for data management.
- Coordinated data entry, tracking, and reconciliation of Phase I studies.
- Diagnosed and identified the root cause of data discrepancies and issued queries.
- Developed, tested, and implemented electronic edit checks and edit check test plans.
- Participated in internal database audits and subsequent development and documentation of action plans.
- Annotated case report forms to meet internal and sponsor specifications.

EDUCATION

University of North Carolina at Chapel Hill, Chapel Hill, NC
M.S., Inorganic Chemistry, Aug 2006

Goucher College, Baltimore, MD
B.A., Chemistry, Biochemistry Concentration
American Chemical Society Certification
May 2003

Publications and Presentations

"Remote Candidate Fraud In Clinical Research: A Cautionary Tale For Interviewers" www.clinicalleader.com 2023
"Case Study: Impact of Implementing CDISC Standards in an Organization – Metrics Results" CDISC European Interchange 2016
"Capturing Rater-Specific Data: Is a New Domain in Order?" CDISC European Interchange 2014
"Fluorescence of substituted pyrrolyl pyridines" Journal of Photochemistry and Photobiology A: Chemistry, 163 (2004) 463-471. Scott P. Sibley, Anne Saunders, Pamela Crum, Kristin Mutolo, Jessica L. Menke and Eric V. Patterson.
"Synthesis and Dynamic Behavior of [NEt$_4$] [Tp'(CO)$_2$Mo=C=C(CN)(p-X-C$_6$H$_4$)] Complexes," Presented at National Meeting, American Chemical Society, Washington D.C., August 2004