Patricia A. Brant, RQAP-GLP

Regulatory Consulting Services LLC

Regulatory Compliance → Quality Assurance → Quality Control → Quality-Driven

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Reliable *Quality Assurance (QA) Professional, Preclinical Toxicology Corporate Compliance*:

- My expertise lies in **Preclinical Toxicology Corporate Compliance**, which embodies complex study designs in multiple scientific disciplines, e.g., general toxicology, developmental and reproductive toxicology (**DART**), Absorption, Distribution, Metabolism and Excretion (**ADME**), Analytical Chemistry (**AC**), and Bioanalytical Chemistry (**BAC**).
- My marketability and corporate value reside in my experience and passion to make a difference; I am committed to producing a positive outcome through respect for the intricate balance of regulatory compliance, corporate business needs, and team dynamics.

Auditing Experience:

- Remote and onsite Facility (CRO & supporting services laboratories-including clinical analysis labs-such as CLIA), third party vendor, and pathologist home office Qualification/Requalification inspections.
- In-process inspection/auditing for GLP/Protocol/SOP compliance (examples-formulation preparations (including dietary); analysis of formulations, blood/urine, and other matrices; necropsy and histopathology procedures; and interim data review.
- Report and complete data review from the following study types (not an all-inclusive list)
    - Toxicology and Developmental Reproductive Toxicology
    - Analytical and Bioanalytical Chemistry
    - Immunotoxicology
    - Necropsy, Histology, Clinical Pathology, and Pathology
    - Implantable medical device (pre-clinical)
- Mock Regulatory Inspections, GAP Analysis, QMS review/analysis, and assistance with SOP generation/review/compliance
- GLP training of personnel, including client specific training programs/needs.
- Willing to do some travel outside of US, have been to Canada, UK, and Japan. I do hold a current US passport.

Current Status:

Regulatory Consulting Services, LLC **January 15, 2021, to present.**

- I am available to customize a **Quality Assurance (QA) and/or Quality Control (QC)** program based on individual corporate needs; these needs could be simple or complex, from a facility or regulatory inspection to providing advice for initiating or enhancing a fully integrated and comprehensive in-house GLP program; assessing the individual needs of a corporation is important and establishing a working partnership based on trust is essential.
- Competence and commitment are exemplified by tiered promotions to increasing levels of responsibility for **>20 years in a Contract Research Organization (CRO)**; my acute critical thinking processes and intuitive skills are amplified in this high intensity environment. Additional strengths lie in continuous process improvement, scheduling, integration, full transparency, collaboration, accountability, team development, and above all, dedication to quality.

- Commendation and recognition from multiple sources [e.g., management, direct reports, colleagues, and peers (internal and external)] are significant; role responsibility demands intense amounts of energy and focus, adaptability to constant change, prioritization of tasks and timely follow-through, expert contributions, accurate and clear decision-making processes, exceptional organizational and communication skills, and a high level of engagement.

Employment History:

CHARLES RIVER LABORATORIES (CRL)*, Ashland, OH
1995 - January 2023
**Formerly WIL Research; acquired by CRL (2015)*

Senior Quality Systems Auditor, Quality Assurance, Regulatory Compliance
June 2022-January 2023 (temporary subcontracted position)

- Functioned as one of the lead hosts for client visits to the facility (qualification and for cause visits). Was the lead at the Ashland site GLP training/scheduling program; facility and process-based audit scheduling/completion/performing lead; and worked on Computer validation projects.

Senior Supervisor, Lab Sciences (LS), Quality Control (QC)
2019 - January 2021

- A separately functioning QC unit, under the auspices of Lab Sciences, was devised in response to the acquisition by CRL; the purpose was to integrate the functions of multiple disciplines, and corresponding LS sub-disciplines, to form a single cohesive unit for eliminating redundancy and maximizing corporate effectiveness, thereby improving first-pass quality. I readily and immediately accepted and assumed ownership as **Senior Supervisor** of this newly created department and very high-profile position. I exceeded the expectations of Management by creating a fully accountable, self-managing and cross-functioning team in an unexpected amount of time. I approached this seemingly insurmountable task by actively soliciting input from each discipline and using innovative pathways to analyze, create, design, and implement operational processes and procedures to successfully integrate these separate disciplines into a single cohesive unit.
- Continually searched for ways to improve my leadership techniques and team interaction, to maximize the exchange of information and ideas for process improvement, e.g., implemented monthly and weekly forums and created novel approaches within the group to recognize the efforts of individuals and encourage team participation; created new tools to drive scheduling to a more structured approach and streamline data review.
- Managed data collection practices to assure compliance with the study protocol, SOP's and GLP's and to assure that high quality data was submitted to QA; liaison between Lab Sciences Operations, the Lab Sciences QC, and QA; provided technical support to Project Scientists, Managers, Study Directors, and Clients.
- Directly managed staff (Formulations, ADME/DMPK, Analytical/Bioanalytical QC personnel); designed several smart sheet tracking systems to manage workflow metrics; kept management abreast of trending and relevant information by reporting updates regarding FDA news, warning letters, SQA and MWSQA news, and internal training progress.

Quality Assurance (QA), **Senior Quality Assurance Auditor ***
1999-2009 & 2014 - 2019

- Recognized for outstanding contributions and competence in QA; expertise in all facets of QA related to operational processes and procedures, applicable regulatory requirements, international standards, corporate policies and procedures, and leadership.
- Conducted GLP and 21 CFR Part 11 training; system validation development, documentation, implementation, auditing, and review; facility inspections at vendors and subcontractors; critical phase, data and, report audits, test site qualification audits; QC, and study oversight; hosted sponsor visits.

Toxicology**, Research Technologist ***
1996 – 1999

Animal Husbandry**, Animal Husbandry Technician***
1995 - 1996

*****_Final status in department following successive promotions_

Computer Proficiency: Microsoft Office Suite (e.g., MSWord, MS Excel, MS PowerPoint); Microsoft OneDrive; Microsoft Teams; Smartsheet; Zoom; Adobe; scientific data collection, validation analyses, and storage systems; Chromeleon; Provantis; WATSON; System Expert and Administrative functions (e.g., CSVMP, CSI).

Professional Affiliations and Awards:

Society of Quality Assurance (**SQA**), member since 2001; **Distinguished Service Award, 2019**

Committees: World Cup, 2014-2018; Good Laboratory Practice Specialty Section (**GLPSS**), 2015-to present; SQA Abstract Submission Reviewer, 2017, 2022, 2023, and 2024; GLPSS EPA subcommittee, 2016 to present; Bioanalytical Specialty Section (**BASS**), 2019 to 2022; Quality Assurance Consultant Support (**QACS**) group, 2021 to present; Communication and History (aka Board of Publications) Committee (**CHC**), 2016 to present; Membership Retention and Development Committee (**MRDC**), 2022 to present; Early Career Specialty Section (**ECSS**), 2022 to present; Histopathology Specialty Section (**HSS**), 2022 to present (2023, 2024 Vice-Chair; 2025 Chair); SQA annual Meeting Planning Committee member 2022-present.

Midwest Society Quality Assurance (**MWSQA**), member since 2001

Elected Officer and Committees: Vice President, 2015 & 2021; President, 2015-2016 and 2022; Past President, 2017-2018, 2023 & 2024; Annual Meeting Planning Committee Chair, 2019 and 2021-2022, 2024; Annual Meeting Planning Committee volunteer, 2017to present. MWSQA Newsletter editor 2021 to present.

Patricia A Brant 02 January 2025