Parker Biopharmaceutical Consulting LLC
Innovative, Reliable Solutions

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Nathan Parker (Principal Consultant) has 26 years of progressive experience in the pharmaceutical industry including operations, technical support and quality assurance management culminating in executive leadership roles (VP Manufacturing, VP Quality, Site Head of Quality). Utilizing his strong technical foundation as a Chemical Engineer, Nathan has supported chemical API, biologic drug substance, cell therapy, medical device, drug product, and combination product manufacturing operations (21CFR 210, 211, 820, 600 and 610; ISO13485; IS09001). In his leadership of manufacturing and quality, he has been able to improve the efficiency and compliance within the organizations he has led. Key accomplishments include: support of numerous successful regulatory inspections (FDA, EMA, TGA, Russia, Korea, Ukraine, Turkey, ANVISA), establishing efficient systems to comply with computerized system requirements (21CFR Part 11 and Annex 11), establishing holistic bioburden and contamination control strategies, reorganizing operations and quality organizations to improve effectiveness and efficiency, and implementing systems and training to improve investigations and on-time completion of deviation reports and corrective and preventive actions.

Drawing on this experience, Nathan can provide in-depth operations, technical and quality expertise for large and small molecule investigational and commercial products in the following areas.

Quality Systems:
Establish strategic direction and streamline quality systems to be compliant, effective, and efficient. Experiences and support include:

- Quality Policy/Plan/Manual
- Development of bioburden and contamination control strategies
- Establishing Key Performance indicators and Quarterly Management Review
- Procedure development, implementation, and training
- Third party (supplier, contract manufacturer) quality evaluations, GMP audits, and quality agreements

Quality and Operation Culture:
Evaluate current culture and support cultural change:

- Assess current culture (questionnaires, interviews, on the floor assessments)
- Collaborate with management, supervision, and quality assurance to implement a cultural change agenda

Manufacturing and Product Investigations:
Coordinate investigations of significant events to identify impact, root cause, and corrective and preventive actions:

- Media simulation or sterility failure investigations
- Deviations requiring in depth analysis, coordination and input from multiple stakeholders (e.g., Out of Specification, particulate matter, and instrument failure investigations)
- Commercial and clinical product complaints

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Personnel Training:
Develop and provide customized training for manufacturing, technical support and quality assurance organizations:

- Quality system processes and documentation (change controls, investigations, complaints, recalls including mock recall events, good documentation practices, GMP)
- Clean room operations, aseptic practices, basic operations (weigh dispense, in-process measurements, cleaning)
- Collaborate with technical support and operations leadership to develop comprehensive performance based training for specific operations

Inspection Preparation and Response:
Support inspection readiness by:

- Completing internal audits
- Developing audit support processes (processes for request delivery and tracking, processes for subject matter expert briefing and preparation to address requests)
- Reviewing documentation (validations, investigations, change controls) and prepping staff to address potential concerns (subject matter expert conduct and best practices training, mock interviews, story boards)

Support inspection response by:

- Collaborating with site leadership to develop practical and comprehensive responses
- Facilitating timely completion of response and remediation actions

Risk Assessments:
Coordinate risk assessments to allow for understanding of current state of compliance and how to most effectively utilize resources:

- Bioburden and contamination control
- Process specific Failure Modes and Effects Analysis
- New equipment or facility modification

Validation:
Support for process, equipment, facility, and analytical validation including:

- Validation strategy and validation master plan development
- Specific validation strategies and protocols for cleaning, analytical method, equipment, facility, and computer system qualification and validation