Bettina Kaplan

Senior Quality Assurance Consultant

Core Competencies

- GxP Quality Management
- Audit Strategy
- SOP Development
- CAPA investigation
- Quality agreement
- Quality Metrics
- Third Party Oversight
- Plant Operations
- USA and ROW Exp

Professional Summary

With over 20 years of experience, Ms. Kaplan managed Quality and Compliance teams in both an API and GMP manufacturing plant operations. She has led site remediations and instituted new/updated Quality Management Systems in many sites throughout her career. Additionally, she had performed quality audits in the USA, EU and ROW and led PAI inspections.

Ms. Kaplan authors and reviews Standard Operating Procedures (SOPs) and other quality documentation. This includes the development and implementation of appropriate GxP quality systems to ensure site compliance and third-party oversight. She is an expert of domestic and international regulatory quality requirements. She provides a culture of continuous improvement for our clients.

Bettina's t expertise includes Oral Solids, Topicals, Liquids, Steriles, Aseptic and Combination products.

Education

B.S.	Chemistry	Stevens Institute of Technology

Professional Experience

DSI Consulting **2013 - Present**

Senior Quality Assurance Consultant

- Providing guidance and oversight as needed in quality systems and compliance arenas for the bio-pharmaceutical industry,
- Develop a supplier management and quality program,
- Support the preparation for and hosting of regulatory agency inspections,
- Build cross functional quality processes to drive innovation, teamwork and efficiency within the organization,
- Drive quality by design (QBD) initiatives into product development to help enable best practices.

Sandoz **2009 - 2012**

Head of Quality & Compliance, US Development Center

- Set up an active Quality & Compliance Organization and developed best in class practices for the US Development Centers to monitor all activities for the US Generic Research and Development Business Unit,
- Managed successful FDA inspections with no FD483 observations and positive Inspector feedback,
- Create the Quality and Compliance groups for two US SDC (Sandoz Development Center) sites,
- Implemented an electronic documentation system based on Next Docs,
- Developed the Quality Systems and manage the Investigations, Deviations and Change Controls for the applicable areas to assure adherence to strictly enforced timelines,
- Oversee the remediation of development projects at the various development and manufacturing sites,
- Obtained DEA Approval for Analytical, Research and Manufacturing capabilities for classes CI-CV,
- Oversee the DEA administration for the site and submit all required information to DEA,
- Participate on Product Launch Teams to assure timelines are met from a Quality & Compliance prospective for regulatory filings,
- Assure the Product Development Group has qualified equipment and that the processes are GMP driven,
- Provide review and approval of all protocols, reports, product transfers, PDRs and other filed documents,
- Provide review and approval of all protocols, reports for all Analytical Method development/transfers,
- Assure the Analytical R&D Group has qualified instruments and GMPs are followed in the laboratory setting,
- Create an SOP System and direct the oversight of the SOP system,
- Assure the review and approval of CAPA's and verification of follow-up and closure of all CAPA's,
- Oversee the approval of materials for use in manufacturing, and the review and approval of all specifications and Certificates of Analysis,
- Provide support for all regulatory inspections.

Elite Pharmaceuticals **2008 - 2009**

Director of Quality Assurance & Compliance

- Strategically maintain a cGMP and cGLP environment of the production facility,
- Coordinate the regulatory inspections (FDA & DEA) to ensure a successful outcome and communicate with the agencies to assure appropriate corrective actions are taken,
- Instituted trending and CAPA programs for complaints, investigations and deviations,
- Perform annual product reviews to meet regulatory requirements,
- Re-wrote all the SOPs to meet current industry practices and the company processes,
- Decreased the turnaround time for complaints and investigations,
- Implemented and oversee a supplier audit program,
- Compile Research & Development data on a routine bases and evaluate the data to determine manufacturing strategies.

Purdue Pharma **2004 - 2007**

Director of Quality Assurance 3rd Party Manufacturing

- Oversaw of all third-party manufacturing and packaging operations to assure ongoing compliance,
- Directed the QA 3rd Party Manufacturing group of 4 direct reports. Group consisted of 2 Single Point of Contact positions, who were individuals responsible for the direct oversight of specific vendors and contractors assuring compliance and monitoring operations on a routine basis,
- Additionally, 2 Senior QA Specialists responsible for the review and disposition of products received in the warehouse for distribution from the vendors,
- Monitored stability and coordinating the complaint responses for the third-party manufactured/packaged product,
- Reviewed and approved all Supplier QA investigations, complaints, laboratory investigations, Planned Deviations, SOPs, Standards and Process/Equipment validation/ qualification documents,
- Worked in conjunction with Supply Management, Procurement, Regulatory Affairs and Package Development on a routine basis to assure open communication between Purdue and the third parties.

Director of Quality Assurance Manufacturing Compliance

- Directed the QA Manufacturing Compliance Group of 27 employees responsible for Investigations, Complaints, CAPA, QA Validation, Incoming QA and In-Process QA,
- Harmonized the unique site-specific quality systems to create a simpler more unified set of compliant quality systems for investigations and complaints using computerized management and tracking systems,
- Developed and maintained a team atmosphere between production and quality appropriate for a cGMP/DEA environment,
- Reviewed and approved all site and Supplier QA investigations, complaints, laboratory investigations, Planned Deviations and Process/Equipment/Utilities/Laboratory validation/qualification documents,
- Oversaw a QA validation department handling over 1000 IQ/OQ/PQ/PV protocols, reports, commissioning documents, URS, FRS, PM Documents and Calibration standards in a year for Process, Equipment, Utilities and Laboratory validation/qualification documents,
- Reduced the processing time for complaints, investigations, deviations, SOPs and validations documents to meet compliance and production requirements; on time results went from 50%-98%,
- Upgraded the In-Process and In-Coming ANSI AQL sampling programs,
- Assure all responses to the warning letters were addressed, resolved, and completed as communicated to FDA.

Sharp Corporation **2003 - 2004**

Director of Quality

- Directed the quality department (QA, QC and validation) at two company sites - 7 direct reports, 48 indirect,
- Strategically & collaboratively worked on changing the culture of production facility to maintain a CGMP environment post receipt of a Warning Letter,

- Harmonized the unique and complex quality systems of multiple sites to create a simpler and more unified set of compliant quality systems,
- Developed a fully functional validation department handling over 250 IQ/OQ/PQ/PV protocols a year,
- Implemented a corporate SOP system and initiated revisions of all SOPs, Corporate or Site specific to a user friendly and industry compliant format,
- Coordinated and hosted Regulatory inspections,
- Created batch records to encompass the entire operation, eliminating loose and uncontrolled forms,
- Instrumental in starting up and staffing a new packaging site,
- Instituted trending programs for complaints, investigations and deviations,
- Oversaw and managed onsite Chemistry and Microbiology laboratories,
- Implemented a robust and effective companywide training program,
- Decreased the turnaround time for complaints /investigations to meet current industry practices: 70% to 95%.

Hoffmann-La Roche **2000 - 2003**

Compliance Coordinator

- Prepared for and hosted all regulatory agency inspections and affiliate visits,
- Prepared responses to the inspections and follow-up on corrective actions,
- Responsible for managing PAI activities to assure an effective governmental inspection,
- Performed internal audits as well as external audits of Roche contract manufacturers, packagers, laboratories and component suppliers for CGMP compliance,
- Participated on product launch teams providing QA guidance and assuring that all actions are taken to promote a successful launch,
- Assured all systems were remediated as promised to the FDA.