KRISTYN ABERCROMBIE

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Technical Skills

- 7+ years of experience in the pharmaceutical industry with a focus on Quality Assurance and Regulatory (FDA, DEA) Compliance.
- Ability to lead a diverse cross-functional team in support of positive strategic outcomes for the company without loss of visibility to regulatory commitments.
- Driver of a continuous improvement mindset by identifying discrepancies in procedures and collaborating with inter-departmental and multi-level personnel to provide a streamlined path for optimal resolution.
- Participated in and hosted regulatory inspections, internal CSCF audits, and supported DEA compliance assessment programs.
- Technical Writing: experience with documentation control systems in drafting, reviewing, and approving SOP's, Forms, Batch Records, Training Course Plans, Investigations, CAPA's, Change Controls and notification letters to regulatory agencies. Ability to understand, interpret and proceduralize government regulations as applicable to functional area and industry type.
- Problem-solving mindset with an aptitude for compliance. Attention to detail and thorough understanding of processes outside of immediate job function.
- Experience with multiple ERP Inventory systems and Microsoft Office Suite (Access, Excel, Office, OneNote, Outlook, PowerPoint, Power BI) for appropriate data tracking, trending, and reporting.
- Excellence in Management through Wichita State University- Center for Management Development (WSU-CMD).
- Certified Medical Laboratory Scientist by the American Society for Clinical Pathology (ASCP).

Experience

Apr 2021-Present *Pfizer* - **Controlled Substance Manager**

- Primary point of contact of Pfizer for local DEA Field Office including host to DEA inspections.
- Reconciliation of inventory via accountability tracking system and source documents (Batch Record, CSTR, SR, Dispensing Reports, API inventory Cards, Sales, Disposal Reports)
- Oversight of Monthly and Annual Reporting to DEA (YER, UN, ARCOS).
- Responsible for purchasing quota tracking, owner/SME for DEA 222 log.
- Developed and delivered training to employees including CDA (CS handling) and DEA 222 (official DEA documentation) and YER (inventory tracking).
- Acted as DEA compliance SME on multiple projects involving cross-functional teams including PC1 (contract manufacturing) and security modifications/updates.
- Mitigated backlog by ensuring appropriate documents are completed for receipt and transfer of all controlled substance materials via imports (from international suppliers), exports (to international facilities) or non-international entities. (DEA 222, DEA 236, DEA 161/36)
- Managed the process for transfer and disposal of Controlled Substance Waste, from point of generation to disposal via reverse distributor. Provided all data required for RFP efforts in qualifying a secondary vendor as contingency measure.
- Routinely reviewed and updated multiple inventory systems (JD Edwards, SAP) during reconciliation activities to guarantee real-time and accurate data of inventory.
- Encouraged a culture of Diversion awareness within the facility and sponsored a mindset to escalate all matters deemed a potential non-conformance.
- Facilitate Supply Chain needs for Controlled Substance materials via domestic and Import/Export transactions.

Apr 2020-Apr 2021 *Fagron Sterile Services* - **Controlled Substance Compliance Specialist**

- Sole SME and point of contact for DEA Compliance for entire 503B facility including with in-network API manufacturers and customers. Responsible for all communication with DEA Field Office including changes to security, processes, Diversion (DEA 106/107), NDC revisions.
- Introduced and successfully completed the transfer of List 1 chemical production, storage, testing and commercial sales between sites with appropriate notification to the DEA.
- Represented Controlled Substance Compliance during any Regulatory (FDA, DEA, State BOP) and Customer Audits.
- Investigated all deviations from procedure, discrepancies, Out-Of-Accountabilities and Non-Conformances related to Controlled Substance Materials.
- Responsible for reconciliation of Controlled Substance Finished Goods and API material within inventory system (Microsoft Dynamics AX).
- Performed monthly and annual reporting to the DEA (YER, UN, ARCOS) and applicable state agencies (Texas, Ohio).
- Management of CII sales orders through CSOS, including accountability checks and resolution of un-dispositioned orders within the system.
- Optimized Controlled Substance processes and procedures to account for increased production needs due to Public Health Emergency.
- Maintain readily retrievable records related to Controlled Substance Materials to promote an environment of DEA Inspection Readiness.
- Responsible for Renewal of DEA registration and applicable State registrations.
- Developed spreadsheets to track reconciliation and usages of controlled substance materials. Analyzed the data to redevelop variance limits over time.
- Provided training to New Hire personnel and CDA's on handling of controlled substance materials to promote an environment of Diversion awareness.

Apr 2019-Apr 2020 *Fagron Sterile Services* - **Quality Batch Release Supervisor**

- Oversight of the Batch Release team consisting of 9 personnel and the final release process for all finished product at multiple facilities.
- Formalized the processes within the batch release team by developing and establishing training processes for team roles.
- Created a method for tracking of pertinent Batch Release data in order to establish limits for processes and identify trends.
- Revised SOP's, forms, and training records via document Control System (MasterControl) to align with FDA regulations and industry standards.
- Quality Approver for Controlled Document Revisions (SOP's, Forms, Batch Records, Labels), GDP-related Investigations
- Master System Approver in ERP Inventory System (AX) for Finished Materials.
- Confer inter-departmentally with appropriate management on issue resolution and development of action plans to mitigate re-occurrences.

Oct 2018-Apr 2019 *Fagron Sterile Services* - **Quality Compliance Specialist**

- Management of the Quality Investigation System (DMS) and analyzed data to identify trends.
- Assisted with multiple Regulatory and Customer Audits at multiple sites.
- Disseminate data on active investigations to appropriate departments and personnel.
- Quality approver on low level investigations, Change Controls, CAPA's, and CAD's.
- Assist with Controlled Document (SOP's, Forms, Training records) revisions.
- Provided GDP/GMP training to New Hire personnel.
- Promoted the harmonization of processes between multiple sites.

Education

Spring 2012 **Bachelor of Science- Biology (Bio-medical), Minor in Chemistry**
Wichita State University

Fall 2013 **Bachelor of Science- Medical Laboratory Science**
Wichita State University

Clinical Experience: Susan B. Allen Hospital (El Dorado, KS)

- Chemistry, Hematology, Immunohematology, Microbiology, Urinalysis/Body Fluids, and Serology