DAVID SERTL, M.S., RAC, CQA

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Quality and Regulatory Scientist

A versatile scientist with a unique understanding of both analytical chemistry and regulatory affairs and their relationship to the quality of FDA-regulated products. Specializing in regulatory requirements for the validation of analytical methods throughout the drug approval process. Utilizing critical thinking, networking and organizational skills to solve problems and move projects to successful completion. Contributing to inter-departmental teams resulting in the successful development and commercialization of 5 new regulated products generating >$200M/year in sales. Recent training in quality and CMC regulatory compliance during the development cycle of biopharmaceutical products.

- Stages of Method Validation
- Drug Approval Process
- Regulatory Compliance
- Quality Investigations
- Root Cause, Corrective Actions
- Study Design, Data Review
- Critical Thinking
- Technical Review
- Networking, Collaborating

Career Summary and Accomplishments

CONSULTANT Quality and Regulatory Affairs for FDA-regulated products 2009 - present

- Multiple contract positions in regulatory affairs and quality compliance for drugs and combination products.
- Ongoing professional development activities, training and certifications in regulatory affairs and quality.

Quality Investigator Chemical Quality, **HOSPIRA**, Rocky Mount, NC (Contract thru Oxford) 2013

Hospira Rocky Mount is one of the world's largest manufacturers of sterile, injectable drugs in a variety of delivery systems.

- Performed investigations of out-of-specification (OOS) results per FDA regulatory requirements (21 CFR 211.192).
- Provided critical support to a vital quality investigation yielding corrective action that reduced delays in the manufacture, release and distribution of the # 1 selling sterile product made at the Rocky Mount facility.
- Completed a Phase 1 investigation eliminating laboratory error as the source of OOS potency result for a drug product.
- Collaborated with analysts and lab management to gather information related to analyses yielding OOS testing results.
- Utilized TrackWise software to research quality issues and trending as well as to document the results of investigations.

QC Analytical Data Reviewer Quality Control, **HOSPIRA**, Boulder, CO (Contract thru Kelly) 2012

Hired to help with FDA compliance remediation project at Hospira Boulder (which manufactures pharmaceutical APIs).

- Trained to perform full technical review of QC stability data in compliance with cGMP requirements (21 CFR 211.194).
- Reviewed analytical data - verifying correct methods were run and good documentation practices were followed.
- Verified that methods were performed properly, that results were calculated correctly and compared with specifications.

Regulatory Compliance Specialist **AEROPHASE INC.**, Longmont, Colorado (Contract) 2011

Aerophase is a drug/device company working to commercialize a device for the targeted delivery of chemotherapy drugs.

- Evaluated the current status of their technology and regulatory compliance activities needed to attract investors.
- Identified and engaged an expert consultant to train in how to communicate with potential investors.
- Coordinated multiple meetings with the consultant resulting in Aerophase being better prepared to gain investors.

Regulatory Affairs Intern **CBR INTERNATIONAL**, Boulder, CO (10 week paid Internship) 2010

CBR is a regulatory affairs consulting company providing integrated program and strategic development services.

- Assisted in the preparation, QC review and submission of IND amendments to the FDA on behalf of clients.
- Performed regulatory research for changes in legislation, regulations and current regulatory agency thinking.
- Prepared slide sets, information sheets and templates regarding key regulatory topics for client or internal use.

Ongoing Professional Development Colorado and international professional organizations 2009 - present

Training, certifications and networking activities to broaden skills and areas of understanding and expertise …

- Trained in principles of quality auditing and earned the ASQ CQA certification (Certified Quality Auditor).
- Utilized online and local resources to study and Earn the RAC certification in U.S. regulatory affairs for drugs and devices.
- Completed 13 online courses, Earned the Pharmaceutical Certificate Regulatory Affairs Professional Society (RAPS)
- Completed 2 certificate courses in GLP and GMP for medical devices at the University of Denver.
- Studying the CMC regulatory aspects of the development and approval process of biopharmaceutical drugs.
- Networking with experts and professional meetings to increase understanding of quality and regulatory affairs.

Analytical Chemist, Research & Development, **RENTECH INC.**, Denver, CO 2002 - 2008

Rentech is commercializing the Fischer-Tropsch (F-T) catalytic process to produce clean fuels from coal and natural gas.

- Owned and managed all aspects of analytical chemistry support to R&D work into the F-T catalytic process.
- Optimized an in-process test method to reduce testing time by 50% and increase the data produced by 100%.
- Produced and organized analytical data to dramatically increase understanding of F-T reactor products.
- Maintained and kept operational a key GC testing instrument to provide 24/7 availability to researchers.
- Troubleshooting and improvement of GC methods for the analysis of hydrocarbons from reactor streams.

Chemist, Analytical R&D, Ross Products Division, **ABBOTT LABORATORIES**, Columbus, OH 13 years pre-2002

The Ross Products division of Abbott develops and manufactures infant formula and adult medical nutritional products.

- Provided key analytical testing support to development of 5 nutritional products generating >$200M/yr in new sales.
- Innovated to develop a critical in-process test that enabled manufacturing of a new line of nutritional products.
- Optimized numerous analytical methods to significantly improve performance and reduce testing time and costs.
- Evaluated and adopted 2 new analytical technologies (Near-IR, Dionex HPLC) to provide new testing capabilities.
- Developed, validated and implemented 5 major analytical methods for FDA-regulated nutritional products.
- Managed complex technical projects to support the quality of new products in development.
  - Developed and validated analytical methods for critical quality attributes of nutritionals.
  - Wrote technical reports and publications, organized data and communicated test results to customers.
- Investigated the quality of testing method and out-of-specification (OOS) test results, implemented corrective actions.

Education and Certifications

Certified Quality Auditor (CQA) certification American Society for Quality (ASQ) 2013
RAC(US) Regulatory Affairs Certification Regulatory Affairs Professional Society (RAPS) 2010
Pharmaceutical Certificate (9 courses in regulatory affairs) RAPS 2009
Certificate courses in GLP and GMP for medical devices, Denver University 2009

Masters degree in Chemistry, Cornell University Bachelors degree in Chemistry, Union College

Top Talents

Critical Thinking (to evaluate, investigate, improve)
Networking (to gather needed information)
Organizing Data (seeing relationships and presenting information)

Accomplishments

Received Abbott Presidential awards for cost savings and excellence in support of international manufacturing.
Provided analytical support to the successful development of 5 multi-$M products in an FDA-regulated industry.
Developed an HPLC method for Vitamin D in infant formula - later adopted by the FDA for compliance testing.

Computer skills Microsoft Office (Word, Excel, PowerPoint,) TrackWise software (writer, reviewer, approver)