Christine Tye-Coleman

Quality Assurance at Clovis Oncology

Summary

Chris is a senior-level quality and compliance professional with over 20 years of pharmaceutical experience. Her expertise is the implementation of quality processes in both large and small organizations with global presence. Chris has proven her expertise by establishing the quality assurance department within several pharmaceutical start-ups. Her ability to identify quality and compliance issues and envision their resolution within the framework of an integrated enterprise is the basis for her visionary leadership.

Specialties

Quality Assurance, Regulatory Compliance, Quality Systems, GMP, GCP, Sterile & Oral Dose, Clinical & Commercial, Change Control, Complaints, Investigations, Corrective and Preventive Action (CAPA), Deviations, Documentation (batch records, product specifications, test methods, qualification/validation protocols/reports, SOP), Stability, Annual Product Reviews, Vendor/Supplier Oversight (contractor qualification, quality agreements, product transfer, auditing), Product Launch, JD Edwards, SAP

Experience

Associate Director, Quality Assurance at Clovis Oncology
March 2012 - Present (3 years 10 months)

Senior Manager, CMC Quality Assurance at Clovis Oncology
April 2011 - February 2012 (11 months)

Director, Quality Assurance at Allos Therapeutics
2009 - April 2011 (2 years)

Principal Consultant at TyeColeman Enterprises LLC
2009 - 2009 (less than a year)

Quality Assurance Director at Celgene
2008 - 2009 (1 year)

Chris directed global product quality assurance and compliance activities for the Pharmion oncology and hematology product families (investigational and commercial sterile and solid oral dosage forms). Chris led oversight of more than 50 third party contractors providing drug substance and drug product manufacturing, packaging, testing, storage and distribution services for those products. Quality assurance product approval and launch activities for multiple EU and International approvals were completed by Chris and her staff in a

timely and efficient manner. The strength of Chris' quality team, systems, and practices was affirmed by the successful conclusion of a 5-day FDA inspection that closed with zero observations.

Quality Assurance Manager at Pharmion

2004 - 2008 (4 years)

Chris, the first Quality Assurance professional hired at Pharmion, was responsible for product quality and GMP compliance. The products included both investigational (clinical) and commercial sterile and solid oral dosage forms. She led Quality Assurance staff in vendor oversight activities, ensuring the products met the dossier and regulatory requirements for distribution globally. During her tenure a comprehensive Global Quality Assurance program, including Quality Policy, Quality Manual, Quality Standards, Standard Operating Procedures, and Work Instructions was developed and deployed. Integrated electronic quality systems were defined and deployed under Chris' guidance, including complaint handling, change management, documentation control and batch processing database systems. Since Pharmion was a pharmaceutical start-up Chris' experience outside of quality assurance was necessary in the implementation of the JD Edwards ERP Forecasting, Planning, Purchasing, and Inventory modules. Pharmion was acquired by Celgene Corporation in 2008.

Consultant at Self Employed

2003 - 2004 (1 year)

Chris consulted on Qualification, Validation, and Process Improvements.

Systems Engineer, Quality Engineer, Quality Assurance Supervisor, Forecasting Analyst at Aventis (formerly Hoechst Marion Roussel, Marion Merrell Dow and Marion Laboratories)

1989 - 2001 (12 years)

Throughout her career at Aventis and its predecessors, Chris ensured quality and compliance in the following areas of the business: Corporate SAP Implementation Incoming and Finished Product Inspection Groups Supplier Auditing Product Development and Transfer Process, Equipment, System Qualification and Validation Chris took a career development opportunity within the Sales and Marketing business unit expanding her experience with Sales and Operations Planning as the Forecasting Analyst.

Secretary/Treasurer at Logicrucible Inc.

1994 - 1999 (5 years)

As partner of the business, Chris designed human-computer interface for computer gaming software.

Skills & Expertise

GMP
Validation
Change Control
GCP
FDA
Sop

Quality System
Quality Assurance
Quality Control
Computer System Validation
CAPA
Pharmaceutical Industry
Regulatory Requirements
GxP
21 CFR Part 11
Software Documentation

Education

University of Missouri-Columbia
BS, Industrial Engineering, 1980 - 1982
Activities and Societies: Tau Beta Pi Alpha Pi Mu Institute of Industrial Engineers

University of Missouri-Rolla
1978 - 1980

North Carolina State University
MS, Industrial Engineering w/ Psychology Minor

Christine Tye-Coleman

Quality Assurance at Clovis Oncology

Contact Christine on LinkedIn