



Stella P. Assink

OVERVIEW

Over 20 years of experience working in the Pharmaceutical industry that includes Quality Control, Validation of laboratory equipment, laboratory methods, automated and computerized systems, manufacturing processes, laboratory audits and process capability studies.

CORPORATE EXPERIENCE

Roche Professional Diagnostics – (Indianapolis Indiana)

October 2007 to present – Validation Consultant

- Documentation Review: Performance Qualifications, Process Validations, Equipment Qualifications, Cleaning Validations

Scientific Protein Labs – (Waunakee, Wisconsin)

September 2006 to March 2007

- Method Validation to harmonize with ICH and USP requirements

Boehringer Ingelheim Roxane Inc. – (Columbus, Ohio)

May 2002 to October 2007 – Project Leader/Team Member

- Validation project for 5 automated encapsulation and packaging lines with associated software applications, facilities, utilities and a Wonderware based Building Management System.
- Development of validation documentation for Unit Dose Vialing system Control System, a Water Control System, Uninterruptible Power System Control System, Engineering InSQL Database Server and a GAP review of Vendor Validation Documentation for Cartoner, Robot and Bar Code Reader
- Responsible for the development of an IOQ Template with contents specific for CSV/ASV

Shionogi Qualicaps – (Whitsett, North Carolina)

January 2005 to April 2005 – Validation Consultant

- Qualification of Hewlett Packard 5890 gas chromatograph and Hewlett Packard 1050 HPLC
- Validation of Analytical Test Methods; Included review of test methods, comparison against current compendial test methods for equivalence,



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Pharmacia Hepar Inc. – API Facility (Franklin, Ohio)

June 1997 to May 2002 – Assistant Validation Manager/Validation Specialist

- Facility Representative for Corporate Global Part 11 Remediation Project
- Validation of computerized systems, spreadsheets used in manufacturing process and laboratory test result calculations and Fourth Shift MRP (manufacturing/resource/planning) software application
- Generation and coordination of manufacturing process capability studies for removal and/or inactivation of viruses, removal of herbicides, pesticides and antibiotics including process scale down and product degradation studies.

July 1993 to June 1997 – Assistant Manager of Quality Control

- Coordination/Execution/Review of process capability studies, validation of computerized systems, laboratory equipment, laboratory assays and software applications
- Performed Internal and Contract laboratory inspections and audits; Performed OOS investigations and wrote investigation reports

Isotec Inc. – Specialty Chemical Manufacturer (Miamisburg, Ohio)

June 1987 to July 1993 – Quality Control Chemist

- Testing of Final Products, In-process samples and Raw Materials, maintenance, calibration and repair of HPLC and IC pumps and detectors

Hilton Davis Chemical Co. – Food Color Manufacturer (Cincinnati, Ohio)

April 1984 to June 1987 – Quality Control Chemist

- Testing of Final Products, In-process samples and Raw Materials, maintenance, calibration and repair of HPLC auto-samplers, pumps and detectors
- Participation in establishment of Compendial Test Method for trace impurities in FD&C Yellow 5 and FD&C Yellow 6

Hepar Industries – API Facility (Franklin, Ohio)

October 1981 to April 1984 – Quality Control Chemist

- Testing of Final Products, In-process samples and Raw Materials

EDUCATION

University of Cincinnati, Cincinnati, OH
Bachelor of Science, Chemistry

PROFESSIONAL AFFILIATIONS:

International Society of Pharmaceutical Engineers (ISPE)
Parenteral Drug Association (PDA)



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PROFESSIONAL EDUCATION/TRAINING:

How the FDA will Exercise Enforcement, Advamed
Good Electronic Records Management, PDA
Computer System Validation, Validation Associates, Inc.
Managing Multiple Projects, Objectives and Deadlines, Skillpath
FDA Investigator Training on Computer Validation, Advamed
Auditing Computer System Providers, Validation Associates
BSE/TSE Issues Forum, PDA
APIs: Manufacture and Validation, PDA
Computer Related Systems and Software Validation, Pharmalinx
Focus on Pharmaceutical Compliance Issues, Applied Analytical Industries
Aberrant Data Investigations in the Analytical Lab Applied Analytical Industries
Assay Validation, PDA
General Filtration, Pall Corporation
cGMP Practices for Bulk Pharma, Center for Professional Advancement

Professional Presentation

Process Scale Down Validation Activities: Strategies for Achieving Successful Scale Down Validation (IIR); La Jolla, California