Mark C. Weinglass

Senior Validation Consultant

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## PROFESSIONAL SUMMARY

SUMMARY:

* Experience with regulatory remediation, field and lab instrumentation, manufacturing and diagnostic equipment, software and hardware validation.
* Authored and executed life cycle documents (SDLC); executed commissioning and validation protocols and regulatory documents; programmed control systems and SCADA.
* Computer system validation (CSV): assure that legacy and newly installed computer systems produce results in accordance with an approved User Requirements document.
* Validation /Commissioning of sterile pharmaceutical process production equipment, both solids and liquids.
* Utilities Validation /Commissioning: assure that legacy and newly installed utilities achieve results in accordance with an approved User Requirements document.
* Current Good Manufacturing Practice (cGMP-21 CFR Parts 210 &211, QSR-21 CFR Part 820): assure that all documents produced for a regulated system comply with FDA regulations.
* Electronic Records; Electronic Signatures (ERES-21 CFR Part 11): assure that all changes made to an electronic record do not obscure the original and are recorded in an audit trail that traces those changes back to an authorized user of the system.
* Assure that Electronic Signatures applied to electronic records are equivalent to conventional handwritten signatures.
* PLC, HMI

EDUCATION: University of North Carolina at Charlotte

Bachelor of Science in Electrical Engineering

PUBLICATIONS: “How to ‘Right-Size’ Computer System Validation Based on Criticality and Complexity” – co-author. Article published in the *Journal of Validation Technology*, autumn 2010 edition.

PROFESSIONAL EXPERIENCE:

05/13 – 10/13 and

2/14 to Present Hart and Associates, Halifax, Nova Scotia

Independent Regulatory Consultant

* Provide regulatory consulting services for medical device manufacturers; specifically verify compliance with FDA 820 regulations; prepare 510(k) submission binders to include submission letter, substantial equivalence statements, device description and classification, risk analysis (FMEA), and summary of design control activities.
* Review and approve regulatory documents in support of consent decree to include device design verification/design validation, and change control.
* Revise requirement documents for devices and manufacturing equipment to be in compliance with QSR and cGMP.
* Summarize open source literature in support of client’s device.

11/13 – 2/14 U.S. Data Management (assigned to Atrium Medical, Hudson, New Hampshire)

Quality (Validation) Engineer

* Reviewed, edited, and approved lifecycle validation documents for medical devices.
* Designed document formats for validation of medical devices.
* Collaborated with systems integrator to set expectations and assure compliance with medical device regulatory expectations.
* Provided training to client for GAMP5 and software validation in support of validation of high volume medical devices.
* Wrote and implemented Gap Analysis documents to determine compliance with QSR.
* Develop a Remediation Plan based on the Gap Analysis to determine validation deliverables.
* Wrote and implemented startup procedures for manufacturing equipment.
* Wrote and implemented Risk Analysis documents.
* Wrote and executed testing protocols, based on Risk Analysis for: ultrasonic welders, in-line connectors, and leak detectors.

08/12 – 05/13 Peak Technical (Assigned to J&J) Lancaster, PA

Senior Validation Consultant

* Work in support of consent decree, including assessments to determine compliance with cGMPs of all computerized systems validation (CSV) documents and manufacturing equipment.
* Review all computer system validation (CSV) documents for manufacturing facilities to determine compliance with cGMP. Equipment included high-speed bottler, pasteurizers, high-speed tablet presses, blistering and vision systems, cartoners, and high-speed blenders.
* Revise requirement documents to be in compliance with user needs and regulatory requirements.
* Develop remediation plans to bring all life cycle documents to current FDA and corporate regulations.
* Evaluated vision systems for [Serialization](http://www.linkedin.com/e/58b49b-hmarnbhp-61/vjb/7238424/rj_em/?hs=false&tok=2A5AbFA3Zp8RY1) project.

02/12 – 08/12 Rockwell (Assigned to CSL Behring) Kankakee, IL

Validation Engineer

* Participated in shut-down and startup projects for a sterile biological manufacturing facility for process retrofit.
* Wrote and executed life cycle validation/commissioning documents for utilities, including: Clean-in-Place (CIP), DI Water, Water-for-Injection (WFI), and Clean-Steam (CS). Documents included: factory acceptance tests (FAT), site acceptance tests (SAT), validation plans (VP), user requirements specifications (URS), installation/operation/ Performance qualification protocols, and final reports.
* Wrote and executed commissioning and validation protocols for temperature- and humidity-controlled cold storage rooms.
* Reviewed and executed test results.
* Wrote deviation reports.

11/11 - 02/12 Pharmaceutical Validation Solutions (Assigned to Genzyme) Boston, MA

Senior Validation Consultant

* Participated in shut-down projects for a sterile biological manufacturing facility for process retrofit.
* Wrote and executed life cycle validation/commissioning documents for utilities, including: Clean-in-Place (CIP), DI Water, Water-for-Injection (WFI), and Clean-Steam (CS). Documents included: factory acceptance tests (FAT), site acceptance tests (SAT), validation plans (VP), user requirements specifications (URS), installation/operation/qualification protocols, and final reports.
* Wrote and executed commissioning and validation protocols for temperature- and humidity-controlled cold storage rooms.
* Wrote and executed commissioning and validation protocols for Building Automation Systems (BAS).
* Reviewed and executed test results.
* Wrote deviation reports.

6/11- 11/11 CorePharma, Middlesex, NJ

Validation Engineer

* SAP remediation project
* Traced delivered implementation to User Requirements.
* Mapped Process Definition Documents (PDD) to Configuration Documents to uncover non-implemented requirements.
* Reviewed and edited SOPs.
* Generated Process Flow Diagrams based on SOPs and PDDs.
* Generated Security Matrix based on department and role.

2/04 – 6/11 EduQuest Hyattstown, MD

Senior Validation Consultant

* Coordinated regulatory remediation projects for medical devices and laboratory diagnostic equipment such as Peritoneal Dialysis, Genetic Analyzers, Infusion Pumps, Parenteral Compounders, Blood Analyzers, Oxygen Level Analyzers, and Magnetic Cell Separators.
* Provided guidance to pharmaceutical and medical device facilities on how to achieve and maintain compliance with FDA regulations and ISO 13485.
* Review and re-write CSV documents to comply with regulations and change control.
* Remediation projects to meet cGMP, 21 CFR Part11, and 21 CFR Part 820, QSR including review and update of Device History Files (DHF) and Device Master Records (DMR).
* Wrote and implemented Gap Analysis documents to determine compliance with QSR.
* Develop a Remediation Plan based on the Gap Analysis to determine validation deliverables.
* Wrote and implemented Risk Analysis documents.
* Wrote and executed testing protocols, based on Risk Analysis
* Qualification activities: IQ, OQ, PQ, EQ and SLC/SDLC to include all facets of document preparation, including writing, reviewing, and approving.
* Analyzed medical devices for potential failure modes by conducting a Failure Modes and Effects Analysis (FMEA).
* Conducted Risk Assessment and update files to determine probability of occurrence, possible loss due to system defects, and determination of validation deliverables.
* Validated and utilized Documentum for document control and distribution of validation deliverables.

5/01 – 2/04 QA Edge (Assigned to AstraZeneca) Wilmington, DE

# Senior Validation Consultant

* Coordinated validation remediation effort bringing into FDA compliance ten major systems which were not in compliance with cGMP and Electronic Records; Electronic Signature Regulation (21CFR Part 11). Systems included: adverse reporting; recall notifications; electronic imaging and regulated document management; product stability and expiration dating analysis; shipping, warehousing, and distribution of sample products.
* Major activities included: development of project scope and approach; planning, estimating, and scheduling; writing master validation plans (MVP), user requirements (URS), System Design Requirements (SDS), Installation Qualifications (IQ), Operational Qualifications (OQ), Process Qualifications (PQ), Test Plans (TP), Test Scripts (TS), and final Validation Reports (VR).
* Developed System Life Cycle (SLC) documents and Standard Operating Procedures (SOPs) based on regulatory risk, system complexity, and criticality.

6/98 – 5/01 EduQuest Hyattstown, MD

Senor Validation Consultant

* Served as team lead and supervisor: SOPs, validation documents, manuals for equipment, software, hardware.
* Provided compliance training.
* FDA readiness audit for Bio-Tech company.
* Review batch records prior to product release.
* Write exception reports for batch records that did not meet the acceptance criteria.
* Make recommendation for disposition of product that did not mee the acceptance criteria.
* Provide guidance on interpretation and implementation of cGMP.
* Provide guidance on interpretation and implementation of QSR.
* Review Design History Files (DHF) for accuracy and completeness.
* Wrote and implemented Gap Analysis documents to determine compliance with QSR.
* Develop a Remediation Plan based on the Gap Analysis to determine validation deliverables.
* Wrote and implemented Risk Analysis documents.
* Wrote and executed testing protocols, based on Risk Analysis
* Investigate customer complaints and update files.
* Development of life cycle templates and documents based on criticality and complexity to meet FDA requirements.
* Reviewed and evaluated client-generated documents used for submission to USFDA.
* Developed audit procedures.

5/95 – 6/98 TRS (Assigned to McNeil Pharmaceutical Consumer Products) Fort Washington PA

Validation Engineert

* FDA-compliant validation of computer-controlled automated and semi-automated control systems for the full range of pharmaceutical manufacturing facilities.
* Computerized Systems Validation (CSV), Process Validation, Supervisory Control and Data Acquisition (SCADA), and Programmable Logic Controllers (PLC).
* Authored and supervised field execution of Installation Qualifications (IQ), Operational Qualifications (OQ), and Process Qualifications (PQ) in a cGMP environment.
* Reviewed and modified vendor qualification protocols.
* Coordinated and supervised field execution of vendor validation activities.
* Updated drawings and documents using Visio.

4/92 – 5/95 Synerfac, Inc. (Assigned To Johnson & Johnson) Lancaster, PA

# Instrumentation and Control Engineer

* Coordinated commissioning and startup activities for a new liquid and solids production plant.
* Authored and executed Factory Acceptance Tests (FAT) for process and packaging equipment.
* Authored PLC programs and operator interface programs using ControlView and WonderWare in an FDA-regulated environment for: automatic batching, homogenizing, automatic weighing and conveying, CIP (clean-in-place), pasteurization, high-speed rotary fillers, and labeling and packaging.
* Generated and updated P&IDs using Visio.
* Operator interface programs consisted of P&ID screens, data logging, event-driven reporting, trending, alarming, and preventive maintenance schedules.
* Specified and selected instruments including control valves, flow meters, conductivity sensors, density sensors, temperature, pressure, and level sensors.
* Authored and executed validation and qualification protocols for PLCs and SCADA, control strategies, and plant process equipment.
* Coordinated, supervised, and debugged installation of equipment during plant startup.
* Trained operators and technicians in proper operation, troubleshooting, and maintenance of plant equipment.

9/91 – 4/92 Synerfac, Inc. (Assigned To Campbell Soup Company) Camden, NJ

# Instrumentation and Control Engineer

* Designed control systems and instrumentation for a pilot plant.
* Authored PLC programs for glass and can filling lines. Designed process control and instrumentation systems for 300-jar washer and cooler, rotary fillers, and conveying systems.
* Specified instruments including modulating control valves, flow meters, pressure sensors, temperature sensors, level sensors, and motion detectors.
* Responsible for equipment startup.

3/91 – 9/91 H.L. Yoh, Inc. (Assigned to Day and Zimmerman, Inc.) Philadelphia, PA

Instrumentation and Control Engineer

* Specified control systems and instrumentation for chemical plant expansion.
* Authored ISA specifications for over 600 field and in-line instruments.
* Consulted with clients to evaluate appropriate control schemes and type of instrumentation for proper plant operation and cost effectiveness.
* Evaluated DCS systems and made recommendations to client.
* Coordinated process and mechanical data between company and client.
* Generated loop and I/O diagrams and installation details, and wrote scope of work.

3/90 – 3/91 Judge Technical Services (Assigned to Rorer Pharmaceutical Corp.) Fort Washington, PA

Project Engineer – Instrumentation, Controls, and Automation

* Designed process instrumentation and control systems for pharmaceutical, liquid, and powder production.
* Projects included: bulk storage, automatic dispensing and control of Sorbitol and aluminum hydroxide, process air controls for drying of pharmaceutical powders to comply with FDA requirements, tray drying, control of pharmaceutical powers, PLC control of granulating, pneumatic conveying and milling of pharmaceutical powders, automatic dispensing of bulk chemicals to water purification systems, conversion of existing systems from pneumatic to electronic controls, interface of existing systems to the Honeywell TDC 3000 controller.
* Authored and executed IQs, OQs, and PQs.
* Wrote specifications and guidelines for instrument selection.

Additional historical information available upon request.

References available upon request.