LAURIE BURNS CASE
QA PROJECTS LLC
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CAREER SUMMARY

Engineering Project Manager and Validation Consultant with extensive experience in the pharmaceutical, medical device, and biotechnology industries. Extensive validation experience from protocol writing through qualification implementation (Installation/Operational Qualifications (I/OQs) and Performance Qualifications (PQs)) for production equipment, manufacturing and packaging processes, and facilities. Develop Cleaning Validation (CV) requirements and issue CV protocols. Experienced in cGMP compliance auditing, nonconformance/deviation review, CAPA, writing operating and maintenance SOPs, and evaluating new technologies. Manage projects of all types including new product development and production, equipment selection, and facility design and construction. Provide focused, organized, well-documented projects meeting cGMP and Quality System requirements.

PROFESSIONAL HISTORY

President, QA Projects LLC (formerly Pharmaceutical Project Management, Inc.), Sea Girt, NJ 1994 - Present

- Daiichi Sankyo, Inc. – On-going support of Quality Assurance and Validation departments with contract solid dosage, oral powder, and investigational drug manufacturing and packaging operations. Review process, packaging, and cleaning validation protocols, executed studies, and final reports. Review new/revised batch record templates. Issued Validation and QA Release SOPs. Supported new manufacturing/packaging projects and new site start-up. Performed audits of contract suppliers. Supported implementation of Trackwise system for QA department. Develop gap analysis of company SOPs against FDA Quality System requirements.
- Bristol Myers Squibb – Support 21 CFR Part 11 compliance program.
- OMJ Pharmaceuticals, Inc. – Issued protocols and performed I/OQ and PQ studies for Chlorine Dioxide sterilization and VHP sterilization for 6 isolators used by the Microbiology department. Issued PQ protocols for steam sterilizers.
- Orthovita Inc. – Performed I/OQ on Carlisle Production Isolator and Steris VHP-1000 generator and PQ for VHP sterilization process. Issued relevant SOPs.
- Bracco Diagnostics – Issued Sterilization Process Validation document for CMC Submission in New Drug Application.
- Hoffmann-La Roche – Review validation data and environmental test data and create summary reports. Project manager for laboratory equipment qualification. Review SOPs for accuracy.
- Pfizer – Performed I/OQs and Sterilization PQ on Carlisle Sterility Test Workstation and Transfer Isolators, and Steris VHP-1000.
- ELF Machinery – Issued and performed I/OQs on liquid filling and labeling machines.
- International Isotopes Inc. – Performed cycle development on Terminal Sterilizer, Production Autoclave, Micro Autoclave, and Gruenberg Oven. Issued PQs for Stopper Washer, Oven, Terminal Sterilizer, and Container Closure Study.
- Akorn Ophthalmics – Issued I/OQs for Perkin Elmer Client Server System for HPLCs and GC, cGMP Production Facility, HVAC System, Klockner Thermoformer, specialty Punch Stations, Tube Filler, and Tube Filler Media Fill PQ.
- Accra Pac Group, Inc. – Issued I/OQs for miscellaneous bottle and tube filling equipment, including bottle filling, capping, labeling, tube filling, tanks, agitators, pumps, room qualification, HVAC system, DI Water system, stability chambers, dust collectors. Performed validation training of personnel. Devised Validation, Cleaning, and Stability Study Policy and associated SOPs.
- BioReliance – Performed I/OQs and Sterilization PQ on La Calene Sterility Test Workstation and Transfer Isolators, and Amsco VHP-1000. Issued PQ for use of isolators in sterility testing.

Pharmaceutical Project Management, Sea Girt, NJ (continued)

- Alkermes Controlled Therapeutics II – Issued Decontamination PQ protocols and completed validation studies for decontamination of Microbiology Sterility Test Workstation Isolator and Transfer Isolator.
- Millipore Corp. – Provided consulting services for I/OQ and calibration of water systems.
- Charter Medical Limited, Inc. - Issued and conducted the I/OQ of Vertrod and Thermatron RF heat sealers.
- Alcon Puerto Rico, Inc. - Issued I/OQ protocol for a Millipore Milli-Q Purified Water System, and associated Operating and Maintenance SOP.
- Fort Dodge Animal Health - Issued and conducted the I/OQ of multiple Millipore RO and purified water systems. Issued the PQ for the purified water system. Wrote operation, maintenance, and environmental sampling SOPs. Issued protocol and conducted I/OQ for Cold Room.
- Aviron - Developed production SOPs and Batch Records for the production of a new influenza vaccine.
- Kensey Nash Corporation - Issued and conducted the validation studies for the Arterial Anchor and Collagen Pad production processes and equipment. Thirty protocols included the I/OQs, PQs, Test Method Validations, and Requalifications for the Injection Molded Anchor Production Process, Collagen Production Processes, Anchor Injection Molding Machine, Hull Lyophilizer, Purified Water System, Nitrogen System, and all Anchor and Collagen Manufacturing Equipment. Revised operating procedures, Q.A. test methods, maintenance procedures, calibration/PM test documents, and material specifications to assure accuracy and completeness.
- THERAKOS (J & J) - Project management support for the transfer of UVADEX®, a new aseptically filled/terminally sterilized product from Hoffman LaRoche to contract manufacturer Ben Venue Laboratories. Coordinated development studies including D-value, filter testing, material compatibility, cleaning evaluation, and production of a full size experimental batch. Coordinated the validation requirements for Terminal Sterilization, Equipment Cleaning, Container Closure, and Process Validation.
- R.W. Johnson Pharmaceutical Research Institute (J & J) - Completed the design of a new computer controlled clinical packaging line for bottles and blister packs. Lines to utilize isolation technology for steroid products and oncology agents.
- Scandipharm Inc. - Located potential development laboratories and contract manufacturing sites for the production of a chewable multivitamin.
- Covance Biotechnology Inc. - Developed validation protocols for a Hewlett Packard HPLC and a Nicolet FTIR Spectrometer.
- Pasteur Merieux Connaught - Completed a Factory Acceptance Test protocol for a Lyophilization Systems Freeze Dryer.
- Biogen, Inc. - Developed SOPs and PQ protocols for a new biotechnology production and laboratory water system (pre-treatment, purified water, water for injection, and clean steam).
- Ethicon Inc. (J & J) San Angelo TX - Conducted the redesign, start-up, I/OQ and PQ for two LaCalhene Isolation Chambers for the Microbiology Dept. Performed the I/OQ for multiple Amsco Vapor Hydrogen Peroxide Sterilizers. Wrote SOPs for the sterilization process and equipment preparation.
- Ethicon Inc. (J & J) Raritan NJ. - Conducted the I/OQ and PQ for multiple LaCalhene isolation chambers/work stations, and the I/OQ for an Amsco Autoclave.
- Gilead Sciences Inc. - Developed a Master Validation Plan for Cidofovir®, a terminally sterilized parenteral product. Master Plan included a summary of all validation programs at BVL, the contract manufacturer.

Ortho-McNeil Pharmaceutical Corp. (Johnson & Johnson), Raritan, NJ 1989 - 1994
Manager of Engineering/New Technology 1993 - 1994

- Designed a component verification system to meet the new FDA cGMP labeling guidelines, and a corrugated case labeling program. Led cross-functional teams to reach objectives.
- Investigated new product tube technologies on the market to determine alternatives to the currently used aluminum tubes for the Ortho-McNeil and ACP product lines.
- Led a steroid production area task force to evaluate engineering, production, and safety issues in the steroid production area.

Manager of Project Engineering 1991 - 1993

- Reviewed production, laboratory, and administration projects managed by the project engineers in the department. Reviewed project estimates, schedules, plans, and completed projects.

Senior Project Engineer 1989 - 1990

- Managed the preliminary engineering programming study for a 260,000 sq. ft. research addition, which determined the space needs of Discovery, Development, Vivarium, and Research Services personnel.
- Completed the engineering design of a 9,400 sq. ft. Pharmaceutical Development Parenteral, Packaging, and Pilot Plant addition/renovation at Ortho-McNeil.
- Completed the engineering design of a 3,700 sq. ft. Quality Assurance Microbiology laboratory facility at Ortho-McNeil.
- Designed and managed the construction and/or renovation of multiple Production, Research, and Administration projects including a vivarium surgery suite, a cafeteria, and a steroid production packaging room at Ortho-McNeil.

Gibco Laboratories, Grand Island, N.Y. 1987 - 1989
Manager of Production - Liquid Media and Serum

- Managed the Liquid Production Department of 50 employees including the Serum Prefiltration, Media and Serum Aseptic Filtration and Filling, Glassware, and Finishing Departments. Reviewed production scheduling and raw materials requirements. Controlled operating budget of $1.4 million and capital budget of $1 million.

Imre Corp., Seattle, WA 1986 - 1987
Manager of Engineering

- Managed the design, engineering and construction of a 30,000 sq. ft. biotech medical device production, laboratory, and office facility. Reviewed all facility and production equipment specifications and service contracts. Wrote manufacturing and maintenance SOPs.

Stearns Catalytic Corp., Philadelphia, PA 1985 - 1986
Automation/Instrumentation Engineer

- Commissioned distributed control systems and instrumentation at various client sites. Prepared Process and Instrument diagrams, instrument control loops, and electrical drawings.

E.R. Squibb & Sons, New Brunswick, NJ 1980 - 1985
Pharmaceutical Engineer - Validation Department

- Completed the start-up and validation of equipment and processes for the new Parenteral manufacturing facility, and for existing production and laboratory areas.

EDUCATION & CREDENTIALS

B.S. Engineering - Rutgers University, 1981
University of Vermont - Civil & Environmental Engineering Major

PUBLICATIONS

Co-author of "Dry Heat Sterilization & Depyrogenation" (in Validation of Pharmaceutical Processes, editors Agalloco/Carleton, Informa Healthcare, 3rd edition, 2008).