

**MEDICAL DEVICE AND PHARMACEUTICAL
VALIDATION SERVICES**

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LexaMed



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Company Profile

LexaMed, Ltd. (**LexaMed**), headquartered in Toledo, Ohio, is a company focused on providing the pharmaceutical and medical device industries with quality, compliant, state-of-the-art services in validation and consulting. Established in June of 2006, **LexaMed** has grown significantly in the past two years and now employs 30 people with more than 20 1099 contractors under contract. Our associates have over two centuries of accumulated experience and are recognized as subject-matter-experts in a variety of fields and are sought after speakers and educators at regulatory and industry conferences. They are active participants in many guideline and standard setting organizations such as AAMI, PDA, ISPE and ISO. They can address situations of any size and subject with technically competent, practical and comprehensive solutions.

LexaMed's consultants are experienced in Validation (product, process, facility, equipment, test methods), Clean Utilities and Support Systems, Quality Systems, Sterilization (EO, steam, radiation, VHP, liquid, novel processes), Microbiology, Environmental Monitoring, Regulatory Affairs and Engineering.

LexaMed's concept of validation involves the integration of individuals with varied skill-sets into multifunctional problem solving teams. This approach allows us to capitalize on the broad-based industrial experience of our staff and to provide the most appropriate and cost-effective practical solutions to a particular validation situation.

LexaMed has directed numerous validation projects domestically as well as internationally that have been successfully inspected by domestic and international regulatory bodies including FDA, TGA, MHRA and Health Canada.

LexaMed can help your firm develop a suitable means to manage validation projects to meet timelines and project requirements as well as identify mechanisms to report on progress and state of control. We are prepared to establish a long-term relationship with your firm and provide qualified resources to support your validation needs.

LexaMed is committed to providing the medical device and pharmaceutical industries with the highest quality services and setting the standard for exceptional customer service. The quality of the service we deliver and the products we provide must always be of the highest quality.



Quality Policy

We as a company and as individuals are committed to continually exploring ways to improve our business and to exceed our clients' expectations. We will accomplish these goals by:

- Continually monitoring turn around times to ensure on time delivery of our products and services.
- Providing accurate, error free work.

- Conducting testing using state of the art methods and equipment that meets or exceed regulatory requirements.
- Offering consulting services that provide competent assistance and timely solutions.
- Maintaining a professionally trained staff and providing on-going training programs to ensure that our scientists are experts in their fields.

LexaMed's Quality Assurance maintains controlled and up-to-date documents in the form of standard operating procedures (SOPs) and associated forms.

Quality is the responsibility of all employees and in order for **LexaMed** to succeed it will be the priority of all to meet the quality expectations of this policy.

Medical Device & Pharmaceutical Validation Services

LexaMed offers validation services in all aspects of the pharmaceutical and medical device industries. We have executed projects scoped at more than US\$2M and ranging in size from qualification of a single piece of equipment to complete turnkey validation of equipment, critical utilities, and greenfield projects for facilities located both domestically and internationally. Locations where we have operated include the United States, Puerto Rico, India, Australia, Ireland, Denmark and Korea.

Our experienced associates are not only contemporary in our knowledge but are also influential in establishing industry practice and regulatory expectations utilizing a risk-based approach.

Capabilities

Our team of validation associates has expertise in all aspects of pharmaceutical and medical device operations, including, but not limited to:

- Process Equipment Qualification
 - Qualification includes IQ, OQ, PQ, design qualification and impact assessment involving a variety of equipment such as autoclaves, refrigerators, freezers, environmental and stability chambers
- Clean Room Qualification including automated controls systems (SCADA, BMS). Qualification testing may include:
 - HEPA filter leak testing
 - Temperature and relative humidity mapping and monitoring
 - Differential air pressure and direction tests
 - Environmental monitoring
 - Viable and non-viable particulate testing

- Cleaning Validation
 - Utilize equipment cleaning procedures to remove residues to levels of acceptability by:
 - Establishment of residual limits and acceptance criteria
 - Sampling selection
 - Analytical method selection

Cleaning validation studies conducted via analysis and sample recovery methods include, bioburden, detergent residuals, drug substance/product residuals. Equipments include blending tanks, fillers and tablet compression.

- Process Validation
 - Validation of critical systems and processes in the manufacturing area which include aseptic processing and clean room qualification to support manufacturing and processing of cytotoxic injectables
- Product Validation
 - Executed validation studies for solid dosage form, parenterals, and liquid products
- Critical Utilities System Qualification
 - Qualification include systems such as HVAC, RO, WFI, Chillers and Isolators for utility recommissioning, and facility start-up and commissioning
 - Validation of compressed air and gases
- Sterilization Techniques
 - Techniques include EO, Steam, VHP, Radiation, UV, Ozone, Pulsed-Light, and Dry Heat

To leverage the asset of an organization's internal validation resources, **LexaMed** provides the required documentation and training needs to aid the client with their validation needs by executing the following deliverables:

Deliverables

- Author protocols and final reports for validation processes
- Validation Master Plan
- Functional requirement specifications
- Design specifications
- Identification of Critical Operating Parameters and defining Acceptance Criteria
- Testing execution
- Technical transfer assistance
- Employee training
- Change control management
- Project management
- Implementation of a Risk-Based Validation Program

Benefits

- Highly qualified and experienced associates
- Reliable service
- Tailored to customer's needs
- Cost affordable
- Quality driven
- Adherence to FDA and other regulatory agency compliance
- Knowledge of current validation and compliance topics by keeping abreast through industry conferences by organizations such as IVT, ISPE, PDA and AAMI
- Ability to satisfy regulatory requirements enforced by various regulatory bodies which include ISO, MHRA, FDA, USP and EMEA

Other Services

To further support our validation service operation, **LexaMed** offers a full complement of microbiology and chemistry services in our corporate laboratories in Toledo, Ohio. We offer tests to support routine release testing such as sterility tests – product and biological indicator and LAL pyrogen testing. We further offer qualification testing such as disinfectant efficacy, D and Z-value, BIER unit exposures, package and container closure integrity, elemental analysis and tissue culture. We also provide testing to support sterilization cycle validations such as biobuden quantitation, sterilant resistance, ethylene oxide residues and microbial identifications. This unique capability has allowed **LexaMed** to provide full service to our clients with competitive pricing and reduced turnaround times to support key project milestones and deliverables.

LexaMed offers dedicated laboratory space, services and professional staff to conduct customized Research and Development evaluations and protocols. Our experienced staff can assist with defining the project and experimental approach and design, author the test protocols, execute the protocols and author the final report. We can also assist with any regulatory submissions as required. These confidential studies offer a unique, cost-effective opportunity for those companies who do not have the dedicated laboratory space or personnel resources to pursue new product or process opportunities. These studies can involve microbiology, chemistry, sterilization, biological or chemical indicators or medical device design, etc. **LexaMed** also has medical device manufacturing space available for prototype assembly and testing.

Auditing is an integral component of **LexaMed** 's core competency. Audits are performed and coordinated by a core group of experienced senior associates, supplemented if needed, by sub-contracted subject matter experts on a project specific basis. Our auditing experience and expertise encompasses many aspects of medical device and pharmaceutical operations. We also offer customized, focused domestic and international compliance audits.

LexaMed maintains client confidentiality, however, on a requested basis referrals can be provided.

Questions

Please direct any questions regarding this *Medical Device and Pharmaceutical Validation Services* Information Package or questions involving validation practices, procedures, capabilities and services to:

Michael A. Rutkowski, Chief Operating Officer
705 Front Street
Toledo, Ohio 43605
Mobile Phone: 631-560-6973
Email: mrutkowski@lexamed.net

Meet Our Validation Service Management Team:

Michael A. Rutkowski, Chief Operating Officer

Robert R. Reich, President

Michael Hartley, Senior Consultant/Project Manager

Robert Brown, Senior Consultant/Project Manager

James Latham, Senior Consultant/Project Manager

Dirk Wieringa, Senior Consultant/Project Manager

Copies of the listed consultants' curricula vitae have been included for your review.

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Curriculum Vitae

MICHAEL A. RUTKOWSKI

CHIEF OPERATING OFFICER

Mobile Phone: 631-560-6973

Summary of Qualifications

Areas of Expertise

- Project Management
- Clean Room Design and Maintenance
- Utility Qualification
- Process Equipment Qualification (liquid and solid dosage)
- Cleaning Validation
- Environmental Monitoring Program

Education

Loyola University
Bachelor of Science

Mike has 28 years of experience supporting validation projects for the pharmaceutical and medical device industries. Specific areas of focus have been design, implementation and management of projects related to aseptic operations including cytotoxic injectables, lyophilized and liquid finished dosage forms. Mike was responsible for directing several facility projects including the construction, qualification and start-up activities for an injectables facility located in India as well as the design upgrade and qualification of an injectables and solid dosage facility located in Puerto Rico. Both of these projects were in excess of \$25M scope and budget.

Validation Experience includes:

- *Confidential Company, California*
Directed validation responsibilities for redesign of LVP pharmaceutical product facility clean rooms and supporting utilities. Responsibilities included:
 - Establishment of facility design and construction specifications
 - Qualification of clean rooms and support areas (Grade A, C and D clean rooms/areas)
 - Utility qualification including compressed air, WFI, process steam, chilled water, HVAC systems (where applicable generation and distribution)
 - Cleaning Validation Program – Establishment and implementation
 - Project Management, Resource loading and budget accountabilities
 - Member of multi disciplinary project team including CM, Engineering and client functional areas

- *Confidential Company, India*
Developed BOD for the installation of filling isolator systems for SVP injectables operation. This was a green field project. Supported qualification of four SVP filling lines including:
 - Member of multi disciplinary project team including CM, Engineering and client functional areas
 - FAT, SAT and qualification of production isolators
 - Qualification of Grade C and D clean rooms/areas
 - Utility qualification including HVAC, Pure Steam, Nitrogen, Compressed Air, process steam, WFI, Purified Water and chilled water systems (where applicable generation and distribution)
 - Project Management, Resource loading and budget accountabilities

- *Confidential Company, Puerto Rico*
The project was a renovation of existing injectables and solid dosage manufacturing facility. Responsibilities included:
 - Establishment of facility design and construction specifications
 - Qualification of clean rooms and support areas (Grade A, C and D clean rooms/areas)
 - Requalification of utility systems including HVAC, WFI, RO Water, compressed air, Nitrogen and Pure Steam
 - Management of Validation resources across five contractor firms
 - Progress reports issued to Executive Management of firm as well as to FDA

- *Confidential Company, Australia*
Responsible for overseeing validation activities associated with the start-up of a liquid pharmaceutical manufacturing line (Cytotoxic). Barrier technology (i.e. CRABs) utilized to support SVP operation. Validation activities included clean rooms, process equipment and establishment of EM Program.
 - Establishment of facility design and construction specifications
 - Basis of Design documentation
 - Quality Agreements with Equipment Suppliers
 - Clean Room Qualification (Grade A, C and D areas)
 - Process equipment including depyrogenation tunnel, filler, capper, external vial rinser
 - Steam Sterilizer Qualification
 - EM Program design and implementation

- *Confidential Company, Pennsylvania*
Member of Facility Team responsible for the qualification of two newly constructed clean room injection molding facility used to support manufacture of sterile medical devices. Responsibilities included:
 - Developing project budget for validation resources
 - Establishment of validation requirements and specifications in concert with internal resources from firm
 - Qualification of Grade D clean rooms and controlled areas
 - Qualification of utilities including RO Water, HVAC, compressed air, chilled water systems (generation and distribution where applicable)
 - Support process design and equipment layout activities

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Curriculum Vitae

ROBERT R. REICH

PRESIDENT

Mobile Phone: 847-977-6141

Summary of Qualifications

Areas of Expertise

- Clean room design and validation
- Environmental monitoring programs
- Sterilization validation: steam, ethylene oxide, dry heat, radiation, VHP
- Aseptic operations
- Isolators
- Biological indicators
- Disinfectant efficacy

Education

Rutgers University

Bachelor of Science – Microbiology

- University of Wisconsin
Masters of Science – Microbiology
 - Indiana State University
Doctorate program Microbiology
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Bob has over 35 years of experience supporting validation projects in the medical device and pharmaceutical industries in various capacities. Specific focus has been on the design and validation of operations related to aseptic operations including both clean rooms and isolators, terminal sterilization of both pharmaceutical and medical devices, operation of multi-site ethylene oxide contract sterilization operation, tunnel and batch depyrogenation, biological indicators and liquid disinfectants and sterilants.

Bob has also served as co-chair and an active participant on numerous PDA, AAMI and ISO technical committees drafting validation-related standards and guidelines, including those for moist heat, dry heat (sterilization and depyrogenation), aseptic practices, packaging, biological indicators, bioburden and disinfectant efficacy.

Examples of Validation Experience include:

- *Confidential Company, New York*
 - Designed and directed validation activities for a new ethylene oxide contract sterilization facility
 - Validation included critical utilities, pre-conditioning rooms, six EO vessels and aeration rooms
 - FAT and SAT qualification of new vessels

- *Confidential Company, Global Pharmaceutical Company*
Directed validation of a clean room manufacturing operation that included:
 - Isolator/VHP validation
 - Moist heat sterilization of components
 - Dry heat sterilization and depyrogenation of components
 - Development of and environmental monitoring program

- *Confidential Company, Puerto Rico*
The project was a renovation of existing injectables and solid dosage manufacturing facility. Responsibilities included:
 - Qualification of clean rooms and support areas (Grade A, C and D clean rooms/areas)
 - Requalification of utility systems including HVAC, WFI, RO Water, compressed air, Nitrogen and Pure Steam
 - Validation of microbiological methods
 - Qualification of biological indicators, including D-value and z-values
 - Management of Validation resources across contractor firms

- *Confidential Company, Wisconsin*
Member of Facility Team responsible for the qualification newly constructed clean room for the aseptic manufacturer of pre-filled syringes. Responsibilities included:
 - Developing project budget for validation resources
 - Establishment of compliant validation requirements and specifications in concert with internal resources from firm and regulatory requirements
 - Qualification of Grade A, C and D clean rooms and controlled areas
 - Qualification of utilities including RO Water, HVAC and compressed air
 - Support process design and equipment layout activities

- Confidential, Medical Device Manufacturer
 - Internal compliance audits against FDA and International regulatory standards
 - Review, modify and validate EO and Radiation processes
 - Design and validate an environmental monitoring program
 - Assist with design and validation of two new clean room facilities
 - Microbial methods validation
 - Assist with 483 responses and CAPA investigations and resolution

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Curriculum Vitae

MICHAEL HARTLEY

SENIOR CONSULTANT/PROJECT MANAGER

Mobile Phone: 858-243-5635

Summary of Qualifications

Areas of Expertise

- Project Management
- Clean Room Design and Qualification
- Packaging/Shipping Qualification
- Utility Qualification
- Process Equipment Qualification
- Risk Based Approach to Commissioning and Qualification
- Media Fills/Aseptic Processing Validations

Education

Menlo College
Business Administration

Mike has 14 years of experience supporting validation projects for the pharmaceutical and medical device industries. Specific areas of focus have been design, implementation and management of projects related to aseptic operations as well as medical device. Mike was responsible for directing several facility projects including the construction, commissioning, qualification and start-up activities for a pharmaceutical aseptic manufacturing facility in NJ as well as qualification of aseptic manufacturing facilities in CA and medical device facilities in PA.

Validation Experience includes:

- *Confidential Company, California*
Directed validation responsibilities for WFI Generation and Storage upgrade project. Responsibilities included:
 - Member of a multi-disciplinary project team consisting of members of the construction, engineering, commissioning teams as well as several functional groups within client operations
 - Identification and implementation of Risk Based Validation approach
 - Identification of validation requirements and generation of VMP
 - Development of validation schedule and integration of schedule into overall project schedule
 - Development of qualification protocols, standard operating procedures and qualification protocol reports for equipment
 - FAT and Qualification of equipment and control system
 - Project Management, Resource loading and budget accountabilities

- *Confidential Company, Pennsylvania*
Directed validation responsibilities for qualification of 2 new ISO 8 Medical Device manufacturing facilities:
 - Member of multi-disciplinary project team consisting of members of the Construction Management, mechanical contractors as well as several functional groups within client operations
 - Development of validation schedule and integration of schedule into overall project schedule
 - Revision of existing VMP and generation of equipment/facility qualification protocols and final reports
 - Qualification of two (2) ISO 8 Cleanrooms
 - Utility qualification including HVAC, Compressed Air, Purified Water, hot heating water and chilled water systems (where applicable generation and distribution)
 - Management of validation team with responsibilities including development and maintenance of project schedule and related budget

- *Confidential Company, New Jersey*
Managed validation activities associated with the start up of a new aseptic manufacturing facility. Responsibilities included:
 - Provide validation guidance for facility design and construction specifications.
 - Qualification of clean rooms and support areas ISO 8, ISO 7, ISO 5
 - Development of Risk Based Validation approach.
 - Generation of Validation Master Schedule and integration into overall project schedule
 - Generation of qualification protocols and final reports for equipment and facility
 - Qualification of manufacturing and lab equipment ranging from temperature controlled environments to flow cytometers, plate readers and microbiological identification system
 - Qualification of QC Lab equipment such as Flow Cytometers, Plate Readers, Microbiological Identification Systems
 - Manufacturing process validation and Aseptic Process Validation
 - Qualification of facility equipment, critical utilities and Building Management System (BMS)
 - Management of Validation and Commissioning
 - Progress reports issued to Executive Management of firm as well as firm Regulatory Affairs department

- *Confidential Company, Washington*
Responsible for overseeing validation and calibration activities associated with existing facility and cleanrooms. Responsibilities included:
 - Revision of existing validation program to remain compliant with current industry and regulatory standards
 - Qualification of production equipment as well as QC lab equipment
 - Design and Development of Cold Chain Shippers
 - Qualification of Cold Chain Shippers per ISTA and PCCDG guidelines
 - Process Validation and Media Fills for API filling line at contract manufacturer as well as Process Validation for Bulk API and Medical Device at Contract Manufacturer

- Developed and maintained annual departmental budget and facilitated in hiring of additional resources
- *Confidential Company, California*
Supervised the Validation Team responsible for ensuring existing aseptic manufacturing facility and manufacturing processes maintained a validated state. Responsibilities included:
 - Created a cleaning validation program for manufacturing facility
 - Supported design, development and qualification of cold chain shippers
 - Qualification of production and laboratory equipment
 - Qualification of critical utilities (LN2, CO2, CCA)
- *Confidential Company, California*
Member of the validation team responsible for the qualification of newly built cleanrooms as well as production equipment and sterilization validation. Responsibilities included:
 - Managed the execution of two (2) ISO 7 Cleanrooms
 - Qualification of production equipment including temperature controlled chambers, temperature controlled rooms and packaging equipment
 - Managed and executed sterilization validations (Gamma & E-Beam) for bioreactor systems and WIP components per AAMI guidelines
 - Managed and executed quarterly dose audits
 - Qualification of Finn-Aqua steam sterilizer
 - Qualification of WFI system (Generation and Distribution)

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Curriculum Vitae

ROBERT M. BROWN
SENIOR CONSULTANT/PROJECT MANAGER
Mobile Phone: 386-334-4540

Summary of Qualifications

Areas of Expertise

- Project Management
- Clean Room Qualification
- Equipment qualification
- Utility Qualification

Education

University of Florida
Bachelor of Science

Robert has 22 years of experience supporting validation projects for the pharmaceutical and medical device industries. Specific areas of focus have been management as well as hands-on execution of facility and equipment qualification projects.

Validation Experience includes:

- *Confidential Company, Pennsylvania*
Member of Facility Team responsible for the qualification of two newly constructed clean room injection molding facilities used to support manufacture of sterile medical devices. Responsibilities included:
 - Qualification of ISO 8 clean rooms and controlled areas
 - Qualification of utilities including RO Water, HVAC, compressed air, hot water and chilled water systems (generation and distribution where applicable)
- *Confidential Company, Australia*
Directed validation responsibilities for injectable pharmaceutical packaging equipment. Responsibilities included:
 - Qualification of a new packaging line including labeling and label verification
 - Qualification of realignment of packaging lines into a newly constructed packaging facility
 - Qualification of automated vial inspection equipment
 - Management of validation resources
- *Confidential Company, Rhode Island*
Directly managed a multi-shift team of 20 consultants to support qualification of a new biologics manufacturing facility. Responsibilities included:

- Qualification of clean rooms and support areas (ISO 5 and ISO 8 clean rooms/areas)
 - Qualification of utilities including WFI, clean steam, compressed gasses, and HVAC
 - Performance of laboratory testing including bioburden, LAL and microbial identification
 - Project Management, resource loading accountabilities
- *Confidential Company, Puerto Rico*
Directly managed the activities of five consultants in qualification of laboratory equipment. The project included the qualification of microbial identification equipment. Responsibilities included project management, resource loading accountabilities.
 - *Confidential Company, Florida*
Managed validation responsibilities for a medical device facility. Responsibilities included:
 - Qualification of packaging equipment
 - Validation of fill volume, label adhesion and particulate contamination of components

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Curriculum Vitae

JAMES LATHAM
SENIOR CONSULTANT/PROJECT MANAGER
Mobile Phone: 847-370-1069

Summary of Qualifications

Areas of Expertise

- Project supervision in support of facility VMP
- Clean Room Design and Maintenance
- Utility and Equipment Qualification
- Aseptic operations
- Isolators
- Process Equipment Qualification (liquid and solid dosage)
- Sterilization validation: steam, dry heat, radiation, VHP
- Environmental Monitoring Program
- Disinfectant efficacy

Education

- University of Louisville
Bachelor of Arts & Science – Biology
 - East Carolina University
Graduate Program – Molecular Biology
-

Jim is a Microbiologist who has over 10 years of experience supporting validation projects for the pharmaceutical and medical device industries. Specific areas of focus have been on design, implementation and validation of equipment and operations related to supporting facility validation master plans (VMP) for both aseptic and non-sterile operations including LVP, SVP, liquid and solid finished dosage forms. Particular validation projects include clean rooms, isolators, critical utilities, controlled temperature units, terminal sterilization of pharmaceutical and medical devices, SIP, CIP, depyrogenation, high level disinfectants and liquid sterilants.

Validation Experience includes:

- *Confidential Company, Pennsylvania*
Member of multi-disciplinary project team responsible for the qualification of two newly constructed clean room injection molding facilities used to support manufacture of terminally sterilized (EO) medical devices. Responsibilities included:
 - Generation of execution protocols for the evaluation of supplied water to newly constructed ISO 8 manufacturing facility
 - Evaluation of environmental impact following change in source water used for facility disinfection
 - Installation Qualification of HVAC systems supplying ISO 8 (particulate) air quality to newly constructed clean room manufacturing facility

- Efficiently scheduled and appropriately tasked validation activities to adhere to time and budget proposal for project execution
- *Confidential Company, Minnesota*
Developed saturated steam cycle for the sterilization of vaccine tools and components within a Rapid Transfer Port (RTP) for Phase I clinical production trials. Responsibilities included:
 - Authored and executed Performance Qualification (PQ) protocol
 - Performed validation oversight and training for client personnel
 - Performed data compilation and analysis
 - Authored final report and compiled validation package
- *Confidential Regional Trauma Center, Michigan*
The project was an evaluation of risk associated with the transmission of communicable diseases from patient to patient following the use of under processed semi-critical medical devices. Responsibilities included:
 - Creation and execution of protocols for evaluation of high level disinfection of semi-critical medical devices
 - Evaluation of the deviation of standard cleaning and disinfection procedure and relative health risks to hospital patients
 - Advisor to hospital administration regarding disinfection procedures for medical instruments
 - Authored final reports for protocol studies
- *Confidential Company, Rhode Island*
Member of multi-disciplinary project team responsible for the critical utilities re-qualification of an existing facility and the qualification of a newly constructed, state of the art, large volume injectable manufacturing facility. Responsibilities included:
 - Provide shift supervision for microbiologists and technicians tasked with executing facility qualification protocols
 - Execution of IQ, OQ and PQ protocols for the qualification of facility critical utilities (WFI, compressed gasses, HVAC)
 - Perform environmental monitoring in support of qualifying ISO 5 to ISO 8 classified areas of manufacturing and testing
 - Perform bioburden (Total Aerobic Count), LAL, TOC and Conductivity to support WFI validation and daily monitoring
 - Perform microbial identification of isolates for establishment and characterization of microbial populations within the manufacturing and clean room environments
- *Confidential Company, Puerto Rico*
Acting in the capacity of Senior Validation Consultant operating in the increased scrutiny of a regulatory agency imposed consent decree responsibilities included:
 - Creation of protocols for the validation of isolator trains in the Microbiology Department
 - Authored and executed PQ protocols for the sterilization of laboratory supplies and sterility testing equipment
- *Confidential Company, Michigan*
Acting in the capacity of Senior Validation Engineer / Quality Assurance Specialist at a government supported critical vaccine supplier operating under receipt of notice to

revoke license, the following responsibilities were carried out to help secure license to distribute manufactured product:

- Conduct FDA readiness audit of Validation Department
 - Participated in PAI and Team Biologics audits
 - Trained permanent validation engineers and technicians
 - Responsible for validation department change control assessments
 - Authored and executed process and equipment validation protocols in response to Regulatory Agency commitments and observations
 - Quality Assurance department support for product and equipment deviation/non-conformance investigations
 - Authored standard procedures for facility wide implementation
- *Confidential Company, Ohio*
Acting in the capacity of Microbiologist / Validation Specialist; activities for the project centered on the qualification of sterilization and production equipment used in the manufacture of biological indicators. Responsibilities included:
 - Authored and executed IQ, OQ, PQ protocols for sterilizers in the biological indicator manufacturing facility
 - Performed calibrations on manufacturing equipment
 - Authored final reports for protocol studies
 - *Confidential Company, California*
Acting in the capacity of Microbiologist / Validation Specialist, project scope focused on the qualification of equipment and processes within the Quality Control department of an LVP, SVP manufacture. Responsibilities included:
 - Execution of IQ, OQ, PQ protocols for Microbiology Department laboratory equipment (incubators, refrigerators, freezers, sterilizers, heat blocks and water baths)
 - Authored final reports for validation studies

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Curriculum Vitae

DIRK WIERINGA

SENIOR CONSULTANT/PROJECT MANAGER

Mobile Phone: 708-899-9993

Summary of Qualifications

Areas of Expertise

- Project Management
- Utility Qualification
- Process Equipment Qualification
- Laboratory Instrument and Method Validation
- Environmental Monitoring Program
- Stability

Education

Governors State University
Bachelor of Science

Dirk has 14 years of experience supporting validation projects for the pharmaceutical, medical device, food and excipient industries. Specific areas of focus have been design, implementation and management of projects related to manufacturing and laboratory operations for excipients, medical devices, biologics, liquid and solid finished dosage forms. Dirk has been involved with environmental qualification, utilities qualification and start-up activities for a major biologics facility as well as laboratory and manufacturing equipment qualifications, laboratory instrument qualifications and analytical method validation.

Validation Experience includes:

- *Confidential Company, Rhode Island*
Directed validation responsibilities for start-up Biologics facility: Responsibilities included:
 - Qualification of clean rooms and support areas (Grade A, C and D clean rooms/areas)
 - Utility qualification including compressed air, WFI, process steam, chilled water, HVAC systems (where applicable generation and distribution)
 - Member of multi disciplinary project team
- *Confidential Company, California*
 - Qualification of WFI system
- Various Companies:
 - Experience with/ programming and validation of automated control systems

- Authored and executed equipment validations for freezers, ovens, incubators, autoclaves and miscellaneous laboratory equipment
- Authored and executed various laboratory instrument and method validations
- Authored and executed various spreadsheet validations
- Project Management, Resource loading and budget accountabilities