

## Relevant Work Experience

Client Description	Description of Role and/or Service Provided
Generic Topical Manufacturer	Audit of facility for client that wished to contract manufacture a pharmaceutical spray dosage form
Specialty API Manufacturer / Supplier	GMP training and consultation to assist client entering the pharmaceutical API business
Generic Manufacturer, multiple dosage forms	Validation of facility and critical utility systems, as well as mock PAI
Investment Consortium	Due diligence for a pharmaceutical company being acquired
Name Brand Inhalation Product Line	Project Manager, construction quality control and validation for sterile respiratory Blow Fill Seal project
Name Brand Aseptic Parenteral Product Line	Preparation of facility SOPs to address FDA 483 observations
Name Brand Aseptic Parenteral Product Line	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Name Brand Aseptic Parenteral Product Line	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Novel Biological Products Manufacturer	Project Manager, validation of new facility for botulinum toxin
Novel Biological Products Manufacturer	HEPA filter integrity testing
Novel Biological Products Manufacturer	Cleaning validation audit in preparation for launching new products
Food Packaging Company	Audit of facility for client wanting to package products in foil pouches at high speed
Name Brand Aseptic Parenteral Manufacturer	Project Manager, turnkey design / build project (sterile aseptic manufacturing of dental anesthetics) that included equipment procurement, validation, and regulatory approval.
Name Brand Aseptic Parenteral Manufacturer	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Novel Drug Delivery System Developer	Assume role of Operations Manager for the phase 3 production of dry powder inhaled drugs
Name Brand Parenteral Product Line	Project Manager, validation of equipment, facility, and utilities in response to FDA 483 observations
Generic Aseptic Parenteral Manufacturer	Validation of equipment for sterile, aseptic, dental anesthetic process
Preprocessed Pharmaceutical Closure Manufacturer	Preparation of Validation documents for equipment for rubber closure manufacturer
Name Brand Parenteral Product Line	Validation of facility, equipment, and critical utility systems for sterile, aseptic antibiotic
Food Processing Trade Group	Presenter of training course, Assuring Confidence in Laboratory Data
Training Seminar Company	Presenter of training course, Change Control
Generic Parenteral Manufacturer, Lyophilized	Validation of Lyophilization equipment and process
Generic Aseptic Parenteral Manufacturer	Validation of facility, equipment, and critical utility systems for sterile, aseptic products
Beverage Packaging Trade Group	Presenter and expert panel participant, Aseptic Processing
Pharmaceutical Engineering Trade Group	Presenter of training courses, Designing a Clean Room and Design of HVAC Systems for Aseptic Facilities
Name Brand Manufacturer, multiple dosage forms	Consultant; critical utilities for European company seeking US license
Generic Parenteral Manufacturer, Terminally Sterilized	Project Manager, engineering renovations and facility, equipment, and utility systems validation of terminal sterilized liquid filled products.
Biological Reagent Manufacturer	Preparation of validation documents for equipment for in-line mixing of buffer solutions

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Client Description	Description of Role and/or Service Provided
Transdermal Patch Manufacturer	Audit of facility for client that wished to contract manufacture transdermal patches
Generic Manufacturer, multiple dosage forms	Validation of equipment for facility that manufactured generic drugs
Investment Consortium	Due diligence for a pharmaceutical company being acquired
Novel Drug Delivery System Developer	Project manager, validation of facility, equipment, and critical utility systems for pharmaceutical company developing novel time release drug delivery system
Public Health Department Facility	Support the facility design for clean room facility
Name Brand Manufacturer, multiple dosage forms	Consultation for variety of in house initiatives, predominantly compliance and regulatory services
Radiological Drug Manufacturer	Validation of new IT data center infrastructure, utilities, and network. Continuing support for validation of IT infrastructure
Generic Manufacturer, multiple dosage forms	Validation of software
Pharmaceutical Manufacturer Trade Group	Assisted with layout and design of new training facility for non-profit pharmaceutical training and research institute (PDA-TRI)
Generic Oral Dosage Manufacturer	Validation of various equipment, utilities, and systems for generic oral dosage manufacture
Name Brand Manufacturer, multiple dosage forms	Consultation for compressed gas system contamination issue.
Vaccine Manufacturer	Project Manager, fulfilling Quality Assurance role for start up of new vaccine production facility. Also functioning as a mentor and leader for the Quality team
Hospital Care Products Manufacturer	Project Manager, design, install, validation of pretreatment water system
Hospital Care Products Manufacturer	Taught course on Contamination Control. Was facilitator in helping them develop their own contamination control plan
Test Reagent Manufacturer, Lyophilized	Validation of Lyophilization equipment and process
Name Brand Biopharmaceutical Manufacturer	Consultant; critical utilities for European company seeking US license
Name Brand Biopharmaceutical Manufacturer	Consultant; warehouse, labeling, and storage audits for European company seeking US license
Generic Aseptic Parenteral Manufacturer	Project Manager, validation of new aseptic processing facility (facility, equipment, and critical utilities)
Generic Aseptic Parenteral Manufacturer	Consultant; remediation issues associated with FDA 483 observations
Novel Drug Delivery System Developer	Preparation of equipment validation protocols for dry powder inhaled drugs
Generic Aseptic Parenteral Manufacturer	HEPA filter integrity testing
Generic Topical Manufacturer	Consultation; water system contamination issue
Generic Oral Dosage Manufacturer	Consultation; environmental controls for oral manufacturing process
Generic Oral Dosage Manufacturer	Consultation; new inventory control software
Law Firm	Served as an expert witness in a patent infringement law suit