

## Kevin Ambler Shannon

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### EXECUTIVE SUMMARY

Degreed Mechanical Engineer and Pharmaceutical Professional with a diverse professional background in HVAC Design, Skilled Carpentry, Validation and cGMP Manufacturing, Facility and Clean Room Operations. Over my 20+ years of experience, I have leveraged my technical background into key leadership roles for developing robust Qualification & Validation Programs, mentoring direct reports and team members, and successfully defending Validated State through customer, international, ISO and FDA audits. My Qualification & Validation expertise covers the entire product development and commercialization life cycle including R&D, equipment, cleaning, aseptic processing, packaging, and computer systems for various biotech and pharmaceutical products.

### PROFESSIONAL EXPERIENCE

#### July 2010 – Present

##### **Validation Manager at Medical Products Laboratories, Philadelphia, PA**

*A cGMP contract manufacturing company with expertise in research & development, manufacturing, packaging and testing of various media including aerosols, rinses, creams, suspensions, semi-solids and solid dose.*

- Developed Qualification & Validation Program in accordance with ISO & FDA Requirements.
- Established & Managed Validation Department, including Job Descriptions, Roles & Responsibilities, and driving daily activities.
- Managed cGMP Improvement Projects for Manufacturing Facility
- Defended Successful FDA, ISO & Customer Audits
- Validation representative for implementation of data management system and Serialization system.
- Validation representative for Cross-Functional Team with Regulatory, R&D, Operations, and Facilities to develop program for managing new products, including ANDA processes.
- Oversaw the development & approval of all GMP SOP's for preventative maintenance, calibration, and Laboratory Cleaning Methods.

#### August 2009 – June 2010

##### **Validation Contractor to MedImmune, Philadelphia PA**

*A subsidiary of AstraZeneca, for the H1N1 Pandemic Influenza Vaccine*

- Developed & Executed Qualification Studies for refrigerators, autoclaves, SIP and CIP systems, ultrasonic washers, viable and non-viable air monitoring equipment.
- SME for environmental monitoring program, installing remote access monitoring in Class 100 (ISO Class 5) Filler. The success of this program led to remote monitoring of all Class 1000 (ISO Class 6) Manufacturing Suites.
- SME for Packaging Processes & Line Equipment.
- Drove preventative maintenance improvements for component replacement frequency, scheduling, and planning.
- Validation Liaison for Vaccine Filling Operation Team.

#### March 2004 – July 2009

##### **Project Lead / Lead Validation Engineering Consultant**

*Projects: Amgen BioNext Project (mammalian cell culture biopharmaceutical), Wyeth Biotech (presently Pfizer, Pneumococcal conjugate vaccine), Human Genome Sciences Large Scale Manufacturing Facility for biopharmaceuticals and Cogenesys Pilot Plant Facility (presently Glaxo SmithKline), Catalent Commercial and Clinical Packaging (packaging of biotech through cosmetic products)*

- Business Development & Validation Lead for various pharmaceutical clients.
- Managed validation personnel and educated permanent staff on operation of systems.
- Developed & Executed various Commissioning, Qualification, and Validation Studies for Clinical & Commercial Packaging, and Pilot/Large Scale Manufacturing Facilities.
- Developed Validation & Cleaning Validation Master Plans.

**October 2002-March 2004 and Summers, 1988-1998****Site Engineer; Installation and Preventive Maintenance; General Contracting with Schrader Mechanical (formerly Shannon's Commercial Refrigeration) Drexel Hill and Landenberg, PA**

*Initially an HVAC and Refrigeration installation and service company which developed into full general contracting.*

- Reviewed contract drawings for accuracy.
- Surveyed potential sites.
- Project procurement and management for key projects.
- Technician in new construction and new tenant fit-outs including demolition, carpentry, HVAC installation, electrical, plumbing, masonry, painting and communication infrastructure.

**June 2001-October 2002****Process Engineer for Kinetics Biopharm (currently Amec Foster Wheeler) Philadelphia, PA, Toronto, Ontario, Canada, Emeryville, California**

*An American consultancy, engineering and fabrication company headquartered in Philadelphia, PA. Projects included Novo Nordisk filling line, Amgen BioNext project, Wyeth Grange Castle IE Waste Neutralization System, Centocor, Bayer.*

- Developed Functional Requirement Specifications pertinent to individual operation of process for projects in cosmetic-based to injection and mammalian cell culture technologies.
- Formulated process flow diagrams and process and instrumentation diagrams with feedback from design team and client.
- Performed equipment selection and sizing for both design development and manufacturing/fabrication, including bioreactors and waste management systems.
- Instituted document control checks where none were previously present.
- Coordinated with automation and electrical disciplines in order to streamline and ensure compliance from design through construction

**July 1998-June 2001****HVAC Engineer for Bala Consulting Engineers, Wynnwood, PA**

*Provides integrated engineering services for intelligent buildings and vibrant campuses, making them more sustainable, valuable, and efficient. Supporting corporate, data center, education, high-rise, multi-unit housing, transportation, life science and healthcare projects.*

- Designed HVAC systems for vast array of applications from schools to convenience stores to new-tenant fit-out to new construction.
- Calculated heat and cooling loads, equipment selection and specifications.
- Coordinated with electrical, plumbing, fire protection and structural disciplines in order to accurately and safely realize the design.
- CAD designed equipment and ductwork layout based on architectural plan.
- Performed punch lists and system inspections in oversight of completion of mechanical construction.

**PROFESSIONAL AFFILIATIONS**

- International Society of Pharmaceutical Engineers, Delaware Valley Chapter
- Irish American Business Chamber and Network, Philadelphia, PA
- Board Member, Penn Treaty Special Services District

## **EDUCATION AND TRAINING**

**1998**

**Drexel University Philadelphia, PA**

B.S., Mechanical Engineering. Minor in Italian.

Certified proficient in Italian by Drexel University and University of Pennsylvania.

**1999**

HVAC Design Certificate American Society of Heating, Refrigeration and Air Conditioning Engineers

**2000**

HVAC Advanced Design Certificate American Society of Heating, Refrigeration and Air Conditioning Engineers

**2010-Present**

International Society of Pharmaceutical Engineers – Participate in ISPE's Symposiums and Education Series to keep current in pharmaceutical and biotechnological trends.

## **RELATED**

PLC and DeltaV Control Modules, Aegis, AutoCAD and Rebis AutoPlant, Microsoft Office, Lotus Notes, Calibration Manager, Maximo, Documentum, Trackwise, Adobe Lifecycle Designer, E21, Pilgrim Data Management Software, Veriteq Vlog, Kaye Validator, Atlas Serialization System

## **INTERESTS**

Songwriter, vocalist and musician in various genres including original and traditional Irish music; founder, Alpha Chi Rho fraternity chapter, Drexel University; fitness; home restoration; conservation.