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Aarash Navabi, CPIP

Pharmaceutical Quality, Commissioning and Qualification Engineer

Professional Summary

Validation and process equipment engineering of Bulk production and manufacturing in the Biopharmaceutical industry in the New England and Boston Area for 8 years. Experienced, educated and knowledgeable in vaccine production and therapeutic drug manufacturing through bioprocesses in both technical and regulatory aspects.

Professional Experience

2010 – 2017 **Genzyme Corporation**

Validation Engineer

- CQV of equipment change over for new drug production (Current)
- RO/DI and WFI Design Qualification and Validation.
- Cleaning Initiative representative (CIP Assessment and Circuit Development Validation)
- Updated validation methods of E2500.
- Buffer and Media MAFT representative
- IQ, OQ and PQ development, execution and reporting
- Clean Utilities Commissioning and Qualification
- Compressed Gases for processes and instrument.

2007 – 2010 **Invensys Process Systems (IPS)**

Nuclear Validation and Application Engineering

- China National Nuclear Corporation (02/2010 – 05/2010)
  - Facility Start-Up, C & V
  - Developing commissioning and validation for CP-1000 reactor cooling and safety controls

Manufacturing and Cleaning Engineering

- Bristol-Myers Squibb Company (09/2009 – 02/2010)
  - Vessel Entry supervisor.
  - Facility start-up, C & V.
  - Riboflavin/ Coverage testing of process vessels.

- Validation and testing process vessel CIP throughout the new site.
- Confined Space entry
- First aid trained

Validation Engineer

- Lonza Biologics (11/2008 – 08/2009)
  - Facility start-up
  - Development and execution of commissioning and qualification documents.
  - Organization of commissioning and validation of 200 and 2000 Liter fermentor skids.
  - Organization of commissioning and validation of clean steam generator and clean steam utilities.
  - Overseeing construction of new suites for an on-site C & V during construction.
  - Trained operators to work with new equipment such as filtration systems and centrifuges and educated them in bioreactor/fermentor design and operation.
  - Trained temperature mapping for OQ and PQ to Lonza associates.
  - Coordination between QA, validation and engineering personnel to develop validation master plan for a speedy execution.

Validation Engineer

- Sanofi Aventis Pasteur (11/2008–12/2008)
  - Facility start-up
  - Cleaning Validation on downstream filling line.

2004 – 2007 **Massachusetts Biologic Laboratories, Boston, MA**

Validation Engineer (12/2004 – 12/2007)

- Developed and performed and executed IQ, OQ, and PQ for equipment
  - Facility start-up, commissioning and validation of pharmaceutical equipment and process systems to meet cGMP and industry standards per CFR 21 and FDA requirements.
  - GE SCADA, PLC, BMS and Electronic Batch recording development and validation.
  - Prepare protocols (DQ, IQ, OQ and PQ) and reports for equipment.

- Developing and reviewing SOP's for validated equipment and processes Approval and review P&ID's and process descriptions.
- Direct communication with Quality Assurance and Regulatory Affairs Departments to comply with FDA regulations during FDA clinical trial inspections.
- Review and Peer-Review of validation protocols, reports and processes.
- Developing validation test methods and alarm testing.
- Validations performed based on validation master plans and managed individually from SAT to process validation acceptance by regulatory affairs.

Certifications

- Certified Pharmaceutical Industry Professional (CPIP), by the International Society for Pharmaceutical Engineers (ISPE)

Education

1999 – 2004	BS in Chemical Engineering, University of Massachusetts, Amherst, MA
2004 – 2008	Biopharmaceutical Engineering Masters Certificate, University of Massachusetts, Lowell, MA

Training and Achievements

- ISPE Speaker
- ASTM E2500
- cGMP Training
- Confined Space Training
- Patent Pending: Pharmaceutical Vessel Light Cooling System
- First Aid Training

Professional Memberships

- Member of American institute of chemical engineers (AIChE)
- Founder and Committee member of YPI (Young Professionals Initiative) of the ISPE Boston chapter.
- Member of international society of pharmaceutical engineers since 2001. (ISPE)