Anurag Kharde

Bradley, IL • kanuragv37@gmail.com • 917350283549

Summary

A highly organized and self-motivated professional with excellent writing, communication, and interpersonal skills. Adept at working under pressure and meeting tight deadlines. Strong problem-solving abilities, with expertise in Six Sigma, FMEA, ISO standards, and statistical tools like Excel, minitab. Experienced in supervising validation teams, enforcing data integrity, and leading CAPA initiatives to ensure compliance with cGMP standards. Extensive knowledge of GMP and CGMP practices, with hands-on experience in developing and executing protocols for equipment validation, including freeze dryers, filler lines, and temperature mapping. Familiar with SAT, cleaning validation, change control.

Experiences

PCI , PA **July 2023 – January 2025**
CQV Engineer

- Supported documentation activities, reviewed test results, and resolved deviations.
- Led validation and qualification activities, ensuring the team followed cGMP standards and met project timelines.
- Assisted Subject Matter Experts (SMEs) with protocols, deviations, non-conformances, and hands-on work using KNEAT.
- Monitored production processes to identify root causes of failures, equipment changes, and process non-conformities.
- Maintained training records, SOPs, and root cause analysis documents; familiar with CAPA, GDP, GMP, 21 CFR, ISO, LOTO, Six Sigma, and change management processes.
- Ensured cGMP compliance during testing and followed GDP for accurate documentation and corrections.
- Collaborated with cross-functional teams and delivered technical presentations related to projects and schedules.
- Executed and approved Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Coordinated testing and review of raw materials, in-process materials, finished products, stability samples, complaint samples, and validation samples.
- Prepared documentation and reports for non-conformance and process defects, reducing manual work and improving efficiency.
- Worked on continuous improvement initiatives by evaluating processes and implementing improvements on the production floor.
- Participated in internal and external audits and inspections, helping reduce validation cycle time and improve efficiency.

Takeda Pharmaceutical, CA **Dec 2022 – July 2023**
CQV Engineer

- Drafted validation protocols.
- Create protocols and reports and non-conformance for water-bath.
- Documentation and commissioning on washer tunnel, depyrogenation tunnel, isolator.
- Developed protocols, and final reports for processes and equipment.
- Scrutinized paperwork, verified documentation, standard procedure and engineering documentation.
- Collaborated with Validation, manufacturer and other departments for process issues.
- Drafted and reviewed SOPs for new equipment and processes.

Pfizer, Kalamazoo, MI **July 2021 – Nov 2022**
CQV Engineer

- Reviewed protocols and final reports to identify data trends and ensure compliance with SOPs.
- Gained hands-on experience in developing and executing validation protocols.
- Worked closely with Subject Matter Experts (SMEs) and cross-functional teams to improve procedures and efficiency.
- Prepared and managed validation deliverables such as testing strategies, qualification protocols, validation plans, traceability matrices, re-validation schedules, and updates to the Validation Master Plan (VMP).
- Developed and executed Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Supported aseptic filling line operations by identifying contamination issues and performing root cause analysis.
- Participated in commissioning and qualification of filling machines to ensure aseptic operation.
- Performed temperature mapping and implemented CAPA, root cause analysis, and FMEA activities.
- Demonstrated strong knowledge of GMP and cGMP requirements.
- Executed protocols and managed non-conformances related to Clean-in-Place (CIP), Steam-in-Place (SIP), and automatic loading/unloading systems.
- Conducted process and cleaning validation while maintaining excellent Good Documentation Practices (GDP).

EDUCATION

University of New Haven - Tagliatelle College of Engineering: West Haven, CT, USA
Master of Science (Industrial Engineering)

Sandip institute of engineering and management,
Bachelor of Engineering (Mechanical Engineering)

Certification

- Six sigma yellow belt
- Six sigma green belt.