VALIDATION ENGINEER/QUALITY ENGINEER

Medical Device Drug Delivery

Create, Innovate, Deliver Solutions! This is what you can expect from a career at Aptar Pharma. We have an exciting new opportunity for a Validation Engineer within our Quality team in North America. Aptar Pharma is part of Aptar Group, a global leader of dispensing systems for the packaging industry. Aptar Pharma has been setting the standard for drug delivery for decades enabling the success of our customers through innovative drug delivery devices and services. **Be Aptar!**

What You Will Do at Aptar Pharma!

The primary mission of the Validation Engineer is responsible for leading design and execution of validation activities and supporting continuous improvement and risk management. Duties include but are not limited to:

- Responsible for leading and executing validation activities in a fast-paced cGMP manufacturing environment: review and approve executed qualification /validation documents, for facilities, processes, and equipment.
- Preparing and/or reviewing of validation protocols/reports (e.g. IQ, OQ, PQ), ensuring compliance and adherence to the design, customer and internal quality requirements, as applicable.
- Conduct, and/or participate, in deviation investigations to identify root causes and define corrective/ preventative actions (CAPAs).
- Organize engineering runs and validation activities with cross-functional teams to meet project objectives. Lead training of cross-functional teams involved in validation.
- Support the review and evaluation of system design requirements (e.g. URS) and design phase implementation initiatives (e.g. FAT/SAT)
- Represent Quality in cross-functional teams
- Support process and product improvement initiatives and analyze product performance to identify trends as necessary.
- Supporting the evaluation of existing system modifications to evaluate risk, establish and implement a qualification strategy, as applicable to the specific change
- Liaise with European design centers to ensure that design transfer and validation practices align with global requirements.
- Drive technical quality activities to completion in accordance with project objectives/timelines
- Supporting document creation, or revisions as needed

What Aptar Pharma is looking for!

- Bachelor's degree or equivalent in an Engineering or other technical discipline.
- 3-55 years' experience in Quality Validation experience within a regulated manufacturing company
- Experience from design conception through commercial implementation (e.g. URS, DQ, FAT, SAT, IQ, OQ, PQ) desired.
- Demonstrated ability to apply problem-solving methodology to identify the root cause and implement solutions.
- Experience data collection and statistical data analysis (e.g. capability analysis)
- Knowledge and experience with Change Controls, CAPAs, Quality Risk Management, FMEA.
- Applied Knowledge of Computerized System Validation (CSV) and Data Integrity Principles is desired (e.g. GAMP5 and 21 CFR Part 11).
- Experience in Facilities related validations is desired (e.g. Cleanrooms)
- Self-Starter with excellent technical understanding, writing and communication skills.
- Able to work with a diverse cross-functional team with minimal supervision.
- Ability to comprehensively document and communicate validation requirements and deviations encountered.
- Quality engineering concepts such as statistical analysis, quality testing, sampling and inspection, process control. Minitab and SAP knowledge a plus.
- Knowledge of ISO, GMPs, 21CFR Part 211 and/or 820 regulations.
- Experience and ability to work within clean rooms

What We Offer

- An exciting, diverse and value based working environment
- Award-winning corporate university offering personal development and training opportunities.
- Competitive base salary
- Contribute to the communities where we reside.
- Innovative benefits plan which includes: 401k plan with Company matching benefit, paid time off, medical, dental, vision, life, disability and more

BE YOU, BE APTAR!
Aptar is an Equal Employment Opportunity (EEO) employer. We believe that a diverse workforce is key to our success. We welcome applications from all members of society irrespective of age, sex, disability, sexual orientation, race, religion or belief It is the policy of the Company to provide equal employment opportunities to all qualified applicants without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, protected veteran or disabled status, or genetic information

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