"Caring for the world… one person at a time" … inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Employees of the Johnson & Johnson Family of Companies work with partners in health care to touch the lives of over a billion people every day, throughout the world. This culture of caring is the focus of our corporate philosophy, that are anchored in the internationally applicable **Credo**

Senior Quality Source Engineer

Overview:

Located in the Manufacturing Site in Bettlach (SO) the Site Senior Quality Source Engineer act as on-site Johnson & Johnson Medical Devices (JJMD) quality engineering representative for the Strategic Collaborator (SC). In partnership with the SC, he/she utilizes quality engineering principles and problem-solving skills to improve and maintain JJMD products and processes, including validation, risk management, product quality issue resolution and critical issue, and quality systems performance monitoring. The Senior Quality Source Engineer is responsible for ensuring that the SC has a clear understanding and ability to execute to the JJMD/SC Quality Agreement requirements, J&J Policies, and applicable regulations and standards.

Tasks & Responsibilities:

- You will be reviewing and approving key quality records as they related to JJMD products such as:
  - Site Validation Master Plan
  - Validation protocols and reports per Change Control Processes
  - High-risk CAPAs (i.e., Field Action, External Observations)
  - New or revised inspection plans and associated sampling strategies
  - Where necessary, collaborate with PSC in failure investigation and corrective action planning for High-Risk CAPAs (i.e. Field Action, External Observations) involving JJMD products.
- You will oversee the coordination of JJMD review and approval of;
  - Non-routine rework in collaboration with other required JJMD functions such as Design Quality, Product Management, and Sustaining Engineering
  - Use-as-Is Nonconformance Disposition in collaboration with other required JJMD functions such as Regulatory Affairs and Medical Affairs
- Support Technical Assessments in collaboration with SC site compliance, JJMD Supplier Quality Compliance, and JJMD Product Management.
- Partners with SC Quality Engineering, JJMD Medical Affairs, and JJMD R&D/PM in the development of Process Failure Mode Effects Analyses (pFMEAs) and corresponding Control Plans.
- Supports SC Quality and Manufacturing Engineering on the resolution of quality issues impacting JJMD products and coordinates additional subject matter expert support needed from JJMD.
- Supports improvement plans to address below-target metrics and negative trends.
- Serves as the Site Liaison's deputy.
- Partners with SC on Recall Prevention and External Audit Readiness initiatives.

Qualifications & Experience

- A minimum of a Bachelor’s Degree, preferably in Engineering or related technical field. 4/ 6 years related experience preferred.
- Experience working in both an FDA and European regulatory environment is preferred.
- This position will require relevant background in manufacturing/operations.
- In-depth knowledge of product/process Risk Management (FDA and ISO standards).
- Experience with a consistent track record of implementing appropriate risk mitigation.
- Technical training and experience using Statistics, Lean and Six Sigma Methodologies is required including Measurement System Analysis, SPC, DOEs, Reliability, etc.
- Strong knowledge of statistical software packages is preferred with the ability to preview, graph and analyze data and be able to present data that facilitates/drives decision-making.
- Ability to perform "hands on" troubleshooting and problem solving.
- Good technical understanding of manufacturing equipment and processes is required.
- Understanding of the NPI (New Product Introduction) process and Process Validation expertise is preferred.
- A thorough understanding of GMP/ISO regulations and validation regulations is preferred.
- Advanced knowledge and shown leadership in the areas listed in the Major Responsibilities and Duties with the position.
- Demonstrated project management and project leadership abilities are required.
- Quality Engineering Certifications are a plus (e.g. ASQ CQE, PMI PMP, 6-Sigma, etc.).
- Business Fluent English and German required

Are you an experienced OH Physician with an international mindset and eye for business? Do you feel attracted by a dynamic environment? Then please send us your online application (CV, Motivation Letter, Working References etc.) by clicking here.