

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.

DePuy Synthes is recruiting for a Quality Systems Team Leader, located in Grenchen,

Switzerland. DePuy Synthes Companies of Johnson & Johnson is the largest, most innovative and comprehensive orthopedic and neurological business in the world. We offer an unparalleled breadth and depth of products, services and programs in the areas of joint reconstruction, trauma, spine, sports medicine, neurological, craniomaxillofacial, power tools and biomaterials. Building on the legacy and strengths of two outstanding companies, more agile and better equipped to meet the needs of today's evolving health care environment. With a focus on activating insights to develop creative, comprehensive solutions, we are encouraged to advance patient care in greater ways than either company could accomplish on its own.

The main responsibilities of the **Quality Systems Team Leader** is to oversee and manage the execution of Quality Systems (QS) at site level, including Non-Conformances (NC), Corrective and Preventive Action (CAPA), Product Quality Escalation, Site Complaint Manufacturing Investigations, Quality Progress Review (QPR), Quality System Management Review (QSMR), and other assigned QS activities to ensure systems are effective and in compliance.

Manage the performance and communication of QS metrics at site level. Ensure site readiness in the deployment of QS initiatives. Support compliance and document control areas, and continuous improvement of the Quality System.

Your Role

- Responsible for the consistent and correct execution of QS procedures at the site to ensure the quality and compliance
 of processes and records for NC, CAPA, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR
 and QSMR
- Develops competency of resources at the site that execute NC, CAPA, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR and QSMR, by providing training and guidance on the execution and documentation of these processes
- Responsible for the timely and compliant execution of site NCs, CAPAs, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR and QSMR, by championing cross-collaboration across functions, sites, and operating companies; identifying barriers for the progress; and elevating issues for resolution
- Manages on-site QPR and QSMR, including coordination, preparation, execution, and tracking of activities
- Manages Product Quality Escalations for nonconformances or issues originating at the site, including the initiation, escalation, coordination, tracking, and closure of activities
- Manages on site the timely collection, escalation and reporting of all Quality System metrics to management
- Maintains original documentation for site NC, CAPA, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR and QSMR as quality records
- Identifies site needs to meet and improve system performance of NC, CAPA, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR and QSMR at the site level, and escalates to appropriate representative and management in a timely manner
- Collaborates with Franchise Quality in the deployment (design, implementation, and post monitoring) of QS initiatives
 impacting the site that promote the continuous improvement of the QS and ensure continuity of the application of globally
 shared processes and systems at site level

- Supports compliance activities by participating in audit readiness; assists in Internal and External audits; serves as Subject Matter Expert for NC, CAPA, Product Quality Escalation, Site Complaint Manufacturing Investigations, QPR and QSMR processes during audits; manages the investigation, response, and remediation of site-specific QS audit observations
- Oversees on site Document Control (as required), including management of change documentation, on-site administration of the change control system, and archival of documents on site.

Your profile

- Degree in Engineering is preferred, or associated relevant Scientific / Technical / Quality discipline
- Six (6) years related experience in Medical Device or Pharmaceutical environment, or equivalent combination of education and experience is required
- Experience in working in a manufacturing / operations environment is preferred
- Knowledge of ISO and QSR regulations is required
- Experience in Quality Auditing and notified body inspections is preferred
- Experience with root cause investigation, change management, risk management and technical writing is required
- Experience in Quality Systems process development, support, integration or enhancement is preferred
- Experience in Project Management is preferred
- A Certification in process excellence is preferred
- Advanced use of computer and software applications is required
- Experience with training or coaching others is required
- Direct supervision experience is preferred.
- Strong communication, influencing and leadership skills: ability to communicate at all levels of the organization, and to interact with and influence cross-functional and cross-business teams to drive results is required
- Strong business acumen, interpersonal skills relating to teams with diverse cultures and business practices is required.
- Strong verbal and written communications skills for multi-level stakeholders
- Strategic and tactical execution abilities, including strong organization skills is required.
- Ability to take initiative regarding innovative approaches to problem solving in a fast-paced, changing business environment is required.
- Ability to apply principles of logical or scientific thinking, root cause and statistical analysis.
- Ability to analyze, graph, and present data in a way that facilitates and drives decision making.
- Strong verbal and written Presentation Skills

If you feel attracted by this challenge and want to be part of a successful and growing organization with excellent working conditions then please send us your online application (CV, Motivation Letter, Working References etc.) here

Please click on <u>DePuy Synthes</u> and <u>Johnson & Johnson</u> if you want to learn more about our business and check our new career channel on YouTube <u>www.youtube.com/user/CareersAtJNJ</u> to understand our working culture!

Johnson & Johnson is an Affirmative Action and Equal Opportunity Employer. You will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, age, national origin, or protected veteran status and not be discriminated against on the basis of disability.



