

Title	Occupation	
Quality Engineer	Full time <input checked="" type="checkbox"/>	Part time:
Department	Reporting to	Date
Quality	Quality Manager	March 2010
Purpose of function		
<ul style="list-style-type: none"> • Key Quality Assurance team player • Partner with R&D as project team member: support the development and Design transfer of new products, in accordance with regulatory requirements, ISO 13485 and 21 CFR part 820 • Participate to the development of comprehensive risk management activities from Design phase to post market analysis • Manage effective Design change control activities during the product life cycle • Manage the customer complaints and CAPA internal processes • Conduct and support internal and/or supplier's audits • Participate to the continuous improvement of the Quality Management System in place • Ensure compliance with company procedures and cGMP rules 		
Main responsibilities and accountabilities		
<ul style="list-style-type: none"> • Complete and maintain the project Quality strategy for new product development or changes to existing products • Partner with R&D for the investigation / correction of product design failures • Support R&D in conducting risk management activities, <i>i.e.</i> dFMEA • Write Verification and Validation test protocols/reports - e.g. stability / transport testing / supervise their executions • Develop, implement and validate Tests Methods (Gage R&R) • Participate in the validation of the critical processes at the suppliers • Manage the customer complaints process: Partner with R& D or Quality Engineering for customer claim investigation. Open and close complaint reports. Communicate the results to the complainant • Ensure effective and efficient application of Quality Engineering tools and techniques (<i>DOE, statistical analysis, sampling plan determination, test method validation</i>). • Attend to TSC meetings : ensure effective design control and transfer • Participate to the finished products release • Lead CAPA related to his (her) activity • Train and certify operators /inspectors to control or tests methods • Conduct and support internal and/or supplier's audits • Ensure good application of cGMP rules within the organization 		

Requested Qualifications (Education and Experience)

- Degree in Engineering preferred or equivalent experience, plus training in quality
- Deep knowledge of medical devices regulations, including FDA/QSR, ISO9001/ISO13485 and reference standards applicable to the activity is a must
- Good knowledge of risk management tools
- Can conduct survey data analysis and statistical analysis (Pareto, hypothesis tests, etc.)
- Basic knowledge in metrology
- Ability to manage a small team of quality inspectors in the future
- Fluent in French and English, German is a plus
- Fluent in Microsoft Office suite
- Knowledge of an ERP system, a plus

Personal Attributes (around core values of Endosense)

- Quality and results oriented Excellent communication skills, both verbal and written in French and English
- Well organized, responsive, pragmatic, hands on attitude
- High resistance to stress

Location

Endosense SA, Meyrin-Geneva, Switzerland