

Technical Support Scientist

R&D | Santa Ana | CA

Job Function:

We are hiring for a Technical Support Scientist. The Technical Support Scientist will provide technical support to internal departments, field employees and external customers. In addition, this person will assist with processing and resolving technical issues, complaints, corrective action preventive action (CAPA) and regulatory submissions. The Technical Support Scientist will also assist with design changes and review of risk analyses files as needed.

This position receives and processes customer inquiries and complaints and will document and convey this information to the appropriate functional department for resolution. In addition, the TSS will lead the activities related to resolving complaints, assessing corrective action, and corrective action preventive action (CAPA).

Job Duties:

- Determine the nature of direct and indirect customer inquiries, and classify them for resolution
- Serve as a resource for R&D and commercial groups to support product evaluations by keeping the focus on technical resolution with in-house groups
- Assist in process improvement projects to improve effectiveness and efficiency of process directly affecting our customers and their adaptation of our products
- Analyze product evaluations for performance and technical trends to enhance our technical response to issues and to realize opportunities
- Manage and monitor customer inquiries associated with complaints
- Manage and coordinate cross-functional activities for corrective/preventive action program
- Ensure timely closure of customer complaints and that established turnaround times are met
- Ensure processes and procedures comply with applicable standards related to complaints
- Provide technical support, as needed, for the preparation of regulatory submissions for FDA/EU/CMDR or other regulatory agencies
- Assist with changes to product design, specification or production processes and review risk analysis files as required
- Assist in the communication with regulatory agencies, notified body, and competent authorities as associated with complaints
- Develop materials (e.g. FAQs) to reduce the number of recurring inquiries on products

Experience/Education:

- MS in Life Science field or equivalent
- 2 or more years of experience in Quality Assurance/Regulatory Affairs, technical and customer support in a medical device discipline preferred
- 2 or more years of experience in cell biology and/or tissue culture
- 2 or more years of experience in Assisted Reproductive Technology or Cytogenetics
- Knowledge of GMPs, CFRs, USP, ISO 13485, CMDR, MDD 93/42/EEC, IVD D 98/79/EC, ISO harmonized standards (EN14971, EN 13408, EN 13824) preferred

- Knowledge of quality control methodology, QA control systems and production methodologies preferred
- Ability to obtain cooperation from other groups and lead cross functional teams
- Experience with risk management and Failure Mode Effects Analysis (FMEA) preferred
- Strong root cause analysis skills required
- Proficient in Microsoft Word, Excel, PowerPoint, Outlook

To Apply: Please visit <https://uscareers-fujifilm.icims.com/jobs/14393/technical-support-scientist/job?mode=apply&iis=ISCareers>

Principals only. No recruiters please.

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