OFFRE D'EMPLOI

REF. GF423

REGULATORY AND QUALITY MANAGER- *IN VITRO* DIAGNOSTIC (F/M)

Location: Lille (North of France) - Eurasanté Biocluster site

GENFIT is a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases, where there is still considerable unmet need.

Within the Regulatory Affairs Department, you will be in charge of rolling out the Quality Management System (QMS) and preparinge the technical file in compliance with the new European Regulation requirements with the ultimate objectives of submission and approval for marketing in Europe & in the USA of *In Vitro* Diagnostic Medical Devices.

Missions

Your responsibilities include, but not limited to:

Regulatory Affairs

- To participate in the definition and evolution of the regulatory strategy for diagnostics in the USA and in Europe
- To coordinate the preparation and participate in the drafting of the technical file/Design History File (DHF) and design controls documents in view of submission for CE marking and/or FDA approval
- In this context, to participate in the definition and creation of the design dossier (Electronic Lab Notebook already in place)
- To define, coordinate and deliver risk analysis and review dossier
- To monitor regulatory and norms' evolutions to properly anticipate potential changes

Quality Management

- To contribute to the evaluation of the QMS already in place, identify gaps and determine actions required to ensure compliance to ISO13485:2016 and FDA QSR 21 CFR Part 820 essential requirements
- To contribute to the definition of the required processes to manage and maintain quality and draft related procedures
- To participate to the definition and follow up of objectives and metrics
- To proactively share proposals to ensure the QMS remain relevant when applicable norms and regulations evolve

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- To manage relationship with design and manufacturing sub-contractors

To achieve those objectives, you will have to:

- To manage partner with US and EU Regulatory IVD expert consultants
- To partner with the european notified body
- To manage relationships with external organizations in the course of audits and inspections
- To lead and conduct audits at sub-contractors

Profile

- Bachelor of sciences
- A minimum of 3 years experience in regulatory affairs and/or quality management in the medical devices, or preferably, in vitro diagnostic medical devices space.
- Comprehensive knowledge of ISO13485:2016 and FDA applicable regulations
- You use Electronic Document Management (EDM) system and Microsoft Office Suite in your daily work
- Excellent English skills and preferably good knowledge of French
- Self starter, you are recognized for your planning and project management skills. You know how to properly set priorities, and you're not afraid to voice your viewpoints.
- Exceptional communication and interpersonal skills, with an ability to effectively engage various stakeholders

Candidature

Interested candidates should submit their resume and cover letter to Aude Jacheet at: jobs@genfit.com.