Clinical Development Quality Lead (M/F)

Lausanne, Switzerland, Vaud

Reference Number:

Location : Lausanne, Switzerland

Who is Aixial Group ?

Aixial Group, we are a CRO (Clinical Research Organization), specialized in Life Science. We work with laboratories to provide technical support on clinical projects from phases I to IV and post market.

Since 2014, we have been part of the Alten family.

We are developing our activities in Switzerland, France, Belgium, Czech Republic, Denmark, UK, US...with even more prospects for expanding internationally.

Aixial Group, operates in outsouring, insourcing, for pharmaceutical, cosmetic, medical device, biotechnology, nutrition,... activities in clinical operations, regulatory affairs, quality, biometrics, pharmacovigilance, HEOR...

Aixial Group continues to grow, and to recruit in the clinical trial professions. Come and join us, and discover our site to follow the news of our offers.

The Team of Aixial Group Switzerland is looking for his next **Clinical Developpment Quality Lead (M/F)** !

MISSION:

The **Clinical Development Quality Lead (M/F)** contributes to the implementation of the Quality Strategy in order to support International's day-to-day clinical trial activities from a cross-functional end-to-end perspective by applying the "pro-active quality principles" and providing continuous support and input during the Clinical Development Activities.

YOUR RESPONSIBILITIES :

• Develop a "risk-based" compound-specific compliance program contributing to document / data accuracy, ultimately resulting in "dossier acceptability" by respective out-licensing partners (emphasis on eCTD Module 5

• Contribute to CRO/Vendor selection and qualification process, assess relevant CROs procedures during selection process to establish a pro-active quality approach, guaranteeing compliance with regulatory requirements.

• Collaborate with the Clinical Trial Manager and other Functional Area Representatives in the Study Team to ensure proper set-up & oversight of outsourced CRO activities, with primary focus on critical data points (primary endpoints) and critical processes.

• Provide compliance support and contribute to "in process / ongoing" oversight through evaluation & follow-up on reported quality events potentially jeopardizing the validity of the clinical study.

• Collaborate cross-functionally to the development and review of critical clinical study documents to ensure cross-document consistency e.g. IB versus Clinical Trial Protocol versus Master Informed Consent Form, …

• Applying the risk-based approach, identify the need to & conduct co-auditing activities / quality visits with company and / or CRO representatives.

• Provide continuous compliance support by acting as an internal advisor on relevant procedures and regulations to ensure correct interpretation and proper implementation.

• Create KQI to identify areas for improvement based on risk-based compliance activities and audit observations.

• Lead / contribute to compound-specific Regulatory Authority Inspections / Due Diligence Activities

• Build collaborative working relationships and ensure adequate communication within the com-

pound-specific study team and cross-functional Quality peers, assist in driving change to build a culture of compliance throughout the Clinical Development organization.

• Provide Audit / CAPA support to the execution of Master Audit Plan executed, assist the company business stakeholders to ensure proper CAPA formulation and follow-up.

• Provide support to the development / maintenance of QM and ClinDev related Procedural Documents

YOUR PROFILE :

• University Degree in Sciences or relevant academic background

• 6-8 years' experience in the clinical setting of the pharmaceutical/biotech industry, including at least 3 years within Clinical Quality Management System & Compliance

• Experience in managing and conducting GCP audits (CROs, TMF, Investigational Sites and CSR)

• Excellence knowledge of GCP. Current and strong working knowledge of GCP, CFR Title 21 and regulatory guidance's including, ICH quality, clinical, multidisciplinary guidance documents, and 21 CFR Part 11 compliance.

• Strong experience in the mechanism of multiple QA vendor's oversight

• Experience in setting and updating SOPs.

• Knowledge of computerized systems validation

• Rigor, flexibility, adaptability, and organization

• Pragmatism focused on efficiency and continuous improvement.

• Fluent in English, French an asset

Why Join Us?

- Make a positive impact and be at the forefront of project: You will be part of ground breaking advancement in clinical research that has positive impacts on millions of people’s lives globally.
- Career Development: People are our biggest asset. We are committed to empower our team continually and build a positive and supportive environment that fosters growth, flexibility, and teamwork. At Aixial Group, you will be coached and mentored throughout your journey to help you advance your professional and personal growth.
- Our commitment to Diversity, Equality, and Inclusion: We aim to create a workforce which promotes dignity and respect, where individual differences are recognized and valued, and where each employee can give their best. Gender equality is at the core of the development strategy of Aixial Group.

#JoinUs

#TogetherWeCreateValue

Your contact person

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