



# PharmD – Technical and Regulatory Project Manager F/M

Auvergne-Rhône-Alpes

Reference Number:

Are you passionate about the life sciences and clinical research? Do you want to grow in a dynamic, international, and collaborative environment where your expertise has a direct impact on the lives of millions of people? Join Aixial Group and help shape the future of clinical research!

AIXIAL Group is looking for its next talent as a **Pharmacist – Technical and Regulatory Project Manager (M/F)**. Your responsibilities will include (non-exhaustive list):

- Managing the name changes of product files such as company names.
- Analyzing regulatory requirements for each file/product.
- Participating in the development of the CMC (Chemistry, Manufacturing, and Controls) regulatory strategy.
- Implementing CMC regulatory watch/monitoring.
- Preparing and drafting renewal dossiers (Marketing Authorization renewals).
- Writing the regulatory part of Module 3 in CTD (Common Technical Document) format for Marketing Authorization dossiers.
- Verifying the consistency of the entire dossier and preparing the Marketing Authorization application.
- Interacting with health authorities or others during ongoing procedures.
- Collecting the necessary data and documents.

## Required Profile and Skills:

- You hold a Pharmacy degree, with a specialization in Regulatory Affairs (Master's level) or equivalent.
- You have at least 5 years of experience in CMC Regulatory Affairs within the pharmaceutical industry, CROs, and/or laboratories.
- Are you looking for experience in pre-market or post-market?
- You have proven experience and strong writing skills in CMC (Module 3).
- You are fluent in both written and spoken English and bilingual in French.
- You demonstrate strong organizational skills and autonomy.
- You have excellent communication skills.

## Who We Are:

We are one of the world's leading Contract Research Organizations (CROs), with the commitment, expertise, and flexibility necessary to successfully conduct clinical studies.

We work with pharmaceutical, biotechnology, cosmetic companies, and many others, providing innovative and adaptable solutions.

We operate in 10 countries across 3 continents, bringing together more than 1,000 talented professionals dedicated to actively advancing clinical research.

We have been part of the ALTEN Group since 2014 and continuously explore new opportunities to grow our business worldwide.

**Joining Aixial Group means:**

- Being at the forefront of clinical research: You will work on cutting-edge projects where your expertise will be fully utilized and have a real impact on the lives of millions.
- Continuously developing your career and skills: Our employees are at the heart of our priorities. At Aixial Group, you will be coached and supported throughout your journey to help you grow both professionally and personally.
- Working in an environment where equality, diversity, and inclusion are integral to our commitment: Our goal is to promote a workplace based on dignity and respect, where individual differences are recognized and valued, and where every employee can give their best. Gender equality is central to Aixial Group's development strategy.

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**Your contact person**

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