

Selectchemie AG, Zurich, Switzerland

Work place: Hybrid or remote from Europe office location (Poland, Serbia, Spain, Turkey, Germany, Switzerland)

## **Project Manager FDF (Located in one of our Europe offices) (100 %)**

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### **About Selectchemie AG**

Selectchemie is an independent Swiss company serving the pharmaceutical and nutrition industry since 1969 as a premier supplier of high quality ingredients and generic finished dosage forms. As a full-service provider we create added value by offering comprehensive technical, scientific, regulatory and commercial support all along the value chain. Worldwide, our 120 experienced professionals with commercial and scientific background, based at the headquarters in Zurich, Switzerland and locations in 18 countries, provide customers, principals and suppliers with solutions tailored to their needs.

### **Join our team**

Our department Generics: Dossiers & FDF develops finished dosage forms (FDF) and generic dossiers in collaboration with co-development partners from the idea to the market. We commercialize such FDF & dossiers under license & supply agreements to a global generics customer base. As a Project Manager FDF, you will contribute to the overall effort in novel generics development, including generic plus and patent-free products.

### **Your tasks and responsibilities**

#### Project management

- Leads projects from project selection until product registration (implementation) or variation approval (in case of transfer and/or upscale).
- Ensures projects success (timeline, budget, quality) via timely and close coordination with partners and contracting parties.
- Challenges CDMOs for efficient manufacturing process and compliance to cGMP, ICH, Pharmacopoeia etc. regulations and guidelines.
- Provides technical expert contribution to dossier preparation and exchanges with regulatory authorities. During product development phase, coordinate initial submissions with regulatory teams.

#### Procurement and contract management

- Familiarises him-/herself with product technology details and requirements, actively study requirements about product formulation, technology, quality and other relevant aspects necessary for successful project completion.
- Supports potential CDMO capability and capacity evaluation, and selection.
- Prepares development and tech transfer agreements with dossier development partners and contract manufacturing organizations. Supports license and supply agreement preparation as well as Quality Technical Agreements with customers and partners.

#### Technical support during product life cycle

- Initiates and supports improvements in product technology and quality.

- Fulfills trouble-shooter role after product launch, thanks to best technical knowledge of the product.
- Supports regulatory activities (new submissions) and variations.
- Supports deviations, OOS and complaints investigations.

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## Your profile

- You have a technical background in chemistry, biology, biochemistry or pharmacy.
- You have at least 5 years' experience in formulation development/production of drug products for human use.
- You have hands on experience in project management for drug product formulation / technology transfer projects, ideally from the generic industry and/or injectable products. Experience with development of oligonucleotides or complex injectables is a plus.
- You are a hands-on person and keen to ensure projects meet their goals.
- You are a project owner person, who is proficient in engaging multidiscipline and globally active teams for the needs of your project.
- You can challenge our service providers for efficient technical and commercial execution.
- Thanks to your creativity you can turn problems into solutions and opportunities.
- If you are passionate about this role but do not meet all the requirements, we encourage you to apply. We value diverse skills and experiences and are committed to helping you grow and succeed.

## What's in for you?

- Entrepreneurial position in a dynamic globally acting team
- Your input is key and you're part of creating our future success
- Close cooperation with colleagues across the entire hierarchy within Selectchemie
- Close cooperation with CDMOs, customers/licensees on a global basis
- Short decision processes
- Attractive compensation package and part or 100% remote working depending on where you will be located
- Travel of about 25%

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**We are pleased to receive your complete application via:**  
**[jobs@selectchemie.com](mailto:jobs@selectchemie.com)**