

## **Senior Manager Regulatory Affairs Biosimilars (m/f)\***

Reference Number: 1001420

### **Company Information**

Our client is one of the biggest life science companies specialized in pharmaceutical research as well as the development, production and marketing of pharmaceutical and biopharmaceutical products for people all over the world.

The position is located in Europe.

### **Position**

- Development of international regulatory Biosimilars strategies (development and PMO initiatives) for incorporation into the respective Biosimilar Development Plan.
- Ensure creative and flexible regulatory approaches for Biosimilar development, while being compliant with relevant internal and external regulations and guidelines.
- Compilation and driving EU Biosimilars Marketing Authorization Applications, FDA Biosimilar License Applications (aBLA/351k) and overseeing marketing applications for other markets, e.g., Japan and Emerging Markets.
- Coordination and initiation of interaction with health authorities, in cooperation with the Regulatory departments (regional, local) and/or the CRO as appropriate.
- Act as Biosimilar Core Team Member. Present regulatory project status, progress, opportunities, issues, risks and challenges and recommendations for solutions to the Core Team and Supply Chain Meetings as appropriate.
- Managing, as chair, international regulatory sub teams, if applicable.
- If applicable, coaching or mentoring of junior RA Manager with regard to regulatory affairs abilities.
- Stay informed of current regulatory, scientific, technical and requirements in Biosimilar drug development.
- Commenting on new/upcoming Regulatory documents (internal/external), assessing impact and, where necessary, assisting with implementation with the Biosimilars structure of our client.
- Participation and contribution to internal Working Groups for development and enhancement of internal working procedures and standards

## **Candidate Profile**

- MD (or PhD) degree in Pharmaceuticals or Biology
- 6 years or more industrial experience (Generics/Pharma, Biotech) and at least 4 years of experience in regulatory affairs in the industry
- Successful BLA/MAA experience with Biologics is required.
- Longstanding development experience with biologics, ideally with Biosimilars.
- Several years of experience as team member in International Development Teams with track record of regulatory accomplishments
- Specific regulatory expertise in at least one of the indications areas of either oncology or immunology.
- Practical experience in handling European and/or US registration procedures and proven track record.
- Solid international regulatory understanding
- Ability to work in matrix organization
- Creative, strategic and analytical thinking
- Strong implementation and communication skills
- Crisis management and solution orientation
- Due to the international nature of the tasks fluency in written and spoken English

## **Mediatum**

Excellence is our standard. Specialization in life sciences is our strength. Mediatum is the premier recruiting boutique for innovative and successful companies in the biotech, pharmaceutical, medical devices and diagnostics industry.

We support and advise our clients in Europe discretely and reliably in the identification, selection and appointment of professionals and executives. Our approach is a unique consulting service which has been widely recognized as being among the best in the industry.

If you are interested in this position please email your CV to

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\* This job description applies equally to male and female candidates, regardless of the wording used in the text.