

Global Head of Regulatory Affairs Biosimilars (m/f)*

Reference Number: 1001378

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

- Guidance and support for the development of international regulatory Biosimilars strategies (development and PMO initiatives) for incorporation into the various Biosimilar Development Plans.
- Having a clear overview of global Regulatory requirements and their impact on the Biosimilar development programs/projects of our client.
- Ensure creative and flexible regulatory approaches for Biosimilar development, while being compliant with relevant internal and external regulations and guidelines.
- Oversight of compilation of EU Biosimilars Marketing Authorization Applications, FDA Biosimilar License Applications (aBLA/351k) and for other markets, e.g., Japan and Emerging Markets.
- Oversight of interactions with health authorities, in cooperation with Regulatory departments (regional, local) of our client and/or the CRO as appropriate.
- Present regulatory opportunities, issues, risks and challenges and recommendations for solutions to the Supply Chain as appropriate.
- Member of the Supply Chain, Challenge Meeting Committees, Clinical Expert Groups and other key internal committees relevant for biosimilars.
- Commenting on new/upcoming Regulatory documents (internal/external), assessing impact and, where necessary, assisting with implementation with the Biosimilars structure of our client.
- Coaching, developing and mentoring of RA Managers with regard to regulatory affairs abilities.
- Stay informed of current regulatory, scientific, technical and requirements in Biosimilar drug development. Stay informed of other relevant regulatory requirements and assess impact and relevance on specific area of Biosimilars
- Ensuring RA 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
- 8-10 years or more of professional experience in the (bio) pharmaceutical industry (Generics/Pharma) as well as in biotech start-up arena, thereof at least 6 years in regulatory affairs
- Development experience with biologics in more than one therapeutic area is required, ideally Oncology and Immunology, ideally with Biosimilars, with track record of regulatory accomplishments
- Experience in handling international registration procedures and proven track record.
- Ability to lead and motivate an international team of RA managers.
- Ability to work with and represent regulatory interests in interactions with other management functions, including presentation to senior management.
- Significant leadership and managerial capabilities
- 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

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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.