Regulatory strategy (first time right), regulatory compliance and life cycle management are of vital importance to a successful business. Michor Consulting (www.michor-consulting.eu) is a young and growing consulting company working in the area of regulatory affairs, quality assurance, compliance, and business strategy and post market maintenance. We are currently looking for a

2 Regulatory Affairs Consultants (40 hrs) or part time (20 hrs)

The Regulatory Affairs Consultant will work at our office in Vienna. The main responsibilities will include:

- Write Module 3 documents – Chemistry-Manufacturing and Controls (CMC)
- Define and implement the Integrated CMC Product Development strategy for the programs and drive alignment with functional leaders
- Work across functions to ensure quality assurance, pharmaceutical development and manufacturing activities are scheduled in accordance with Program Core Team timelines and executed on time according to plan
- Align CMC team members and sub-teams on content and strategy and create synergy in activities taking place at multiple sites. This includes external/internal manufacturing campaigns, process/analytical development, functional characterization, release testing, comparability campaigns, stability studies, regulatory filings, and other CMC-related activities.
- Lead the CMC Team to track, compile, review, and ensure timely delivery of documents in support of regulatory filings and responses
- Works with the CMC team to build and review monthly program updates to the Program Core Team and Portfolio Review Committee to ensure transparency of progress and drive key program decisions.

Experience/Skills/Education:

- Master's degree (PhD preferred) in a relevant subject: Biotechnology, chemistry, biology or a similar background.
- 3-5 years experience in a similar position preferred but beginners are also welcome.
- Computer proficiency and adaptability working with a variety of databases, word processing, spreadsheet, etc.
- Experience with vaccines and biotech products preferred
- Ability to create effective reports and analysis and communicate them in a timely and effective manner.
- Ability to work in a team environment with shifting priorities and requirements.
- Experience with writing module 3 documents, CMC preferred
- Ability and willingness to learn legal aspects of drug, medical device and food registrations.
- Proficient in English and German.
- Willingness to work at client sites in Europe.

Salary will be based on experience but will meet the legal requirements according to the Austrian laws and regulations.

Contact Details:

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