Quality Assurance Specialist

Job description:
We are looking for a full-time, highly motivated individual to work as a Quality Assurance CMO specialist with cGMP experience for novel biotherapeutic products.

About Microviable
Microviable Therapeutics is a preclinical stage biotech company developing a novel class of orally administered biological drugs based on microbiota-derived products.
Microviable is developing unique products based on complete microbiota ecosystem products and rationally defined and designed bacterial consortia, to address unmet challenges in human diseases. The current pipeline includes preclinical data for our lead candidate seeking to initiate cGMP manufacturing for first-in-human clinical trials.

Position:
We are seeking a Quality Assurance specialist with experience in biological drugs manufacturing at cGMP to assist with the development and implementation of QA documentation in a new facility, monitor QA of the manufacturing process and supervise the already implemented ISO certifications of the company.

Responsibilities:
- Create, review, implement, approve, and maintain QA documentation
- Provide QA oversight to ensure quality and cGMP compliance of manufacturing process
- Batch record review and deviation management (creation, review, feedback)
- Prepare and review API, raw materials, bulk, and finish product release specifications
- Review and approval of pharma bulk and packaged batch records
- General compliance activities to support on-site inspections
- Develop and implementation of CAPA plans
- Assists in development of appropriate Standard Operating Procedures, laboratory data collection & documentation systems (paper and electronic) and training of personnel to ensure cGMP compliance
- Support ongoing programs and supervise current ISO certifications
- Assist the technical team on daily QA items
- Communicate with the team and ensure QA implementation across the organization and activities

Qualifications:
- More than 3 years of QA experience in a GMP environment in the pharma industry
- Strong experience on manufacturing and related QA
- Proven ability to develop and implement QA strategies
- Experience generating manufacturing documentation and product data sheets
- Knowledgeable on EU regulations for GMP manufacturing
- Ability to work independently with minimal supervision.
- Willingness to work collaboratively in a team environment
- Highly motivated and organized
- Fluency in Spanish and English

Microviable Therapeutics SL
C/Los Prados, 166
33203 Gijón, Asturias

Benefits:

- Competitive salary
- Ability to grow in a young and enthusiastic team
- Work towards the development of novel biological drugs to help patients in real need.
- Free coffee and snacks!!
- Enjoy the beautiful location of Asturias, Spain, with the best combination of a great culture, delicious food and beautiful mountains close to the beach.

When, where, and how?

- For immediate consideration
- In Oviedo&Gijón, Asturias, Spain.
- Full time

If you are interested in working with us, email your credentials at: info@microviable.com

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