



Immunic Therapeutics is a dynamic biotechnology company with a pipeline of selective, orally available immunology therapies for the treatment of chronic inflammatory and autoimmune diseases. Currently, three small molecule product candidates are in various stages of clinical development. For more information, please visit: www.imux.com.

We are looking for a

Clinical Compliance Manager (m/f/x)

The Clinical Compliance Manager is member of the Clinical Development Operations (CDO) team reporting to the VP, Program Management and CDO. This position supports the clinical development operations function and will primarily be responsible for the following activities;

- Quality Management System development related activities:
 - Coordination of CDO SOP development including review, input and ownership
 - Lead CDO process improvement and lessons learned efforts
- Training coordination related activities:
 - Development and provision of SOP and GCP/regulation training for CDO team members
 - QC of CDO team members training documentation
- Clinical study quality oversight related activities:
 - Support Quality Management and CDO with audit and inspection preparations
 - Support CDO team members with CAPA management
 - Perform spot checks / QC of TMF for Immunic sponsored clinical studies
 - Review and approval of clinical trial related documentation
- Support CDO team members with risk and issue management related activities for Immunic sponsored clinical studies
- Point of contact for all GCP and process related questions by CDO team members

Qualifications

- At least 3 years of experience in Good Clinical Practice (GCP) and Quality Assurance Environment in Pharmaceutical Clinical Development or Clinical Research Organization, preferably in same role or clinical compliance specialist role.
- In depth expertise in worldwide regulations (including FDA, EMA) related to clinical development and post approval.
- Risk management, mitigation and problem-solving
- Excellent written and oral communication skills
- Proven ability to multi-task and thrive in a fast-paced environment
- Works and meets deadlines while being detailed oriented
- Self-motivator
- Dedication to quality in all work tasks and deliverables
- An academic degree in Life Science (advanced degree preferred).



What you can expect:

- A permanent full time position with attractive pay in an international, highly motivated and collegial team
- Full office, hybrid or full home-based is being considered
- A dynamic, flexible, open and multi-cultural working environment
- Participation in our company's success through our stock option program
- An innovative, fast growing company

We are a passionate and ambitious team that loves to work together. Immunic is an exciting place for fresh ideas – apply now and become part of our international team!

Please send your meaningful application specifying your salary expectations as well as the earliest possible starting date by email to Erika von der Decken: jobs@imux.com.

