



Quality Assurance – Pharma GMP, GDP – Regulatory Affairs Pharma (CMC/ CTD) (m/w/d)

The Company

Entourage is a management and personnel consultancy focusing on pharmaceuticals, medical technology and health care. With the placement of permanent scientific staff and consultants, the company, based in Munich, Basel and Milan, recruits experts for the leading life science companies in Europe. With Project Consultants, Entourage realizes projects for its clients through highly qualified temporary staffing and work contracts. With Management Consultants, Entourage bundles selected interim managers and management consultants into a top-class consulting unit that implements interdisciplinary pharmaceutical and medical technology solution scenarios in projects.

Your Profile

- ▶ **Master of Science in pharmacy** or graduate pharmacy state examination (pharmacist), PhD students are welcome
- ▶ Intrinsic motivation and strong interest in the area of quality assurance under GMP, GDP, Regulatory affairs (RA), (production, CMC and laboratory: small molecules, biologics)

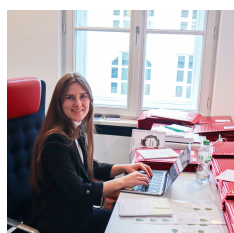
Your Tasks

- ▶ Perform and support **pharmaceutical product manufacturing** and **GMP-quality** related processes
- ▶ Developing, supporting and improving Pharmaceutical Quality- and Risk Management Systems (EU GMP Guide, Part I, Part II, Annexes, ICHQ9/ICHQ10)
- ▶ Evaluation and assurance of process controls
- ▶ **Preparation of documents** for process and method validation: plans, risk analyses, flow charts, reports
- ▶ Preparation, review and training of quality related controlled documents
- ▶ Preparation and Participation in customer/authority **audits**
- ▶ Execution and documentation of root cause analyses for deviations and out-of-specification results, risk management
- ▶ Managing deviations, complaints, non-conformities, and CAPAs

Your Benefits

- ▶ **Practice-oriented work** with a high degree of personal responsibility
- ▶ Personal coaching and specialized training programs ("buddy program") by experienced consultants on EU GMP, EU RA, EU GDP, FDA GMP, and EU and FDA devices
- ▶ **Individual development** through intensive support by experts from HR and management consulting
- ▶ Workplace in the heart of Munich with a unique ambience and/or work at client site and/or work from home-office
- ▶ Member of a young and motivated team
- ▶ Technical equipment with iPhone and MacBook
- ▶ **Competitive salaries**
- ▶ Add-on education across applied life science projects within ENTOURAGE

Contact



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