07/05/2024

GERMANIA	
Posizione	Life Science Consultant, Business System Owner
Scadenza	30.06.2024

We are seeking a highly skilled and accomplished Life Science Consultant to join our team in Germany. The ideal candidate will have a proven track record of success in the life science industry, specializing in Quality and GMP Compliance, Computerized System Validation (CSV), and Supply Chain Management.
As a Business System Owner (BSO) for a leading pharmaceutical company, you will bring a wealth of expertise in regulatory compliance, project management, and innovation to ensure the success of criti-cal projects. Major Accountabilities
1. Business System Ownership: • Act as the BSO delegate, focusing on the implementation of production planning tools with-in the life science industry.
• Collaborate with stakeholders to gather and analyze business requirements for computer-ized systems, ensuring alignment with regulatory standards and industry best practices.
2. Validation Expertise: • Develop comprehensive validation strategies, including risk assessments, validation plans, protocols, and reports, to ensure system integrity and compliance.
• Implement rigorous change control processes, assessing the impact of changes on comput-erized systems, and ensuring compliance with regulatory requirements.
3. Project Management: • Lead and manage diverse high-value projects in the life science industry, demonstrating proficiency in Lean time management and quality management systems for cGMP-regulated environments.
• Enhance team control and structure through the implementation of project management tools.
4. Regulatory Compliance: • Utilize in-depth knowledge of industry regulations and standards, ensuring compliance with quality and GMP requirements. Proficient in FDA and EMA guidelines.
5. Innovation and Problem-Solving: • Demonstrate creative problem-solving skills, aligning innovative solutions with rigorous regulatory frameworks, including GxP requirements.
• Continually hone analytical, management, and communication skills.
Education: • Master's Degree in Sciences or Biotechnology., Language: Fluent in English, Fluent in Spanish, Fluent in Italian, Additional European language expertise is an advantage
Work experience: At least 5 years of practical experience as Technical lead of a pharmaceutical plant
Skills
• Knowledge of relevant industry standards & methods (ISO (ISO-9001 and 14971), ICHQ, GxP, Qualification and Validation, Quality Management, QMS, Process Management, Lean Management, Risk Management, Change Management, Quality and Project Management, Audit)
• Basic project management, good organization, and planning skills
• Knowledge of CSV, Quality and GMP Compliance, Supply Chain Management, Innovation, Master Data Management, IT Project Management, Quality Assurance, Audit, Training, Risk Management, Change Control, Plant Design, Process Validation and Root Cause Analysis.
• Good analytical skills, • Effective Communication, • Demonstrates problem-solving and idea- generation skills
We offer great benefits
• Flat hierarchies and responsibility from the beginning, • People-oriented culture, • Diversity and inclusion-focused environment, • Global client projects in a multinational environment, • Flexible working hours and home office, • Involvement in global conferences, • Individual professional development, training, and coaching, • Unlimited full employment contract, • Excellent remuneration package consisting of a competitive salary plus a substantial bonus
If you have the necessary background and experience and would like to join a small team responsible for a truly global operation, then please send your application to recruiting(at)kvalito.ch including your: • CV, cover letter and supporting documents (i.e., diplomas, certificates, references) • Availability - earliest start date • Salary expectations • Location preference
How to apply: Requested application types: via the portal Internet address:
http://www.kvalito.ch
Required attachments: Required attachments: CV, certificates Call up job offer details in the BA job search: 10000- 1197983749-S
Email to : magdalena.kurpierz@kvalito.ch