23/03/2024

Life Science	
Luogo di lavoro	Germania - Heidelberg
Profili ricercati	**Life Science Consultant, Business System Owner (BSO)** **Life Science Consultant, Cell & Gene Therapy Supply Chain Process Manager**
Requisiti generali	**Life Science Consultant, Business System Owner (BSO)** https://kvalito.ch/career/?job_id=z5G7h3l6a1kMvyS65NP3c6Et3LVQqYKm4wAztFV-rws= 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 critical projects. Major Accountabilities 1. Business System Ownership: Act as the BSO delegate, focusing on the implementation of production planning tools within the life science industry. Collaborate with stakeholders to gather and analyze business requirements for computerized 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 computerized 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. Minimum Qualifications and Experience 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 (ISO9001 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 **Life Science Consultant, Cell & Gene Therapy Supply Chain Process Manager** The purpose of the role is managing pharmaceutical document management and logistics optimization, focusing on developing processes and GXP Documentation for Cell & Gene Therapy. Major Accountabilities: • Develop and maintain documentation such as SOPs, WIs, and guidance documents, ensuring precision and clarity. • Validate and innovate supply chain processes; create Service Orders, Request Forms, and Pro-ject charters. • Manage logistics for products in Cell & Gene Therapy • Oversee distribution and transport deviation, logistics, and supply chain management. • Implement and manage work instructions for logistics for the CGT of pharmaceutical products. • Conduct training on operations, mock shipments, packing instructions, and shipping solution assembly. • Optimize end-to-end logistics operations, ensuring timely and accurate delivery of pharmaceu-tical products. • Analyze data to extract actionable insights, supporting data-driven decision- making and con-tinuous process improvements. • Facilitate cross-functional collaboration, ensuring cohesive documentation processes and en-hancing operational efficiency. Education • Degree in Science, Mechatronics, Biomedical Engineering or equivalent Language: • Fluent in English • Professional working proficiency in French • Elementary proficiency in German • Additional European language expertise is an advantage Work experience: At least 3 years of work experience in the field of expertise Skills: • Proven experience in pharmaceutical supply chain management and logistics. • Demonstrated working experience in the

	area of gene therapies, immunotherapies, and/or cell therapies • Familiarity with GXP documentation and regulatory compliance in the pharmaceutical industry. • Knowledge of relevant industry standards & methods (ISO 14971, ISO 13485) • Equipment know-how in Packaging & Laboratory • Good knowledge of Software, Hardware & Firmware (ABB RobotStudio, Adobe Illustrator, Adobe Photoshop, MATLAB, Miro, Python, RoboExplorer, SOLIDWORKS • Good organization, and planning skills • Demonstrates problem-solving and idea- generation skills • Very good communication, negotiation, and interpersonal skills. Ability to work in interdiscipli-nary teams 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
Modalità di candidatura	Send CV, cover letter and supporting documents (i.e., diplomas, certificates, references) • Availability - earliest start date • Salary expectations to this email address magdalena.kurpierz@kvalito.ch
Scadenza	31.06.2024