

Competence Profile:Kyra Cole

Kyra Cole

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Profile

Results-driven project owner and physicist with over 8 years of experience in atomic, molecular, and optical physics, specializing in data analytics, digital transformation, and project management. Proven track record in leading cross-functional teams to deliver data-driven solutions in highly regulated sectors such as pharmaceuticals and manufacturing. Fluent in English and German, with work authorization in both the USA and the European Union.

Core Competencies

Competence Area	Description
Digital Transformation & Digitalization	Design and implementation of digitalization frameworks and systems in the pharmaceutical and life sciences industry.
Pharma & Life Sciences	Expertise in clinical software development, GxP validation, HIPAA compliance, and MES implementation.
Project & Program Management	Leadership of complex projects in highly regulated environments, from requirements gathering to delivery.
Data Analytics & Business Intelligence	Development of analytics dashboards and utilization of advanced analytical techniques for process optimization.
Requirements Engineering & Validation	System validation and ensuring regulatory compliance in aerospace and pharmaceutical industries.
Research & Development	Leadership of EU-funded research projects and development of innovative technologies.

Automotive & Functional Safety

Development of driver assistance systems and ensuring functional safety according to industry standards.

Detailed Competence Areas

Digital Transformation & Digitalization

- Architected an open clinical framework for digitalization in pharma and clinical software development.
- Defined and deployed a Core MES (PAS-X) system across multiple BioNTech sites to enhance operational efficiency.
- Managed a digitalization program for the Idar-Oberstein site comprising 15 projects, with responsibility for supply chain and customer-specific processes.
- Led software development, change management, and requirements management to deliver high-quality solutions.

Pharma & Life Sciences

- Developed clinical software ensuring GxP validation and HIPAA compliance.
- Implemented and validated Manufacturing Execution Systems (MES) to ensure regulatory compliance and improve process efficiency.
- Developed Master Batch Records (MBRs) for individualized cancer treatments while ensuring quality and compliance.
- Managed chain of identity and custody processes to ensure product and patient safety.

Project & Program Management

- Led cross-functional teams in highly regulated environments to successfully deliver projects.
- Managed the entire project lifecycle, from conception to delivery.
- Served as primary liaison between organizations (e.g., BioNTech and Körber Pharma) to ensure effective communication and project alignment.
- Coordinated team resources to maximize efficiency and achieve project objectives.

Data Analytics & Business Intelligence

- Developed data analytics dashboards for manufacturing and laboratory data to improve decision-making efficiency.
 - Utilized GPU acceleration for simulations and advanced data analysis.
 - Developed heat conductivity simulations and evolutionary algorithms.
 - Implemented high-performance fitting algorithms for 3D data analysis.
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Technical Skills

- **Programming Languages:** C/C++, CUDA, LabVIEW, Python, SQL
- **Systems:** MES (PAS-X), ERP (SAP), NiceLabel, Nymi, LIMS, PCS
- **Methods:** SCRUM, Project Management, Six Sigma, DoE+

- **Software:** Microsoft Office, Mathematica, DOORs, PTC, MS Project

Certifications

- SA Certified SAFe® 5 Agilist
- Green Belt Six Sigma
- Negotiation Training
- Business Administration for Start-ups
- Laser Safety Officer Certification
- Functional Safety
- Project Management
- Data Science and Machine Learning (MIT xPRO, 2025)

Education

- **Diplom Physicist (Master of Science equivalent)** - Johann Wolfgang Goethe University (1998-2006)
- **Professional Certificate in Data Science and Machine Learning** - MIT xPRO (2025)