AFRIKA KOMMT! 2025-2027

An Initiative of German Industry for Future Leaders from Africa

Overall remarks: AK is a fellowship position I.e Alongside making meaningful contributions, the primary focus is on your professional development and learning.

Profile Name: GMP Technical QA for Manufacturing & QA for Quality Control Fellow

Company: ID:AK_14_BNT_01	**BioNTech SE / Biopharma**	Company Logo

Education:	**Bachelors Degree in Sciences (Pharmacy, Biotechnology, Engineering)**
Professional Experience:	2-5 years in a relevant GxP Industry or regulatory body [Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP)], with an understanding of general GMP/GDP concepts; and preference for at least 1-2+ years of this time in the pharmaceutical industry (GMP / GDP for medicines). Additonal experience in vaccines (human or animal) or biologics is a plus. Level and areas of education (including graduate work or other trainings) are also considered in combination with industry experience.

Maximum years' experience needed:	Graduate / work experience 1-4y	Other
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Additional Qualifications:	Experience in: Has worked in a GMP/GDP facility with experience in one or more of the following areas: • Process and method qualification/validation, C&Q, QBD • Product Specfications, IPCs, QTPP, • Material/Vendor Qualification & Management • Risk Mgt, Exceptions/Investigations, Change Control • APQR, Product Complaints • QMS, Computerized Systems Validation, GMP Training, Document Management, Data Integrity Regulatory & Compliance English language skills required (reading, writing, speaking); German language skills and any experience leading/driving teams is a plus.

This profile focuses on the indicated skill sets:	People Leadership	Expertship/ Specialist	Project/Program Management	Other
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Country Focus:	All nationalities are welcome to apply. Preferred nationality: Rwandese

Division / Location / Department:	GMP QA, Germany (approximately 70%) GMP QA, BioNTainer Global/Rwanda (approximately 30%)

Planned Tasks & Activities:	• Train in various GMP Technical QA for Manufacturing/QC areas under the guidance of a SME, including but not limited to: • QA review & approval of lifecycle documents for process, facilities, manufacturing equipment, TT, qualification/validation, and GMP readiness (SOPs, URS, C&Q documents, protocols & reports, monitoring, QBD) • QA review & approval of lifecycle documents for method development, equipment, controls/reference standards, TT, qualification/validation (SOPs, protocols, reports) • Review and help assess exceptions, investigations, change control, and associated risks from technical QA perspective. • Support review and approval of product Specfications, IPCs, QTPP, MRB • Support material/vendor qualification, approval, and management. • Maintain validation registers. • Quality on the floor (on the shop floor, QASF) • Ensure GMP compliance in all areas of GMP overseen by Technical QA & QA on the shop floor. • Support Data Integrity risk assessment for GMP QA. • Liaise with key personnel to ensure tasks are completed in a timely manner. • Additional training may be advantageous as time permits for the following GMP QA Operations/Systems and Compliance areas, including but limited to: • QMS (including Veeva / ZenQMS electronic systems) oversight and management, GMP Training, Document Management • APQR, Regulatory & Compliance
Remarks:	The candidate may be required to rotate between Germany and the Global BioNTainer QA Sites (e.g., Rwanda) depending on site activities and timelines.