



## AFRIKA KOMMT! 20=26-2028

### An Initiative of German Industry for Future Leaders from Africa

**Overall remarks:** AFRIKA KOMMT! is a [fellowship position](#) in Germany in which, alongside making meaningful contributions, the primary focus is on your professional development and learning.

#### Fellowship Profile:

##### Fellow as Global Patient Safety Regions Scientific Specialist (Pharmacovigilance) (m/f/d)

<b>Company:</b> ID: AK15_ME_01	Merck Healthcare KGaA / Regulatory, Quality Safety (RQS)	
<b>Education:</b>	A thorough Bachelor background in life-sciences, ideally Pharmacist. Chemists, Biochemists, Biologists, Neuroscientists etc., and Physicians are also eligible	
<b>Professional Experience:</b>	<p>3-5 years of experience in the Health Care industry, preferably in post-marketing Pharmacovigilance GVP or Clinical Trials under GCP, Quality Assurance GMP, or Project Management within a multinational organization</p> <p>Experience of working in a regulatory authority is an extremely valuable asset.</p> <p><b>Compulsory:</b></p> <p>Profound understanding of Adverse Reaction reporting and related pharmacovigilance quality related processes</p> <p>Health authority regulation understanding based on country.</p> <p><b>Desirable:</b></p> <p>Pharmacovigilance understanding in more than one African country.</p>	
<b>Maximum years' experience needed:</b>	Graduate / work experience 2 – 5y	Or other: <input checked="" type="checkbox"/>
<b>Additional Qualifications</b>	<p><b>Compulsory:</b></p> <ul style="list-style-type: none"> <li>• Good understanding of global and Regional and local Pharmacovigilance Regulation and Guidance documents</li> <li>• Pragmatic and collaborative approach of implementing regulatory guidance into own area of work</li> <li>• Excellent communication (written and spoken) in English, additional languages are an asset</li> <li>• Attention to detail and focus on quality</li> </ul> <p><b>Desirable:</b></p> <ul style="list-style-type: none"> <li>• Initial project management experience, including stakeholder and interface management</li> <li>• Good time management and self-organizational skills</li> </ul>	
<b>Country Focus:</b>	All African nationalities	
<b>Division / Location / Department:</b>	<p>Merck R&amp;D Healthcare business, Regulatory, Quality and Safety - Global Patient Safety (GPS) Germany, Darmstadt.</p> <p>This opening is in GPS Regions, a department acting as bridge between headquarters and affiliates.</p>	

<b>Planned Tasks &amp; Activities:</b>	<ul style="list-style-type: none"> <li>Contribution to Submission and Launch Readiness - support oversight and guidance to local patient safety on additional Risk Minimization Measure (aRMM) materials (includes distribution of core aRMM materials and implementation plans to local patient safety and request training for the local patient safety), as well as Safety Communications (SCs) (includes distribution of master SC and implementation plans to local patient safety); support creation and/or update of core aRMM materials for internal local training and communication plan, as well as core implementation plan, together with global, regional and local functions to prepare local colleagues for upcoming launches or for distribution of updated aRMM, contribute and support to maximize efficient use of IT solutions for Risk Management activities, aRMM materials and SCs at local and regional level (e.g. use of tracking systems)</li> <li>Project Assignment in Global Patient Safety Regions as applicable</li> <li>Support in Regions improvement projects and strategic initiatives</li> <li>Interact with R&amp;D functions on collaboration and improvement projects</li> <li>Support in PV Training activities and education</li> <li>Support in CAPA Management with Audits and Inspections</li> </ul>
<b>Remarks:</b>	N/A