

## AFRIKA KOMMT! 2023-2025 An Initiative of German Industry for Future Leaders from Africa

Profile Name: International Global Regulatory Affairs & Scientific Policy Specialist

Company: AK12_MK_02	Name of Company / Merc		M	RCK
Education:	Master level education (MS, MBA or Pharm D)			
Professional Experience:	<ul> <li>1-3 years' experience in drug development or regulatory affairs in the biotech/pharmaceutical industry</li> <li>Knowledge of drug development process/EMA/ICH regulations and processes</li> <li>Understanding/experience in policy development and implementation</li> <li>Understanding of relevant regional legislative processes and intersection with regulatory requirements</li> <li>Demonstrated ability to work cross-functionally and obtain results from individuals who have no reporting relationship</li> </ul>			
Maximum years' experience needed:	Graduate / work experience 1-2y	Young professional (2- 4y)	Professional (4y+)	Other (specify, if applicable)
		$\boxtimes$		
Additional Qualifications:	<ul> <li>Experience in:</li> <li>Fluency in English</li> <li>Ability to work in matrixed, multinational work environment</li> <li>Ability to work effectively as part of a global organization with internal leaders and external association key stakeholders</li> <li>Good analytical skills, and ability to summarize complex information</li> <li>Strong presentation skills</li> <li>Teamwork</li> <li>Personal adaptability and initiative</li> </ul>			
This profile focuses on the indicated skill sets:	People Leadership	Expertship/ Specialist	Project/Program Management	Other
		$\boxtimes$		Policy network
Country Focus:	All nationalities			
Division / Location / Department:	Global Regulatory Affairs & Scientific Policy (Global Regulatory Affairs)			
Planned Tasks & Activities:	<ul> <li>This position will assist with the continual monitoring and technical analysis of international regulatory guidelines and</li> </ul>			

	<ul> <li>pharmaceutical legislation as well as policies and practices impacting Merck pipeline and portfolio.</li> <li>Liaise with the regional/country regulatory affairs to ensure awareness on international regulatory environment/trends and assessing jointly their relevance to Merck Biopharma, compiling for internal audience the respective information and impact assessment</li> <li>Coordinate collection of international regulatory knowledge and policy updates for internal exchanges</li> <li>Perform project management supportive activities (meeting minutes, follow up of action items, meeting preparation, consolidation of advocacy activities)</li> <li>Contribute to developing global regulatory policy position and policy materials</li> <li>Contribute to/support development of local/regional advocacy activities</li> <li>Participate in external industry working group to support Merck internal industry more advaced and policy materials</li> </ul>
	<ul> <li>Participate in external industry working group to support Merck international advocacy roadmap and coordinate regulatory policy activities internally</li> <li>May handle information requests from Merck GRASP or internal</li> </ul>
Remarks:	customers in R&D, under supervision