

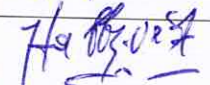
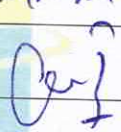
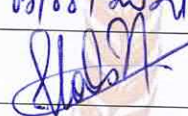
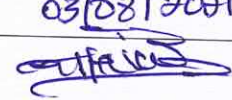


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 <b>RWANDA FDA</b> Rwanda Food and Drugs Authority	Title: <b>COMPENTENCE MATRIX</b>	

Title	Author	Checked by			Approved by
		Quality Assurance Analyst	DM/PV-SM	DM/FDIE	
	DM/FDIC				HoD/FDISM
Names	Dr. Marylin M. MURINDAHABI	Dr. Vedaste HABYALIMANA	Lazare NTIRENGANYA	Theobald HABİYAREMYE	Alex GISAGARA
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Signature					

A Quality Management System is most effective when all employees in an organization understand and apply the skills, training, education and experience needed to perform their roles and responsibilities.

Competence is defined as “the ability to apply knowledge and skills to achieve intended results”. Demonstrated competence is sometimes referred to as “qualification”

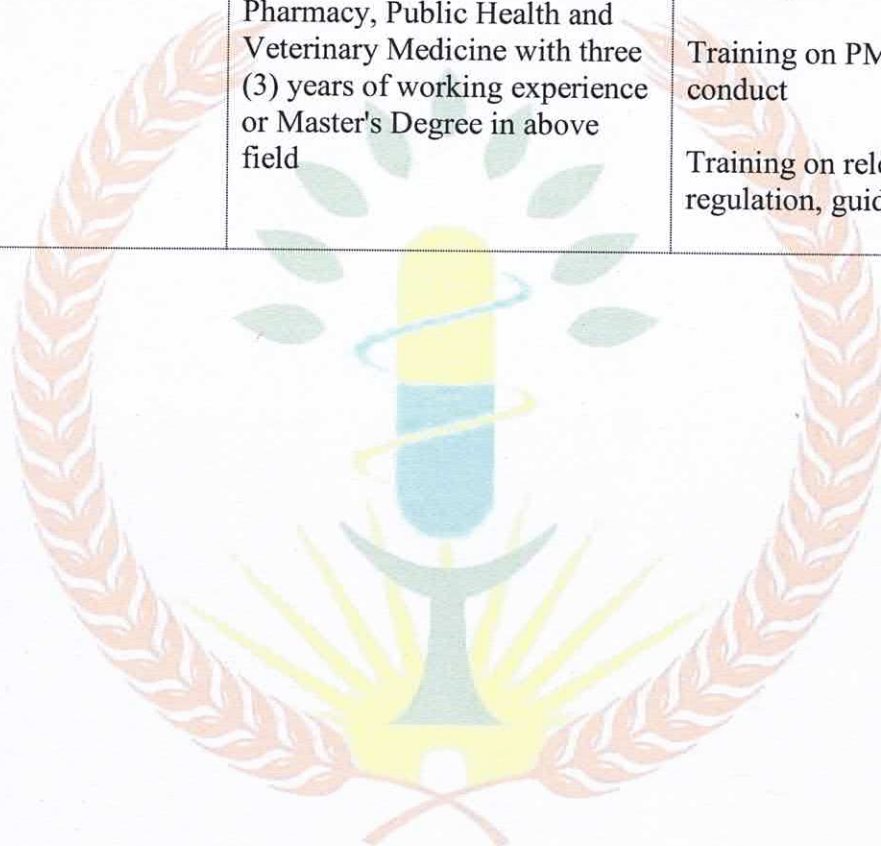


Activity to be performed	Role/Responsibility	Competences Required		
		Minimum Education	Trainings to be done	Minimum Experience
1.				
1. GMP Inspection of Pharmaceutical Manufacturing Facilities	GMP Inspector	Bachelor's Degree in Pharmacy, Chemistry, Biomedical Engineering, Medical Biotechnology, Veterinary Medicine, Biology and other related qualification	Basic GMP training, Advanced GMP training, TOT on GMP, PRIMS/IRMIS training, training on Policies, Laws, Manuals, Regulations and Guidelines and SOPs.	Observer status in at least 2 GMP inspection processes, attendance in at least 2 GPRC meetings
	Lead GMP Inspector	Bachelor's Degree in Pharmacy, Chemistry, Biomedical Engineering, Medical Biotechnology, Veterinary Medicine, Biology and other related qualification	Basic GMP training, Advanced GMP Training, TOT on GMP Training on PRIMS, training on relevant laws, regulations, guidelines and SOPs	GMP Inspector in at least 5 inspection processes, attendance in at least 5 GPRC meetings, certified GMP trainer
2. Inspection of Medicine shops and Pharmacies	GDP Inspector	Bachelor's Degree in Pharmacy, Chemistry, Biomedical Engineering, medical biotechnology, Veterinary Medicine, Biology and other related qualification	Basic GDP training, training PRIMS, training on Rwanda FDA Laws, applicable Regulations, guidelines and SOPs	Observer status in at least 2 GDP inspection processes
3. Inspection of medicines at the ports of entry & Exit	Port of Entry Inspector	Bachelor's Degree in Pharmacy, Biomedical Engineering, medical biotechnology, Veterinary Medicine, Biology, public health, and other related qualification	Basic GDP training, Basic GMP training, training on PRIMS/electronic Single Window System, training on relevant Laws, Regulations, Guidelines and SOPs	Observer status for one month at port of entry
4. Enforcement of compliance to Rwanda FDA Laws and Regulations	Enforcement Specialists/ Inspector of Drugs	Bachelor's Degree in Pharmacy, Biomedical Engineering, Medical Biotechnology, Veterinary Medicine, Biology, public health, electrical	Basic GDP training, Basic GMP training, PRIMS training, Basic training on Rwanda FDA relevant Laws, Regulations, Guidelines and SOPs, Basic training in Enforcement	Observer status in at least 2 enforcement processes



		engineering and other related qualification	methods, Basic training in prosecution process and chain of evidence	
5. Inspection of clinical trial sites	GCP Inspector	Bachelor's Degree in Pharmacy, Medicine, Chemistry, Veterinary Medicine, Medical Biotechnology and other related qualification.	Basic and Advanced GCP training, training on relevant Laws, Regulation, Guidelines and SOPs	Observer status in at least 5 GCP Inspections.
6. Pharmacovigilance Inspection	Pharmacovigilance Inspector	Bachelor's Degree in Pharmacy, Medicine, Veterinary Medicine and other related qualification	Training on PV inspection, Training on relevant Laws, Regulation, Guidelines and SOPs	Observer status in at least 5 PV Inspections
7. Clinical trial review	Clinical trial reviewer	Bachelor's Degree in Medicine, Pharmacy, Biotechnology, Veterinary Medicine with 3 years of relevant working experience or Master's Degree in Medicine, Pharmacy, Biotechnology, Clinical Trials, Veterinary Medicine, Epidemiology, Public Health	Training on Good clinical trial practices  Training on relevant laws, regulation, guidelines and SOPs  Training on clinical trial review	Assisted clinical trial review for 3 applications
8. Causality assessment for ADR/AEFI reports	Pharmacovigilance specialist	Bachelor's Degree in Medicine, Pharmacy, Public Health and Veterinary Medicine with three (3) years of working experience or Master's Degree in above field	Training on pharmacovigilance  Training on causality assessment  Training on relevant laws, regulation, guidelines and SOPs	Assisted causality assessment for 10 AD/AEFI reports
9. Investigation of medicine signals	Pharmacovigilance specialist	Bachelor's Degree in Medicine, Pharmacy, Public Health and Veterinary Medicine with three (3) years of working experience	Training on pharmacovigilance  Training on signal detection	Assisted signal assessment for 3 medicine signals

		or Master's Degree in above field	Training on relevant laws, regulation, guidelines and SOPs	
10. Risk based sampling	PMS specialist	Bachelor's Degree in Medicine, Pharmacy, Public Health and Veterinary Medicine with three (3) years of working experience or Master's Degree in above field	<p>Training on risk-based sampling</p> <p>Training on PMS planning and conduct</p> <p>Training on relevant laws, regulation, guidelines and SOPs</p>	Assisted 3 PMS planning and sampling activity



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# FOOD ESTABLISHMENTS

Activity to be performed	Role/Responsibility	Competences Required		
		Minimum Education	Trainings to be done	Minimum Experience
11. GMP Inspection of Food Manufacturing Facilities	GMP Inspector	Bachelor's Degree in Food Sciences& Technology, Chemistry, Biotechnology, Microbiology and Agro-Processing with five (5) years of relevant working experience. and other related qualification	Basic GMP training, Advanced GMP training, TOT on GMP, PRIMS/IRMIS training, training on Policies, Laws, Manuals, Regulations and Guidelines and SOPs.	Observer status in at least 2 GMP inspection processes, attendance in at least 2 GPRC meetings
	Lead GMP Inspector	Bachelor's Degree in Food Sciences& Technology, Chemistry, Biotechnology, Microbiology and Agro-Processing with five (5) years of relevant working experience.	Basic GMP training, Advanced GMP Training, TOT on GMP Training on PRIMS, training on relevant laws, regulations, guidelines and SOPs	GMP Inspector in at least 5 inspection processes, attendance in at least 5 GPRC meetings, certified GMP trainer
12. Inspection of food outlets	GDP Inspector	Bachelor's Degree in Food Sciences& Technology, Chemistry, Biotechnology, Microbiology and Agro-Processing with five (5) years of relevant working experience.	Basic GDP training, training PRIMS, training on Rwanda FDA Laws, applicable Regulations, guidelines and SOPs	Observer status in at least 2 GDP inspection processes
13. Inspection of food at the ports of entry & Exit	Port of Entry Inspector	Bachelor's Degree in Food Sciences& Technology, Chemistry, Biotechnology, Microbiology and Agro-Processing with five (5) years of relevant working experience.	Basic GDP training, Basic GMP training, training on PRIMS/electronic Single Window System, training on relevant Laws, Regulations, Guidelines and SOPs	Observer status for one month at port of entry
14. Enforcement of compliance to	Enforcement Specialists/	Bachelor's Degree in Food Sciences& Technology,	Basic GDP training, Basic GMP training, PRIMS training, Basic	Observer status in at least 2 enforcement

Rwanda FDA Laws and Regulations	Inspector of Food	Chemistry, Biotechnology, Microbiology and Agro-Processing with five (5) years of relevant working experience.	training on Rwanda FDA relevant Laws, Regulations, Guidelines and SOPs, Basic training in Enforcement methods, Basic training in prosecution process and chain of evidence	processes
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The logo of the Rwanda Food and Drugs Authority (FDA) is centered on the page. It features a circular emblem with a pink laurel wreath. Inside the wreath is a stylized sun with yellow rays at the bottom, a blue and yellow vertical bar in the center, and a blue spiral above it. Below the emblem, the text "RWANDA FDA" is written in large, bold, grey capital letters. Underneath that, "Rwanda Food and Drugs Authority" is written in a smaller, red, sans-serif font.

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