



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Regulatory Excellence Ecosystem for Regulators: Sharing Saudi FDA best practice to actively support growth and development of regulators

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SFDA Resources & Expertise

No. of SFDA staff 3000+ employees. (300+ MD expertise) holding PhD, Master's, and Bachelor's Degrees in different specialties, including Biomedical Engineering, Medical Physics, IVDs, Biochemistry, Optimists, Dentists, physiotherapists, Health Informatics, biotechnology, etc.



The SFDA has established plans and procedures to support growth and development of the team. These include:

- **Clear and detailed onboarding and induction plan and manual for new employee**
 - It include step by step plan for 6 months and include all the references needed during this time
 - It also show SFDA expectations for new employees, checking points and timeline
 - It is updated on regular basis based feedback for new employees



- **Comprehensive program for new employees on medical device regulations and Saudi law**
 - 6-8 months extensive program
 - Cover the main technical and regulatory knowledge needed
 - Include regular assignments and final exam



- **Annual completion of a competency matrix for each employee to track development**

- Education
- Background
- specialty
- Technical skills
- Scientific and regulatory knowledge
- Soft skills

Education	Details	notes						
Bachelor's discipline		Please provide information if you got familiar about specific types of medical devices or specific parts of regulatory requirements.						
Master's discipline		Please provide information if you got familiar about specific types of medical devices or specific parts of regulatory requirements.						
Experience	Details	notes						
Previous experience		if you worked in different roles please provide information about each role						
Roles								
Role and tasks description								
Years								
SFDA experience		if you worked in different roles please provide information about each role						
Roles								
Role and tasks description								
Years								
Technical Documentation	Details	notes						
Number of assessed TF (estimate)		specify (individual assessment / team assessment / case study)						
Application Number		if applicable						
Devices' Type/Categories of assessed TF								
Specialty								
Standards backgrounds		please specify the standards and your level of knowledge (Basic, beginner, intermediate, advance)						
Skills and Training	Name of the training course	Duration	year	where	Level of the course (basic, beginner, intermediate, advance)	Your current level (basic, beginner, intermediate, advance)	note	
Regulatory Affair								
Overview of international practices								
Technical Documentation								
Quality Management System (QMS)								
Risk Management (RM)								
Sterilization								
(Shelf-life/Stability)								
Packaging & Transportation								
Clinical Evaluation								
Clinical Investigation								
Performance Evaluation								
Biological Evaluation								
Chemical characterization								



Based on the updated matrix and strategic priorities, annual development plan will be created for each employees which will cover :

- Capacity-building programs are conducted annually based on the team's needs in advanced regulatory sciences and technologies.
 - Group Capacity-building programs (regulations, science and innovation, new technologies)
 - Individual comprehensive international training in regulatory, scientific, and engineering workshops.
- Participation in international and local conferences, technical workgroups, and committees of various international and national organizations.



Based on the common needs and strategic priorities, the following will be assigned annually :

- An external Experts' Committee comprising doctors, scientists, and biomedical engineers will support the team to assess advanced and novel technologies.
- An advisory board members will be selected from national and international universities, research centres, and the health sector will also support the team when needed.



The SFDA support to the growth and development of regulators worldwide :

- Cooperation with international organizations (participate in providing capacity building programs, providing technical consultation support and being active in technical workgroups)
- Providing Global capacity building program through WHO collaborating centre for medical devices regulation at Saudi FDA (Biannually)



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Towards Medical Device Harmonization

Thank you