

Medical Device Regulations Seminar - 7 & 8th September 2011

Day 1 - General Forum -- Draft Regulations and Existing Regulatory Systems

	Session 1	Chair - Dr Bomela
Time	Topic	Presenter
08.00 - 08.30	Registration	
08.30 - 09.00	Welcome	DG - Ms Precious Matsoso
09.00 - 09.30	Key Note Address 1	DMOH - Dr Gwen Ramokgopa
9.30 - 10.15	Draft Medical Device Regulations overview and the rationale	Advisor HT - Ms Nonkonzo Molai
10.15 - 10.45	Tea Break	
	Session 2	Chair - Dr Gantsho
10.45 - 11.30	International Best Practices <ul style="list-style-type: none"> - Differences between medicines and medical devices - Lessons learnt from the pharmaceutical sector - Different approaches to the regulation of devices - Pitfalls and successes from industry 	Michael Gropp - GHTF
11.30 - 12.15	GHTF - Overview, Recommendations, regulator establishment of GHTF, skill and capacity - to be a influential member of GHTF, Broad discussion of GHTF Risk Classification	Dr Isabelle Demade - EU Regulator
12.15 - 1300	AHWP - Recommendations	Mr Jack Wong - AHWP
13.00 - 14.00	LUNCH	
	Session 3	Chair - Elsabe Klinck
14.00 - 17.30	Country Presentations	
	Process of Implementation - phased in approach, Transitional arrangements, Timelines (listing and licensing), Resources, Capacity and Technical Skills, Administration, communications, electronic requirements, alignment with other regulatory jurisdictions	

14.00 - 14.45	Saudi Arabia - Saudi Food and Drug Administration (SFDA)	Dr Tayer - SFDA
14.45 - 15.30	United Kingdom - Medicines and Health Products Regulatory Agency (MHRA)	Dr Susanne Ludgate - MHRA
15.30 - 16.00	Tea Break	
16.00 - 16.45	Australia - Therapeutic Goods Administration (TGA)	Michael Flood - ex TGA
16.45 - 17.30	Open Discussion	Chair - Elsabe Klinck
17.30 -	Cocktail function	
Day 2 - Technical Forum		
TIME	TOPIC	PRESENTER
08.00 - 8.30	Registration	
Parallel Session 1	MD & IVD Registration and Licensing Process	Chair - Mr A.B Khalaf Co-Chair - Brian Goemans
8.30 - 9.00	GHTF Risk Classification and Rules	Isabelle Demade - EU
9.00 - 9.45	Practicing GHTF recommendations in regulatory systems - Process of Implementation and adaption of GHTF rules - Timelines, Capacity, Resources and Skills for Regulators - Pitfalls and Best practices	Michael Flood - ex TGA
9.45 - 10.30	Broad overview of Regulation process and implementation plan Notification of MD on the Market - Listing For Products on the market - Licensing of all devices and companies in the market	Nonkonzo Molai - Advisor HT
10.30 - 11.00	TEA	
11.00 - 11.45	Criteria for Conformity Assessment body and Inspections - Selection criteria - Roles and requirements, Implementation process and requirements for Manufacturers, importers etc	SANAS

11.45 - 12.30	Duties of License holders - Licencing process, fees - Training - Servicing and Maintenance requirements	Terry Downes
12.45 - 13.45	LUNCH	
Parallel Session 2	Conformity Assessment Procedures	Chair - Dr Lynn Hanmer
8.30 - 9:15	Roles and requirements of regulatory authorities	Susana Ludgate
9.15 - 9.45	Distributing safe and effective MD: a certification body perspective - Requirements for Manufacturers, importers etc Best practices Capacity, turnaround times, forms etc - Pitfalls and -	Jack Wong
9.45 - 10.30	Mutual recognition	Dr Tayyer - Saudi FDA
10.30 - 11.00	TEA	
TIME	TOPIC	PRESENTER
11.00 - 11.45	Process for Combination Devices	Michael Gropp
11.45 - 12.45	Call up, and Registration: Additional requirements for registration – call up process. Implementation – turnaround, forms and guidelines, processes - comparison of STED and CSdT	Elsabe Klinck - Chairperson of Regulatory Sub Committee - MAC-HT
12.45 - 13.45	LUNCH	
Parallel Session 1	Post Marketing Surveillance - FSN	Chair - Mladen Poluta

14.00 - 15.00	Post Market Surveillance and Recall of MD and IVD's - Adverse Event Reporting (process, timelines etc) - Requirements for manufacturers - Requirements pre-market vs post market	ECRI or Dr Tayyer
15.00 - 15.30	TEA	
	Parallel Session 2	Users and Duties of Heads of HC Facilities
		Chair - Dr Mbulawo
14.00 - 15.00	Shared Responsibility in MD regulations	Michael Cheng
	Mandatory Adverse event reporting	
	Implications for users and hospital managements	
15.00 - 15.30	TEA	
	Plenary Session - Round Table Discussion	Chair - Dr Zokufa
15.30 - 16.00	Regulator skills and capacity building	Jack Wong
16.00 - 17.30	Open Discussion - All Speakers of the Day	ALL
17.30 - 18.00	Closing	MOH - Dr Gwen Ramokgopa