

# REGULATORY RELIANCE WORKSHOP



MARCH 20, 2025



ROYAL TULIP CANAAN, NAIROBI



# Regulatory Reliance Workshop

Date: March 20, 2025

Venue: Royal Tulip Canaan, Nairobi

Time	Session	Speaker	Session Coordinator
0830hr – 0900hr	Welcome and Introductions Remarks from HA & Industry Reps	Dr. James Mokoro (Reckitt Benckiser) Dr. Robert Miano (IMS) Steve Kipkoti (Medtronic)	Main Plenary
0900hr – 0930hr	Survey Analysis Report	Dr. Daisy Chonge (KAPI)	
0930hr – 1000hr	GReP Guideline & Continental Reliance Framework	Dr. John Mwangi (Bayer)	
<b>1000hr – 1030hr</b>	<b>Coffee Break</b>		
<b>Best Practice sharing from around the world</b>			
1030hr - 1100hr	PPB – General overview of reliance practices / Policy / Guideline	Pharmacy and Poisons Board - Kenya	Main Plenary
1100hr - 1130hr	Pharma - Middle East/Egypt	Radwa Ahmed Saad El Gamil (EDA) Rim Mahmoud Mahmoud Eltanahy (EDA)	
1130hr – 1145hr	Pharma – Ghana & Nigeria	Onwusah Arit (Novartis)	
1145hr – 1200hr	Regional Reliance Experience	Chehimi Inas (Novartis)	
1200hr - 1215hr	Medical Devices – Middle East & Africa	Rana Chalhoub (MECOMED)	
1215hr - 1220hr	Q & A Session		
<b>Reliance practices beyond New Registrations (MA) by Industry &amp; HA</b>			
1220hr - 1230hr	Practical Approach to Reduction of Product Shortages using Reliance	Angelika Joos (MSD)	Main Plenary
1230hr - 1255hr	Pharma – Industry experience in PACs	Dr. Mangia Francesca (Roche)	
<b>1255hr – 1355hr</b>	<b>Lunch</b>		

Breakout Sessions			
1355hr – 1450hr	<b>Pharma: Panel discussion</b> <ol style="list-style-type: none"> <li>1. NDAs</li> <li>2. Post Approval Changes</li> <li>3. GMP</li> <li>4. Clinical Trials &amp; PV</li> </ol>	Pharmacy and Poisons Board – Kenya	Main Plenary
1355hr – 1450hr	<b>Session 1: Medical Devices</b> Industry’s perspective on the practice of regulatory reliance beyond new registrations: <ol style="list-style-type: none"> <li>1. Post Approval Changes</li> <li>2. Quality Audits</li> <li>3. Clinical Trials &amp; Medicovigilance</li> </ol>	Dr. Asma Awad (Roche)	Breakout Room 1
	<b>Session 2: Medical Devices</b> Industry’s perspective on the practice of regulatory reliance beyond new registrations – Experiences from Asia-Pacific - APACMED	Rana Chalhoub (MECOMED)	
	<b>Session 3: Medical Devices</b> Local Authority’s Perspective on Reliance Practices & Initiatives for: <ol style="list-style-type: none"> <li>1. New Registrations &amp; Re-registrations</li> <li>2. Post Approval Changes (Change Notifications)</li> <li>4. Quality Audits</li> <li>5. Clinical Trials &amp; Medicovigilance</li> </ol>	Dr. Solomon Koech (PPB)	
1450hr - 1520hr	<b>Q &amp; A</b>		
1520hr- 1530hr	<b>Coffee Break</b>		
1530hr - 1635hr	Case Studies	Dr. Peter Odhiambo (Bayer) Dr. Wycliff Choge (BBraun)	Main Plenary
1635hr - 1650hr	Wrap-up, way forward, workshop recommendations	Dr. Peter Odhiambo (Bayer)	
1650hr – 1700hr	Closing Remarks	Dr. James Mokoro (Reckitt Benckiser)	
<b>End of Workshop</b>			



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