AGENDA

DAY 1	**MONDAY, DECEMBER 14, 2015**
	OPENING THE WORKSHOP • Welcome, introductions, and logistics **INTRODUCTION TO THE WORKSHOP** • Purpose of the FDA Workshop • What is an IVD and why are IVDs Regulated • Feedback from participating Nations on the issues they encounter • Presentation by TFDA Fellows
GROUP PHOTOGRAPH and LUNCHEON	
	FEATURES AND CHALLENGES OF REGULATORY SYSTEMS • Features of Regulatory Systems • Regulatory Autonomy • Communication • Collaboration **ELEMENTS OF REGULATORY SYSTEMS** • Global approaches to IVD regulation • Responsibilities of Regulatory Authorities • Importance of consequences for non-compliance
SUMMARY OF DAY 1	

AGENDA

DAY 2	TUESDAY, DECEMBER 15, 2015
	RECAP AND INTRODUCTION TO DAY 2 **REVIEW OF INFORMATION PROVIDED TO A REGULATORY AUTHORITY** • Examination of documentation submitted for marketing authorization purposes • Confirming validity • Review of any national requirements (e.g. language / labelling / environmental)
LUNCHEON	
	BREAK OUT SESSION 1: IVD LABELING and REVIEW • Case studies **GROUP DISCUSSION – WHAT DID WE LEARN DURING BREAK-OUT SESSION 1?** **THE VALUE OF QUALITY MANAGEMENT SYSTEMS - IVD MANUFACTURING INDUSTRY** • Benefits to IVDs • Elements of the Quality Management System • MDSAP / Inspection harmonization
SUMMARY OF DAY 2	

AGENDA

DAY 3	WEDNESDAY, DECEMBER 16, 2015
	RECAP AND INTRODUCTION TO DAY 3 **POST-MARKETING ACTIVITIES** • Implementing the manufacturer's requirements • Importance of reporting adverse events • Implementing manufacturer's corrections • Tracking the device performance through the supply chain • Oversight of organizations in the supply chain
LUNCHEON	
	BREAK OUT SESSION 2: POST-MARKET VIGILANCE AND TRACKING FOR PRODUCT FAILURE • Case studies **GROUP DISCUSSION – WHAT DID WE LEARN DURING BREAK-OUT SESSION 2?** **WORKSHOP SUMMARY** **CERTIFICATES**
CLOSING REMARKS • Moving forward • Opportunities for networking/collaboration • Closing statements	

DEPARTURE