Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

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4-8 December, 2017 I New Delhi

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WG6 – QUALITY SYSTEM AUDIT & ASSESSMENT

CHAIR: ABDULLAH AL RASHEED
CO-CHAIR: SHIRLEY SUM
ADVISORS: VINCENT LAM, ALBERT LEE

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	Work Item	Deliverables	Timeline	Status
1	Reviewing IMDRF proposed documents N8R2 and N24R2	Guidance document	Q2, 2015	Done
2	Finalizing Importer & Distributor Guidance doc.	Guidance document	Q3, 2015	Done
3	Conducting training session during annual meeting on I/D adopted guidance documents	Workshop	Q4, 2015	Done
3	Aligning WG6 documents with WG7 documents		Q1, 2016	Done
4	Reviewing IMDRF final document N11 &N22	Guidance document	Q1, 2016	Done
5	Reviewing IMDRF final document N3 &N4	Guidance document	Q3,2016	Done
6	Reviewing IMDRF final document N5 &N6	Guidance document	Q1, 2017	On hold
7	Submit the IMDRF documents for comments as draft proposed documents for AHWP ME	Draft documents	Q2, 2017	On hold
8	Final documents to be submitted for comments	Final documents	Q3, 2017	On hold
9	Endorsement on the adopted documents during annual meeting	Final adopted document	Q4, 2017	On hold
10	Conduct training session on MDSAP document	HK Training	Q1,2017	Done
11	Conducting training session during annual meeting on IMDRF MDSAP guidance documents	Workshop	Q4, 2017	Done
12	AHWP/WG6/NXPDRX <DRAFT> Guidance on Understanding the Roles of IMDRF documents concerning auditing	Guidance document	Sept 2017-April 2018	DRAFT for review

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Benefits of MDSAP DOCs.

- This collection of IMDRF MDSAP documents will provide the fundamental building blocks by providing a common set of requirements to be utilized by the Regulatory Authorities for the recognition and monitoring of entities that perform regulatory audits and other related functions.

- It is provide frame work to AHWP
- It is start with specific requirement and how to recognize AO passing through training and building capacity.
- Its including the distributors, AR, importer and even people involving in installation to cover MD life cycle
- It allow ISO/IEC 17021-1:2015 to act as the ***generic base requirements*** and then utilize this IMDRF MDSAP document to ***add prescriptive requirements*** for medical device Auditing Organization and to negate or eliminate certain of these generic base requirements, which were meant for ***commercial entities***, when the Auditing Organization is also a Regulatory Authority

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IMDRF/MDSAP WG/N3 FINAL:2016
Requirements for Medical Device Auditing Organizations
for Regulatory Authority Recognition

- Specific Requirements for Medical Device Auditing Organizations:
  - Management of impartiality
  - Liability and financing
  - Structural requirements
  - Resource requirements
  - Personnel involved in the auditing activities
  - Outsourcing
  - Confidentiality

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IMDRF/MDSAP WG/N4FINAL:2013
Competence and Training Requirements for Auditing Organizations

- Adherence to this document and its requirements will help mitigate the risk of inconsistent or ineffective assessments of manufacturers by ensuring that Auditing Organization personnel have the necessary
  - Commitment,
  - Competence,
  - Experience, and
  - [illegible]aining before conducting an audit or undertaking a decision making function.
- [illegible]ite Experience

- Regulatory requirements
- Medical devices knowledge
- Auditing Standards and Techniques
- Statistical Analysis

  [illegible]uditors, Final Reviewers, and Technical Experts shall demonstrate at least four years of relevant full-time experience
  [illegible]etence Requirements Three broad categories of competencies are required for potential Lead Auditors, [illegible] Experts, and Final Reviewers:
  [illegible]mpetencies: those generic skills, personal attributes, and behaviors applicable to all personnel and developed through [illegible]aptability, diligence, critical and analytical thinking, communication, etc.)
  [illegible]encies: those generic skills applicable to all personnel developed through experience and required to perform audits (e.g. [illegible]gement; time management; teamwork; effective use of information technology; etc.)
  Competencies: those unique skills developed through experience and specific knowledge applicable to personnel depending on the [illegible]ctivities needed to address subject areas (e.g. regulatory requirements, risk assessment, health and safety impacts, etc.)
  - To [illegible] the various md technologies

IMDRF/MDSAP WG/N5FINAL:2013
Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations

- This document defines the content of the Regulatory Assessment Program. Its define how Regulatory Authorities will recognize, monitor, and re-recognize Auditing Organization under the framework of the IMDRF MDSAP.
- Recognition, monitoring and re-recognition is based on a process based assessment method utilizing assessment tasks related to the requirements found in IMDRF MDSAP WG N3 and N4. The assessment method defined in this document will be used to perform the different assessment activities within the Assessment Program.

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IMDRF/MDSAP WG/N11FINAL:2014
MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

- This document defines:
  - The process and lifecycle for recognizing, maintaining, or ceasing recognition of an Auditing Organization.
  - The process of managing, grading, and closure of assessment nonconformities issued to an Auditing Organization; and,
  - The outcomes of an initial, surveillance, or re-recognition assessment process of an Auditing Organization.

- Overview on MDSAP Assessment Cycle, Program & Criteria
- Deliverables related to nonconformities(grading), reporting, remediation plan & nonconformities closure

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THANK YOU