Resolutions towards Endorsement

21th AHWP Meeting
25 Nov 2016, Cebu, Philippines

Mr. Bryan So
Executive Deputy Secretary General, AHWP

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Resolution towards Endorsement

AHWP New Member Economy Applications

1) Kingdom of Bahrain
2) Sultanate of Oman
3) United Arab Emirates
4) Zimbabwe

AHWP New Liaison Member Application

1) APACMed

AHWP Terms of Reference (TOR)

1) AHWP Vision & Mission
2) Official Observer
3) Working Group Technical Document Endorsement Mechanism

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

1) Guidance on Regulatory Practices for Combination Products
2) Guidance for Minor Change Reporting
3) Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”
4) Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Resolution towards Endorsement

WG Documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
8) Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative
9) AHWP Safety Alert Dissemination System (SADS)
10) Post Market Resource Center
11) Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
12) Competence and Training Requirements for Auditing Organizations
13) MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization
14) MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes
15) Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative

AHWP New Member Economy Application

Kingdom of Bahrain

Application for AHWP member economy was received from National Healthcare Regulatory Authority, Kingdom of Bahrain:

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  – Primary (Regulatory Authority) – Nada Ghassan Al Sayegh

Endorsement

Yes / No?

(Apology due to travel schedule)

AHWP New Member Economy Application

Sultanate of Oman

Application for AHWP member economy was received from Ministry of Health, Sultanate of Oman:

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  – Primary (Regulatory Authority) – Dr. Mohammed Hamdan Al Rubaie

Endorsement

Yes / No?

(Short speech by Dr. Mohammed Hamdan Al Rubaie, Pharmaceutical Affairs & Drug Control)

AHWP New Member Economy Application

United Arab Emirates

Application for AHWP member economy was received from Ministry of Health and Prevention, United Arab Emirates:

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  – Primary (Regulatory Authority) – Dr. Amal Al Awadhi

Endorsement

Yes / No?

(Apology due to travel schedule)

AHWP New Member Economy Application

Zimbabwe

Application for AHWP member economy was received from Medicines Control Authority, Zimbabwe:

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  - Primary (Regulatory Authority) – Ms G. N. Mahlangu
  - Secondary (Regulatory Authority) – Mr R. Rukwata

Endorsement

Yes / No?

(Short speech by Ms. Petronella Murambinda, Medicines Control Authority)

Resolution towards Endorsement

AHWP New Member Economy Applications

1) Kingdom of Bahrain
2) Sultanate of Oman
3) United Arab Emirates
4) Zimbabwe

AHWP New Liaison Member Application

1) APACMed

AHWP Terms of Reference (TOR)

1) AHWP Vision & Mission
2) Official Observer
3) Working Group Technical Document Endorsement Mechanism

AHWP New Liaison Member Application

APACMed

Application for AHWP liaison member was received from Asia Pacific Medical Technology Association (APACMed):

- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  - Ms Catherine Derrein, Chair of RA Committee (primary)
  - Mr Jason Guo, Vice Chair of RA Committee (secondary)

Endorsement

Yes / No?

(Short speech by Mr Fredrik Nyberg, CEO)

Resolution towards Endorsement

AHWP New Member Economy Applications

1) Kingdom of Bahrain
2) Sultanate of Oman
3) United Arab Emirates
4) Zimbabwe

AHWP New Liaison Member Application

1) APACMed

AHWP Terms of Reference (TOR)

1) AHWP Vision & Mission, Goals
2) Official Observer
3) Working Group Technical Document Endorsement Mechanism

Amendment to AHWP TOR – AHWP Vision, Mission and Goals

FINAL DOCUMENT

Background

- The current AHWP Terms of Reference (TOR) is specified under the Final Document AHWP/SECRETARIAT/F001:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.
- Currently there are no Vision and Mission addressed.
- AHWP member economy has expanded to countries beyond Asian areas.
- To visualize the strategic plan of AHWP and to clarify the plan of AHWP as the roadmap for success.

Amendment to AHWP TOR – AHWP Vision, Mission and Goals

Newly Proposed Text

Clause 1.1 Vision

*To **Achieve International Harmonization** of Medical Device Regulations through **Collaborative Efforts of Regulators and the Industry** in Asia **and Beyond**.*

Clause 1.2 Mission

*To **Strategically Accelerate** Medical Device Regulatory Convergence through **Promotion of an Efficient and Effective Regulatory Model** for Medical Devices.*

** The above new clause Vision and Mission are proposed to be added in AHWP TOR before the clause 1.1 with numbering of all the following clauses to be updated accordingly.*

Amendment to AHWP TOR – AHWP Vision, Mission and Goals

Proposed Text

Clause 1.3 Goals

- *To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and beyond.*
- *To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.*
- *To promote capacity building in member economies and to foster strategic membership expansion.*
- *To work in collaboration with related international organizations such as IMDRF, WHO, ISO, IEC.*

** The above revised clause for Goals are proposed to be in AHWP TOR after the clause 1.1 and 1.2 (Vision and Mission).*

Amendment to AHWP TOR – AHWP Vision, Mission and Goals

FINAL DOCUMENT

- ➢ Prepared by Secretariat
- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Further discussed at TC Pre-meeting, Nov 2016
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Amendment to AHWP TOR – Official Observer

FINAL DOCUMENT

Background

- The current AHWP Terms of Reference (TOR) is specified under the Final Document AHWP/SECRETARIAT/F001:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.
- To set up a role of Official Observer of AHWP , for **close collaborating partnership with international organizations** and other regulatory authorities, which have constraints to join AHWP liaison membership.

Amendment to AHWP TOR – Official Observer

Newly Proposed Text*

Clause 1.4 Official Observers

- *The AHWP leadership may designate Official Observers on the basis of expected contribution and value.*
- *Official Observers must be approved by the unanimous consent of the voting members present in AHWP annual meetings.*
- *Official Observers do not participate in the decision making process.*

** The proposed clause is changed into bullet point format for this presentation.*
*** The above new clause Official Observer are proposed to be added in AHWP TOR after the clause 1.3 Goals with numbering of all the following clauses to be updated accordingly*

Amendment to AHWP TOR – Official Observer

FINAL DOCUMENT

- ➢ Prepared by Secretariat
- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and Tele-conference in Nov 2016
- ✓ Reviewed and commented by AHWP & TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Further discussed at TC Pre-meeting, Nov 2016
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

Background

- The current AHWP Terms of Reference (TOR) is specified under the Final Document AHWP/SECRETARIAT/F001:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.
- Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- To facilitate the acceleration of process for WG technical document endorsement.

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

Proposed Text

Clause 2.1

AHWPTC is the executive arm of the Working Party. It performs the following roles and responsibilities to support the Working Party:

- *Execute the Working Party's decisions and resolutions;*
- *Make recommendations to the AHWP Chair for decisions;*
- *Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;*
- *Provide expert opinions and advices;*
- *Develop **and submit** policy papers **for resolutions**;*
- ***Develop and submit technical documents and white papers for endorsements;***
- *Plan and organize meetings, training, seminars, workshops and experience sharing sessions;*
- *Work with related organizations and participate in their activities; and*
- *Report on the progress of its activities to the AHWP Meetings.*

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

Newly Proposed Text

Clause 3.2 Resolutions, Endorsements & Decision

*C. AHWPTC Representatives may initiate resolutions of **AHWPTC technical documents and white papers** for discussions and **endorsements through electronic means** and/or at AHWPTC Meetings by AHWPTC Representatives.*

*D. A simple majority is needed for any **endorsements** of AHWPTC technical documents and white papers through **electronic means** by **AHWPTC Representatives**.*

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

- ➢ Prepared by Secretariat
- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Further discussed at TC Pre-meeting, Nov 2016
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

1) Guidance on Regulatory Practices for Combination Products
2) Guidance for Minor Change Reporting
3) Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”
4) Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Amendment to AHWP House Rules – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

Background

- The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F001:2014 resolved in the 19th AHWP Meeting and announced on 21 November 2014.
- Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- To facilitate the acceleration of process for WG technical document endorsement.

Amendment to AHWP House Rules – WG Technical Document Endorsement Mechanism

Proposed Text

Clause 14

Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat

A. *Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions/**endorsements**.*

D. *Documents prepared for resolutions/**endorsements** and/or approvals shall be labeled "PROPOSED FINAL".*

E. *Documents accepted, approved, and/or prepared for already passed resolutions/**endorsements** shall be labeled "FINAL".*

Amendment to AHWP House Rules – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

- ➢ Prepared by Secretariat
- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Further discussed at TC Pre-meeting, Nov 2016
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

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4) Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Guidance on Regulatory Practices for Combination Products

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 1 – Pre-market: General MD
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

1) Guidance on Regulatory Practices for Combination Products
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5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Guidance for Minor Change Reporting

FINAL DOCUMENT – REFERENCE DOCUMENT

- ➢ Prepared by WG 1 – Pre-market: General MD
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

1) Guidance on Regulatory Practices for Combination Products
2) Guidance for Minor Change Reporting
3) Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”
4) Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”

FINAL DOCUMENT – GUIDANCE DOCUMENT

- Prepared by WG 2 – Pre-market: IVDD
- Discussed in AHWP TC Leaders Meeting, Mar 2015
- Reviewed and commented by AHWP TC Leaders
- Posted on AHWP Website and completed Calls for Comments
- Further discussed with related IMDRF WG, with no further comment received
- Posted on AHWP Website for endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

WG Documents

1) Guidance on Regulatory Practices for Combination Products
2) Guidance for Minor Change Reporting
3) Definition of the Terms “Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device”
4) Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 2 – Pre-market: IVDD
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and for Calls for Comments

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

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5) Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 2 – Pre-market: IVDD
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

AHWP House Rules

1) Working Group Technical Document Endorsement Mechanism

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1) Guidance on Regulatory Practices for Combination Products
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6) Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Submission Dossier for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 2 – Pre-market: IVDD
- ➢ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
8) Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative
9) AHWP Safety Alert Dissemination System (SADS)
10) Post Market Resource Center
11) Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
12) Competence and Training Requirements for Auditing Organizations
13) MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization
14) MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes
15) Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative

Guidance document on Risk Categorisation of Software as a Medical Device

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 3 – Pre-market: Software as a Medical Device
- ➢ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
8) Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative
9) AHWP Safety Alert Dissemination System (SADS)
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14) MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes
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Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 4 – Post-market
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
8) Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative
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AHWP Safety Alert Dissemination System (SADS)

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 4 – Post-market
- ✓ Reviewed the existed documents on SADS and updated
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
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Post Market Resource Center

FINAL DOCUMENT – REFERENCE DOCUMENT

- ➢ Prepared by WG 4 – Post-market
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG Documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
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Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 6 – Quality Management System: Audit & Assessment
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG Documents (Cont.)

7) Guidance document on Risk Categorisation of Software as a Medical Device
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15) Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative

Competence and Training Requirements for Auditing Organizations

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 6 – Quality Management System: Audit & Assessment
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG Documents (Cont.)

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15) Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative

MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 6 – Quality Management System: Audit & Assessment
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG Documents (Cont.)

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MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 6 – Quality Management System: Audit & Assessment
- ✓ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

Resolution towards Endorsement

WG Documents (Cont.)

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Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representative

FINAL DOCUMENT – GUIDANCE DOCUMENT

- ➢ Prepared by WG 7 – Quality Management System: Operation & Implementation
- ➢ Discussed in AHWP TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP TC Leaders
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Endorsement

Yes / No?

ASIAN HARMONIZATION WORKING PARTY

Thank You