AHWP TC WG01a IVD Subgroup

Survey on IVD Medical Device Regulations

Name:_____

Email Address:_____

Organization:_____

Country/Economy:_____

Section 1: Definition of IVD Medical Devices

1. How do you define an "IVD medical device" in your country/economy?

_____

_____

_____

2. Does the definition differ to that of GHTF?

☐ No there's no difference.

☐ Yes, the difference is like the following:

_____

_____

_____

_____

Section 2: Classification of IVD Medical Devices

1. How many classes of IVD medical devices are there in your country?

(a) The classes:

_____

_____

(b) Please describe each class of the device:

_____

_____

_____

_____

2. Have you established the classification rules for IVD medical devices?

☐ Yes, please describe:

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_____

_____

_____

☐ No, please describe how you plan to classify IVD medical devices:

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_____

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3. How do you relate the classes of IVD medical devices to risks on public and risks on user?

☐ Risks on public, please describe:

_____

_____

_____

☐ Risks on user, please describe:

_____

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_____

Section 3: Conformity Assessment

1. Do you evaluate the safety and performance of IVD medical devices based on related risks and hazards, e.g., using the GHTF's EP?

☐ Yes

☐ No, please describe the way you evaluate the safety and performance of IVD medical devices in your country/economy:

_____

_____

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_____

2. Do you recognize ISO13485:2003 as the standard for the QMS of manufacture of medical devices, including IVD medical devices?

☐ Yes

☐ No, please describe the standard for the QMS of medical devices, including IVD medical devices required in your country/economy:

_____

_____

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3. Do you recognize ISO14971:2007 as the standard for risk management of medical devices (including IVD medical devices) manufacture?

☐ Yes

☐ No, please describe the standard for the risk management of medical devices (including IVD medical devices) required in your country/economy:

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4. Do you recognize international standard, e.g., ISO, IEC, etc., for demonstrating the safety and performance of the IVD medical devices?

☐ Yes

☐ No, please describe standards for demonstrating the safety and performance of the IVD medical devices in your country/economy:

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_____

_____

_____

5. Do you recognize standards developed by professional/scientific society, e.g., CLSI, for demonstrating the safety and performance of the IVD medical devices?

☐ Yes

☐ No, please describe the way you seek professional opinion from the scientific and medical societies in your country/economy:

_____

_____

_____

_____

6. In your regulations, what is required to prove the clinical utility of IVD medical devices?

(a) Literature

☐ Yes, please describe the requirements:

_____

_____

_____

☐ No, please describe why:

_____

_____

_____

(b) Clinical experience

☐ Yes, please describe the requirements:

_____

_____

_____

☐ No, please describe why:

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_____

(c) Clinical investigation

☐ Yes, please describe the requirements:

_____

_____

_____

☐ No, please describe why:

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_____

(d) Expert opinion

☐ Yes, please describe the requirements:

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_____

_____

☐ No, please describe why:

_____

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_____

7. In your regulations, what is required to prove the analytical and clinical performance of IVD medical devices?

(a) Analytical performance characteristics

☐ Yes, please describe the requirements:

_____

_____

_____

☐ No, please describe why:

_____

_____

_____

(b) Clinical performance characteristics

☐ Yes, please describe the requirements:

_____

_____

_____

☐ No, please describe why:

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8. How do you demonstrate the conformity to your regulations with regard to the safety and performance of IVD medical devices?

☐ by risk-based safety and performance evaluation (e.g., GHTF's EP for demonstrating the safety and performance of IVD medical devices)

☐ by product comparison (conducting comparison studies between the new device and comparable products or Gold standard)

9. Have you ever conducted the following technical documentation pilot programs:

☐ STED pilot program

Please describe the duration, cases involved, device type, and the review process:

_____

_____

_____

_____

_____

_____

☐ CSDT pilot program

Please describe the duration, cases involved, device type, and the review process:

_____

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10. Please choose the appropriate elements required in your product technical review submission:

☐ Device description including variants (configurations) and accessories

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Reference to previous device generation(s) and/or similar devices

If you don't ask for this kind of information, please describe why:

_____

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_____

☐ Essential Principles for demonstrating the safety and performance of IVD medical devices checklist

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Risk analysis and control summary

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Design and manufacturing information

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Device design

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Manufacturing process

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Product verification and validation

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Labeling

If you don't ask for this kind of information, please describe why:

_____

_____

_____

☐ Declaration of conformity

If you don't ask for this kind of information, please describe why:

_____

_____

_____

Section 4: Post-market Surveillance and Vigilance System

1. Scope of Post-Market Surveillance and Vigilance System (You can choose more than one)

☐ Recalls

☐ Safety alerts

☐ Adverse event reporting

☐ Sample test

☐ Others (please specify):

_____

_____

2. Please describe the regular post-market surveillance and vigilance activities carried out by manufacturers or their representatives

_____

_____

_____

_____

3. Please describe the regular post-market surveillance and vigilance activities carried out by traders:

_____

_____

_____

_____

4. Regular post-market surveillance and vigilance activities carried out by users:

_____

_____

_____

_____

5. Who is required to report adverse events? (You can choose more than one)

☐ Manufacturers

☐ Importers

☐ Distributors

☐ User facilities

☐ Users

☐ CAB (Conformity Assessment body)

6. What is the timeline for reporting adverse events? (You can choose more than one)

☐ Death Reporting timeline:

☐ Happen in your jurisdiction only

☐ Happen inside and outside your jurisdiction

☐ Serious injury: Reporting timeline:

☐ Happen in your jurisdiction only

☐ Happen inside and outside your jurisdiction

☐ Near incident Reporting timeline:

☐ Happen in your jurisdiction only

☐ Happen inside and outside your jurisdiction

☐ Device malfunction Reporting timeline:

☐ Happen in your jurisdiction only

☐ Happen inside and outside your jurisdiction

7. What are the means of reporting?

☐ Email, Please specify the email address:

_____

☐ Specific form, please specify the form location:

_____

☐ Website, please specify reporting website:

_____

8. What is the definition of recall in your regulations?

_____

_____

9. Do you require Manufacturers/representatives to report recalls/corrective actions?

☐ Yes

☐ The actions happening in your jurisdiction only

☐ The actions happening inside and outside your jurisdiction

☐ No

10. What is your country/economy recall notification procedure?

☐ Email, please specify email address:

☐ Specific form, please specify the form location

☐ Website, please specify reporting website

11. If you have any website for the regulation of medical devices, please specify:

_____

_____

Section 5: Release of survey information

1. Do you agree if AHWP TC WG01a IVD Subgroup publishes the information that you have provided in this survey?

☐ Yes

☐ No

Remark:

1. Thank you so much for your time and effort to complete this survey. Please note thatthe information collected in this survey will be used by AHWP TC WG01a IVD Subgroup as a reference for formulating the future activities for a harmonized basis of IVD medical device regulations.
2. Please return this questionnaire to the Chair and Co-chair of WG01a by sending emails to both EMMohandis@sfda.gov.sa and JFChern@itri.org.tw or by fax to both +966-1-2757245 and +886-3-5734092.

-THE END-