IMDRF International Medical Device Regulators Forum

IMDRF Membership Application Form (Cover Page)

Applications must be submitted at least two (2) months before an IMDRF Management Committee face-to-face Closed Session, which are usually held two (2) times each year (for example, March and September (variable each year)).

If the application is for a Regional Harmonization Initiative (RHI) the application must be submitted by the Chair of the RHI. Any questions should be directed to the Chair of the IMDRF Management Committee which is listed on the IMDRF website.

Contact Details for Applicant:

Name of Applicant Organization:

Contact Person(s):

Title:

Address:

Phone:

Email:

Type of Membership

Select type of membership

Depending on the type of application, please complete the corresponding section:

Management Committee Member Application	Please go to page 2
Official Observer Application	Please go to page 4
Affiliate Member Application	Please go to page 8
Regional Harmonization Initiative Application	Please go to page 11
All applications must include the signature page	*Please go to page 13*

MANAGEMENT COMMITTEE MEMBER APPLICATION FORM

ONLY complete this section if applying to become an IMDRF MC member

1. Has your organization been an Official Observer for the past three (3) consecutive years?

◯ Yes ◯ No

2. Please discuss the ways in which you have demonstrated leadership and influence regarding medical device regulation within your region.

3. List the MDRF Management Committee face-to-face Closed Sessions (including teleconferences) your organization has attended in at least the past three (3) consecutive years.

4. List the IMDRF Working Groups to which your organization has appointed experts and has been actively involved in during the past three (3) consecutive years.

5. Does your organization have sufficient capacity to Chair the IMDRF MC and provide the Secretariat service for a year, including hosting two (2) face-to-face Sessions and two (2) scheduled teleconferences?

◯ Yes ◯ No

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OFFICIAL OBSERVER APPLICATION

ONLY complete this section if applying to become an Official Observer

1. Is your organization a regulatory authority?

Yes No

2. Please discuss the ways in which you have demonstrated leadership and influence regarding medical device regulation within your region.

3. List the IMDRF MC Open Sessions (including teleconferences) your organization has attended in at least the past two (2) consecutive years.

4. List the IMDRF Working Groups to which your organization has appointed experts and has been actively involved in in the past two (2) consecutive years.

5. Does your organization have laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principals?

◯ Yes ◯ No

If yes, please provide the relevant law or regulation a comprehensive description of its contents and a description of related enforcement activities:

6. Please describe any activities or initiatives your organization has taken or are currently undertaking to bring scientific or regulatory innovation in the field of medical devices, including any guidance developed in emerging and technical regulatory issues.

7. Does your organization have a system for conformity assessment of devices building on GHTF and IMDRF guidance documents?

◯ Yes ◯ No

If yes please provide a description of your conformity assessment program:

Contribution to IMDRF

8. Describe how your organization contributes or can contribute resources and expertise to the objectives of IMDRF and how its membership would be a benefit to IMDRF:

Implementation of IMDRF Guidelines

9. Describe your organization s policy/strategy regarding the implementation of IMDRF guidelines:

10. Please indicate which IMDRF documents were implemented and provide relevant documentation to support evidence of implementation:

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AFFILIATE MEMBER APPLICATION

ONLY complete this section if applying to become an IMDRF Affiliate Member

1. Is your organization a Regulatory Authority?

◯ Yes ◯ No

2. Describe your organization's current or future policy/strategy or plan regarding the implementation of IMDRF guidelines

Additional information (not mandatory):

3. Please describe any activities or initiatives your organization has undertaken or is currently undertaking in the field of medical devices including any guidances developed in emerging and technical regulatory issues:

4. Does your organization have a system for conformity assessment of devices building on GHTF and IMDRF guidance documents?

◯ Yes ◯ No

If yes, please provide a description of your conformity assessment program:

5. Please indicate which IMDRF documents were implemented and provide relevant documentation to support evidence of implementation:

6. Does your organization have laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles?

◯ Yes ◯ No

If yes, please provide the relevant law or regulation a comprehensive description of its contents and a description of related enforcement activities:

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REGIONAL HARMONIZATION INITIATIVE APPLICATION

ONLY complete this section if are a Regional Harmonization Initiative

1. Are you an association/initiative comprising medical device regulatory authorities representing the majority of countries in a certain region/area of the world?

◯ Yes ◯ No

If yes, please describe the countries/region you are representing:

2. Does your RHI have a mandate of regional harmonization amongst your members?

◯ Yes ◯ No

3. Please provide a brief description of the activities your organization is pursuing related to the common goals of fostering global regulatory convergence leveraging resources and making available safe and effective medical devices globally:

4. Please provide a brief description of how your RHI recognizes or plans on recognizing IMDRF documents. Please also provide a brief description of your plans for gathering feedback from membership regarding implementation of IMDRF documents.

5. Please state who would be representing your RHI (e.g. Member, Chair, Secretariat etc):

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SIGNATURE PAGE

Signature

Date