IMDRF International Medical Device Regulators Forum

IMDRF Membership Application Form

Applications must be submitted at least two (2) months before an IMDRF Management Committee meeting, which are usually held four times each year (for example, January, March, June, September (variable each year)).

If the application is for a Regional Harmonization Initiative, 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.

Type of Membership

Select type of membership

If other, please specify:

Contact Details for Applicant:

Name of Applicant Organization:

Contact Person(s):

Title:

Address:

Phone:

Email:

Depending on the type of application, please fill out the corresponding section:

Management Committee Member

1. Have you been an Official Observer for at least the past 3 years?

   ☒ Yes ☐ No

2. List the IMDRF meetings (including teleconferences) your organization has attended in at least the past 3 consecutive years:

3. List the IMDRF Working Groups to which you have appointed experts and have been actively involved in:

OFFICIAL OBSERVER

Authority

1. Are you a Regulatory Authority?

☐ Yes ☐ No

2. Do you 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:

3. Please describe any activities or initiatives you undertook or are currently undertaking to bring scientific or regulatory innovation in the field of medical devices, including any guidances developed in emerging and technical regulatory issues:

4. Do you 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

5. 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

6. Describe your policy/strategy regarding the implementation of IMDRF guidelines:

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

AFFILIATE MEMBER

Authority

1. Are you a Regulatory Authority?

☐ Yes ☐ No

2. Do you 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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◯ Yes ◯ No

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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. Do you have a mandate of regional harmonization amongst your members?

Yes ☐ No ☐

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

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

Signature _____ Date _____