

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

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

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.		roups to which you have appointed experts and have been
	actively involved in:	
OF	FICIAL OBSERVER	R
Auth	nority	
1.	Are you a Regulatory Author	ority?
	Yes	No
2.	Do you have laws and regulimber foundations and pri	ulations in place for medical devices that build on GHTF and inciples?
	Yes	No
	If yes, please provide the relevan description of related enforcement	t law or regulation, a comprehensive description of its contents and a nt activities:
3.	Please describe any activit	ies or initiatives you undertook or are currently undertaking
		tory innovation in the field of medical devices, including any
	guidances developed in en	nerging and technical regulatory issues:
4.	Do you have a eyetom for a	conformity assessment of devices building on GHTF and
4.	IMDRF guidance documen	
	Yes	No
	If yes, please provide a description	on 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:				
RE	GIONAL 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 goals of fostering global regulatory convergence, leve available safe and effective medical devices globally:	eraging resources and making
4.	Please state who would be representing your RHI (e.	
Signa	ature	Date