MDSAP MEMBERSHIP APPLICATION FORM

This form may be used when requesting any type of membership to MDSAP. Document MDSAP P0003 includes information on the roles and responsibilities for all MDSAP membership types. Applications or questions must be submitted to the Chair of the MDSAP Regulatory Authority Council Secretariat (RAC). For additional information, please refer to the MDSAP web page: https://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/

Contact Details for Applicant:

Name of Applicant Organization:
Contact Person(s):
Title:
Address:
Phone:
Email:

Type of Membership Requested:

- ☐ Affiliate Member
- ☐ Official Observer
- ☐ RAC Member

Affiliate Member Application

1. Are you a Regulatory Authority?

   ☐ Yes ☐ No

Current Laws/Regulations

2. Do you have any laws and regulations in place for evaluating a medical device manufacturer's QMS based 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. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on this topic.

3. Do you have any other laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles? For example: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance.

   ☐ Yes ☐ No

   If yes, please provide the relevant law or regulation, a comprehensive description of its contents and a description of related enforcement activities. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on these topics.

Completion of MDSAP Training

4. Have you successfully completed the MDSAP on-line training modules?

   ☐ Yes ☐ No

   If yes, please list names of personnel that have successfully completed the on-line training modules. Please also include contact information and dates of completion:

Objectives for MDSAP Membership

5. Please describe your organization's objective for becoming an Affiliate Member and how you will benefit from participating in the program as an Affiliate Member:

Contribution to MDSAP

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

Implementation of MDSAP Guidelines

7. Describe your policy/strategy regarding the implementation of MDSAP guidelines:
8. Please indicate which MDSAP documents you intend to implement or have implemented and provide relevant documentation to support evidence of implementation:

Membership Commitments

9. Do you commit to fulfill training, information, and meeting obligations?

☐ Yes ☐ No

10. Do you commit to providing an annual report to the RAC on the utilization of MDSAP audit reports and/or MDSAP certificates?
    ☐ Yes ☐ No

11. Do you commit to promote MDSAP and advocate adoption and use to non MDSAP members?
    ☐ Yes ☐ No

_____	Click here to enter a date.
Signature	Date

Official Observer Application

1. Are you a Regulatory Authority?

   ☐ Yes ☐ No

MDSAP Participation History

2. Have you been an Affiliate Member for at least the last three (3) consecutive years?

   ☐ Yes ☐ No

3. Have you participated in MDSAP forums for the last three (3) consecutive years?

   ☐ Yes ☐ No

Current Laws/Regulations

4. Do you have laws and regulations in place for evaluating a medical device manufacturer's QMS based on international standards and 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. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on this topic.

5. Do you have any other laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles? For example: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance.

   ☐ Yes ☐ No

   If yes, please provide the relevant law or regulation, a comprehensive description of its contents and a description of related enforcement activities. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on these topics.

Objectives for MDSAP Membership

6. Please describe your organization's objective for becoming an MDSAP Official Observer and how you will benefit from participating in the program as an Official Observer:

Contribution to MDSAP

7. Describe how your organization has contributed or can contribute resources and expertise to the objectives of MDSAP and how its membership would be a benefit to MDSAP:

Implementation of MDSAP Guidelines

8. Describe your policy/strategy regarding the implementation of MDSAP guidelines:

Confidentiality Agreements

9. Do you have confidentiality agreements with all RAC Members?

   ☐ Yes ☐ No

   Please list all confidentiality agreements your organization has with participating RAC Members which covers the scope of MDSAP activities.

Membership Commitments

10. Do you commit to fulfill training, information, and meeting obligations?

    ☐ Yes ☐ No

11. Do you commit to providing an update on utilization of MDSAP at annual MDSAP Forums?

    ☐ Yes ☐ No

12. Please describe how your organization will be able to commit resources to fulfill obligations set forth in the MDSAP P0003), including, but not limited to provision of resources required for the development, implementation, maintenance and expansion of the MDSAP as Official Observers to the RAC and Subject Matter Expert Work Groups:

Click here to enter a date.

_____ _____

Signature Date

RAC Member Application

1. Are you a Regulatory Authority?

   ☐ Yes ☐ No

MDSAP Participation History

2. Have you been an Official Observer for at least the last two (2) consecutive years?

   ☐ Yes ☐ No

3. Have you participated in all MDSAP meetings designated as "OPEN to RAC Members, Official Observers, and Affiliate Members for the last two (2) consecutive years?

   ☐ Yes ☐ No

Current Laws/Regulations

4. Do you have laws and regulations in place for evaluating a medical device manufacturer's QMS based on international standards and 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. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on this topic.

5. Do you have any other laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles? For example: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance.

   ☐ Yes ☐ No

   If yes, please provide the relevant law or regulation, a comprehensive description of its contents and a description of related enforcement activities. Where applicable, please also reference the use of any international consensus standards, and/or any guidances developed on these topics.

Objectives for MDSAP Membership

6. Please describe your organization's objective for becoming an MDSAP RAC Member and how you will benefit from participating in the program as an MDSAP RAC Member:

Contribution to MDSAP

7. Describe how your organization has contributed or can contribute resources and expertise to the objectives of MDSAP and how its membership would be a benefit to MDSAP:

Implementation of MDSAP Guidelines

8. Do you confirm that no changes to the MDSAP Audit Approach are needed for use of MDSAP within your regulatory framework?

☐ Yes ☐ No

9. Describe your policy/strategy regarding the implementation of MDSAP guidelines:

Confidentiality Agreements

10. Do you have confidentiality agreements with all RAC Members?

    ☐ Yes ☐ No

    Please list all confidentiality agreements your organization has with participating RAC Members which covers the scope of MDSAP activities.

Membership Commitments

11. Do you commit to Chair the RAC and provide the Secretariat for a period of two years (with all MDSAP communications being in English)?

    ☐ Yes ☐ No

12. Do you commit to providing an update on utilization of MDSAP at annual MDSAP Forums?

    ☐ Yes ☐ No

13. Please describe how your organization will be able to commit resources to fulfill obligations set forth in MDSAP P0003, including, but not limited to provision of resources required for the development, implementation, maintenance and expansion of the MDSAP as Members of the RAC and Subject Matter Expert Work Groups:

Click here to enter a date.

_____ _____

Signature Date