

1.0 OBJECTIVE

- 1.1 To lay down a procedure for enrolment of new Medical Device Adverse Event Monitoring Centres (MDMCs) and Regional Training Centres (RTCs) under Materiovigilance Programme of India (MvPI).

2.0 SCOPE

- 2.1 This document shall be applicable for requirements to enroll a new MDMC and RTC under MvPI.

3.0 PROCEDURE

- 3.1 Access the Adverse Drug Reactions Monitoring System (ADRMS) portal using the link - <https://adrmsipc.in/adrms/index.html>

3.2 Create an Account (If Not Already Registered)

- 3.2.1 Click on “Sign Up Here”.
- 3.2.2 Under Account Type, select: “Programme Coordinator”.
- 3.2.3 Fill in the following details:
- Name
 - Create Username and Password
 - Date of Birth (DD/MM/YYYY)
 - Gender
 - Mobile Number
- 3.2.4 Click on “Get OTP”, enter the OTP received on your mobile number.
- 3.2.5 Click on “Create New Account”.

3.3 Sign In

- 3.3.1 Go back to the login page.
- 3.3.2 Enter your newly created Username and Password to login.

3.4 Add Institute Request

3.4.1 Once logged in, click on “Add Institute Request”.

3.4.2 Fill in the following institute details:

- a. Institute Name
- b. Address
- c. Pin Code
- d. Phone Number
- e. Email Address
- f. Select Institute Type
- g. Institute Category
- h. District
- i. State
- j. Country
- k. Click “Save”.

3.4.3 The request will now appear under Request List as Pending.

3.5 Approval Request

3.5.1 Take a screenshot of the pending institute request.

3.5.2 Email it to NCC-MvPI (Email ID- shatrunjay.ipc@gov.in or mvpi-ipc@gov.in).

3.5.3 NCC-MvPI will review the request and inform IPC's IT team for approval.

3.5.4 After approval, NCC-MvPI will send an email stating that the institute has been approved now the applicant can proceed with the MDMC Application.

3.6 MDMC Application

3.6.1 Log in again to the ADRMS portal.

3.6.2 Go to Dashboard → Click “MDMC Application”.

3.6.3 Fill out all five sections of the form.

- 3.6.4 Institutional Information
- Name of Institution
 - Name of Affiliated Hospital
 - Institution Type
 - Institution Category and distance between Hospital and Institution (in km)
 - Number of Beds in the Hospital
 - Patient Statistics (Inpatient/Outpatient)
 - Total Number of Departments
- 3.6.5 Logistic/ Infrastructural Facilities to function as a MDMC under MvPI:
- Name of Department to function as MDMC
 - Availability of Computers & Logistics for MvPI (Yes/No)
 - Workplace allocated for MvPI (Yes/No)
- 3.6.6 Details of Proposed Coordinator:
- Designation Qualification
 - Total Experience (in years)
 - Experience in Materiovigilance
 - Details of Training/CME on MvPI in the last 2 years
- 3.6.7 Details of Proposed Deputy Coordinator:
- Designation Qualification
 - Total Experience (in years)
 - Experience in Materiovigilance
 - Details of Training/CME on MvPI in the last 2 years
- 3.6.8 Contact details
- Principal/Dean/Medical Superintendent/ In charge
 - Coordinator
 - Deputy Coordinator
- 3.6.9 Terms of Reference
- Read the Terms of Reference.

- b. Click on “We have undergone terms of reference”.

3.6.10 Submit the Application

- a. Click “Next - Preview & Submit”.
- b. After submission, take a screenshot of the submitted application.
- c. Email the screenshot to NCC-MvPI for further processing.

3.7 NCC-MvPI will evaluate the application. If found satisfactory, NCC-MvPI will send a confirmation email approving the MDMC application on a probationary basis for a period of three months. The email will include the ‘Healthcare Institution Readiness Assessment Checklist for Engagement as MDMC’ (Annexure I), which shall be completed and submitted by the institute to NCC-MvPI within 15 days of receipt. The checklist will be used to assess the institute's preparedness for functioning as an MDMC. Institutes obtaining a score of ≥ 10 out of 15 in the checklist will be considered eligible for recognition as an MDMC, subject to satisfactory performance during the probationary period. The institute will be monitored during the probationary period on the following basis:

- Submission of Medical Device Adverse Event (MDAE) Reports.
- Conducting training and promotional activities.
- Any other outstanding activities promoting MvPI.

NOTE: The competent authority at NCC-MvPI reserves the right to accept/reject the MDMC application. In exceptional cases, it may waive the requirement of the probationary period and approve the application based on appropriate justification

3.8 NCC-MvPI will monitor institute’s work for next 3 months.

3.9 If the performance of MDMC is found satisfactory for the 3 months of probation, then NCC-MvPI will send an email to formally recognize the Institute as MDMC attaching the Approval Certificate and will also add the Institution’s name and details in the official list of MDMC.

3.10 An Induction-cum-Training Programme will be organized by NCC-MvPI for newly enrolled MDMCs.

3.11 Change of Coordinator or Deputy Coordinator:

If the MDMC wants to change the Coordinator or Deputy coordinator due to any reasons, send an email on ID- shatrunjay.ipc@gov.in or mvpi-ipc@gov.in keeping the head of the institution in cc, mentioning the name, designation, email, phone number of the respective person.

3.12 Technical Support Group Meetings will be held every 3 months to review the progress of MDMCs. If the performance of any MDMC is found unsatisfactory, it may be derecognized by MvPI with appropriate justification and the updated list will also be sent to National Accreditation Board for Hospitals & Healthcare Providers (NABH).

3.13 If the MDMC demonstrates good performance by regularly submitting reports and conducting training activities, IPC may also consider designating the institute as a Regional Training Centre under the MvPI.

4.0 SAFETY AND PRECAUTIONS

- 4.1 Do not use any SOP if it is not signed and issued by competent personnel or the authorized signatories.
- 4.2 Do not use adhesive tape or whitener on SOP.
- 4.3 Do not share the SOP information outside the organization.

5.0 REFERENCES

In-House

6.0 ABBREVIATIONS

ADRMS	:	Adverse Drug Reactions Monitoring System
IPC	:	Indian Pharmacopoeia Commission
MDAE	:	Medical Device Adverse Event
MDMC	:	Medical Device Adverse Event Monitoring Centre
MvPI	:	Materiovigilance Programme of India

NA	:	Not Applicable
NABH	:	National Accreditation Board for Hospitals & Healthcare Providers
NCC	:	National Coordination Centre
NHSRC	:	National Health Systems Resource Centre
RTC	:	Regional Training Centre
SCTIMST	:	Sree Chitra Tirunal Institute for Medical Sciences and Technology
SOP	:	Standard Operating Procedure

7.0 ANNEXURE(s)

- 7.1 Annexure I : Healthcare Institution Readiness Assessment Checklist for Engagement as MDMC

REVISION LOG		
Version	Description of Change	Release Date
00	New document for posting on IPC's website	21-JULY-2025
01	Updated document; refer Enclosure-1 for details of changes	29-JULY-2026



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Materialovigilance Programme of India (NCC-MvPI)

**Enrolment of New Medical Device Adverse Event Monitoring Centres (MDMCs)
and Regional Training Centres (RTCs)**

ENCLOSURE-1

Clause	Existing status	Proposed change
3.7	NCC-MvPI will evaluate the application. If found satisfactory, IPC will issue a confirmation email approving the MDMC application on a probationary basis for a period of three months. The email will also state that, to receive formal recognition as an MDMC, the institute will be monitored further during this probationary period on the following basis: •Submission of Medical Device Adverse Event (MDAE) Reports. •Conducting training and promotional activities. •Any other outstanding activities promoting MvPI.	NCC-MvPI will evaluate the application. If found satisfactory, NCC-MvPI will send a confirmation email approving the MDMC application on a probationary basis for a period of three months. The email will include the 'Healthcare Institution Readiness Assessment Checklist for Engagement as MDMC' (Annexure I), which shall be completed and submitted by the institute to NCC-MvPI within 15 days of receipt. The checklist will be used to assess the institute's preparedness for functioning as an MDMC. Institutes obtaining a score of ≥ 10 out of 15 in the checklist will be considered eligible for recognition as an MDMC, subject to satisfactory performance during the probationary period. The institute will be monitored during the probationary period on the following basis: •Submission of Medical Device Adverse Event (MDAE) Reports. •Conducting training and promotional activities. •Any other outstanding activities promoting MvPI

 सत्यमेव जयते IPC	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Materialovigilance Programme of India (NCC-MvPI) Enrolment of New Medical Device Adverse Event Monitoring Centres (MDMCs) and Regional Training Centres (RTCs)
---	---

	New note added.	NOTE- The competent authority at NCC-MvPI reserves the right to accept/reject the MDMC application. In exceptional cases, it may waive the requirement of the probationary period and approve the application based on appropriate justification.
Annexure I	New Annexure added.	Annexure I - Healthcare Institution Readiness Assessment Checklist for Engagement as MDMC.