

Indian Pharmacopoeia Commission
Materiovigilance Programme of India (MvPI)

ADRMS- Company User Registration

**Registration Form for Marketing Authorization Holders (MAHs) under Materiovigilance
Programme of India (MvPI)**

We hereby submit the details of our company/institution for registration under the Materiovigilance Programme of India (MvPI) and request enrolment in the Adverse Drug Reaction Monitoring System (ADRMS). As a Marketing Authorisation Holder (MAH), we affirm our commitment to ensuring medical device safety and maintaining full compliance with applicable regulatory requirements.

Company Details

Company Name:

Company Category (Autonomous/Government/Private/Semi-Government):

Address:

Pin Code:

District: State:

Country:

Phone No.: Institute Email Address:

Coordinator Details

Coordinator First Name: Last Name:

Gender:

Mobile No.: Email Address:

Terms of Reference (TOR):

- a) The Marketing Authorization Holder (MAH) shall ensure timely and accurate reporting of all observed or received Medical Device Adverse Events (MDAEs) as per the defined regulatory requirements.
- b) The MAH must submit MDAE reports and completeness of the reports with all required details.
- c) The MAH should cooperate with the National Coordination Centre-MvPI (NCC-MvPI), Indian Pharmacopoeia Commission (IPC) for any follow-up queries, additional investigations, or Root Cause Analysis (RCA), if needed.
- d) In case of any change in the designated safety contact person or authorized representative, the MAH shall inform NCC-MvPI promptly through email communication to mvpi-ipc@gov.in
- e) MAHs should actively participate in MvPI training sessions, workshops, or stakeholder meetings to strengthen vigilance practices and improve the quality of MDAE reporting.

Declaration:

We, the undersigned, have read and understood the above Terms of Reference and agree to undertake the responsibilities associated with reporting Medical Device Adverse Events under the Materiovigilance Programme of India (MvPI).

Signature
Proposed Coordinator of MvPI

Signature with Seal
Head of the Company

