

	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Materiovigilance Programme of India
	Annexure- I Healthcare Institution Readiness Assessment Checklist for Engagement as MDMC

Format No: IPC/MvPI/007/01/FMT/01

Instructions for Use: For each checklist item, mark "Yes" if the criterion is fulfilled or "No" if the criterion is not fulfilled. Assign 1 point for each "Yes" response and 0 points for each "No" response. The total score is calculated by summing the scores for all checklist items.

Sr. No.	Checklist Item	Yes	No
1	A Materiovigilance Coordinator/Deputy Coordinator/Nodal Officer has been officially designated by the centre/institution.		
2	Medical Device Adverse Event (MDAE) reporting forms (electronic/printed) and reporting guidance are readily available in relevant departments.		
3	A system (register, logbook, database, or ADRMS) is available for recording and tracking reported MDAEs.		
4	Awareness materials (posters, IEC materials, QR codes, or digital displays) promoting MDAE reporting are displayed at appropriate locations within the centre/ institution.		
5	Healthcare professionals receive orientation or training on identification and reporting of MDAEs at least twice every year, including induction training for newly joined staff. The institution conducts awareness, educational, research, or dissemination activities related to materiovigilance.		
6	MDAEs and reporting updates are periodically reviewed and discussed during institutional or centre-level meetings, such as Pharmacy and Therapeutics Committee (PTC) meetings, departmental meetings, or clinicians' meetings.		
7	Suspected MDAEs are reported through ADRMS or forwarded to the designated MDMC/NCC within the prescribed reporting timeline.		
8	Where applicable, patients and caregivers are informed about reporting medical device-related adverse events.		
9	The centre/institution has obtained approval from the institute/management to conduct the MvPI Internship Programme and facilitates internship training for eligible candidates.		

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	Note- NCC-IPC provides eligible candidates as interns for collecting and reporting MDAE under supervision of concerned authority at the centre.		
10	Healthcare Professionals are encouraged to report MDAEs through appreciation, acknowledgement, feedback or other motivational mechanisms.		
11	Patient case records used in the centre/institution include a dedicated section for documenting suspected MDAEs.		
12	Adequate infrastructure (computer, internet, printer, scanner, and essential office resources) is available for MDAE reporting through ADRMS. Note- IPC provides financial assistance to MDMCs to support the smooth implementation of materiovigilance activities at the centre. (Refer to SOP: IPC/MvPI/010). https://ipc.gov.in/images/mvpi/Conducting-sensitization-programme-or-CME-or-ALT.pdf		
13	The Materiovigilance Expert Committee (MEC) conducts and documents institutional or departmental audits of materiovigilance activities at least once every year. Note- For constitution and working of MEC, refer to NMC order. Draft page of file with number CDN-20011/139/2025-COORDINATION-NMC - eOffice		
14	The institution periodically reviews reported MDAEs and implements appropriate Corrective and Preventive Action (CAPA), wherever required.		
15	Standard Operating Procedures (SOPs) or documented procedures are available for identification, documentation, and reporting of MDAEs. Note- If not available, refer to IPC website (About Us - Indian Pharmacopoeia Commission) or mail to mvpi-ipc@gov.in		

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Total score obtained = _____ / 15

Interpretation of Scores:

Total Score	Interpretation
13–15	Well Established – Ready for engagement as an MDMC
10–12	Established – Ready with minor improvements
7–9	Developing – Requires strengthening before engagement
0–6	Yet to Improve – Not yet ready; reassessment required after corrective actions.

Abbreviations

ADRMS	:	Adverse Drug Reactions Monitoring System
CAPA	:	Corrective and Preventive Action
IEC	:	Information, Education and Communication
MDAE	:	Medical Device Adverse Event
MDMC	:	Medical Device Adverse Event Monitoring Centre
MvPI	:	Materiovigilance Programme of India
NCC	:	National Coordination Centre
SOP	:	Standard Operating Procedure

Name: _____

Designation: _____

Sign with date: _____

Contact Number: _____