



INDIAN PHARMACOPOEIA COMMISSION
Materiovigilance Programme of India (IPC-MvPI)

Impartiality Policy

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The top management's commitment to impartiality shall be demonstrated through:

1. Documenting the IPC-MvPI's policy on safeguarding impartiality and ensuring that it is understood at all levels of the organization. Implementing good practices like establishing "Code of Conduct" and requiring internal and external personnel to abide by it.
2. Having a defined institutional structure and impartiality policy and procedures, appropriate implementation of these policy and procedures and operation and conduct of its activities and personnel.
3. Having a system that ensures appropriate management of conflict of interest for ensuring objectivity of its certification functions.
4. Taking action to respond to any threats to its impartiality arising from the actions of other parts of the organization, persons outside of the organization, subcontractors, related bodies or other bodies or organizations.
5. Maintaining a professional environment and culture in the organization that supports a behavior of all personnel that is consistent with impartiality.
6. Making policy on impartiality available to public through website.
7. IPC-MvPI shall not have any relationship with the client except third party conformity assessment. There shall be a minimum separation of 2 years before application can be entertained, in case the IPC-MvPI has had a relationship with the client which is generic in nature, for example, internal audit, in house training, etc. In cases where the relationship pertained to medical devices specific (design/ processes/product/packaging & labeling/ marketing related) activities, then IPC-MvPI shall carry out impartiality risk analysis before entertaining the application. The purpose of the risk analysis shall be to ascertain if longer separation than two years is required from the last date of end of relationship as stated above or that the risk is of such unacceptable level, so as to prohibit certification by the IPC-MvPI. Based on the risk analysis, appropriate decision shall be taken and the justification for the same shall be recorded.
8. Although, testing is considered as a conformity assessment activity, in case IPC-MvPI (the legal entity) also has a laboratory and if the manufacturing facility it has certified/intends to certify, has a contract/arrangement for getting its raw material and products samples, as per the

frequency described in the relevant standards/ customer requirements, tested in its lab, then this is considered as an unacceptable threat to impartiality. In such cases, IPC-MvPI will not certify such manufacturing facility and vice-versa. This provision shall also be applicable if the laboratory is a separate business unit within same legal entity as the certification body as well as if the lab belongs to a related body (a separate legal entity).

- 9.** The requirement in **(8)** above is not applicable in case the manufacturing facility uses a number of laboratories by rotation or otherwise. If IPC-MvPI and its client are both part of government, then the two bodies shall not directly report to a person or group having operational responsibility for both. IPC-MvPI shall, in view of the impartiality requirement, be able to demonstrate how it deals with a case where both itself and its client are part of government. The certification body will demonstrate that the applicant receives no advantage, and that impartiality is assured.
- 10.** When a relationship poses an unacceptable threat to impartiality then certification will not be provided.
- 11.** IPC does not have any related body that threatens the impartiality of IPC-MvPI certification body. In cases where the relationship pertained to any services which were medical device manufacturing specific (design/processes/product/packaging & labeling/marketing related) activities, etc., then IPC-MvPI shall carry out impartiality risk analysis before entertaining the application. Purpose of risk analysis will be to ascertain if, longer separation than two years is required from the last date of end of relationship as stated above or that the risk is of such unacceptable level so as to prohibit certification by the certification body. Based on the risk analysis appropriate decision will be taken and the justification for the same will be recorded.
- 12.** IPC-MvPI shall not certify a manufacturing facility which has received consultancy for design/processes/product/packaging & labeling/marketing, internal evaluations/audit or training, where the relationship between the consultancy organization/individual and the certification body poses an unacceptable threat to the impartiality of the certification body. Allowing a minimum period of two years to elapse following the end of the relationship product consultancy is one way of reducing the threat to impartiality to an acceptable level however, it will be considered based on the nature of services offered.
- 13.** IPC-MvPI shall not outsource/subcontract any part of the certification work, evaluation, marketing, etc., to a legal entity that is engaged in designing, manufacture, installation, distribution or maintenance of the medical devices. It shall also not be outsourced to organizations who are engaged in management system consultancy, internal auditing and training and similar services to manufacturing facilities.

- 14.** All IPC-MvPI personnel, either internal or external, or committees, who could influence the manufacturing facility certification activities, will act impartially, and shall not allow commercial, financial, or other pressures to compromise impartiality. IPC-MvPI shall require personnel, internal and external, to reveal any situation known to them that may present them or the certification body with a conflict of interests. These aspects will be ensured through a signed agreement between the individuals and IPC-MvPI. IPC-MvPI shall use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not use such personnel, internal or external.
- 15.** IPC-MvPI's personnel involved in certification activities will be bound by the certification body's impartiality policy and act impartially in their work through contractual or employment conditions and assignment conditions for each evaluation/audit activity. The IPC-MvPI shall also take an undertaking with respect to freedom from conflict of interest for every audit/evaluation assignment allotted to the individuals.
- 16.** While carrying out evaluation/audit, IPC-MvPI's personnel involved in certification activities shall not provide any advice, consultancy or recommendation to the client on how to address any deficiencies that may be identified during the evaluation/audit.
- 17.** IPC-MvPI shall require its personnel, internal and external, to report any situation of influence or pressure from the client that may threaten their independence in the course of certification activities. Based on such report, IPC-MvPI shall take appropriate actions to ensure its independence in its certification work.
- 18.** IPC-MvPI shall be responsible for ensuring that neither related bodies, nor sub-contractors, nor internal or external assessors/auditors operate in breach of the undertakings that they have given. It shall also be responsible for implementing appropriate corrective action in the event that such a breach is identified and that action may include suspension or permanent termination of employment/empanelment depending on the severity of the situation.
- 19.** IPC-MvPI shall ensure that a conflict-of-interest analysis is carried out in accordance with the requirements specified in clauses 5.2.2/ 5.2.3 of ISO/IEC 17021-1:2015, at least once annually and whenever a significant change occurs in the IPC-MvPI's activities, such as changes in the organizational structure and business activities or of the legal status and mergers with, or acquisitions of other organizations. This analysis will be approved by the impartiality committee established by IPC-MvPI.
- 20.** IPC-MvPI shall not certify another certification body for its quality management system
- 21.** Further, where risks to impartiality have been identified as a result of risk analysis, IPC-MvPI shall mitigate threats against impartiality. These shall be through any of the following mitigation means:

- Shall not provide certification, since the situation poses unacceptable threat to impartiality.
 - The certification body and any part of the same legal entity and any entity under the organization control of the certification body shall not offer or provide internal audits to its certified clients because the carrying out of internal audits by the certification body and any part of the same legal entity to its clients is a significant threat to impartiality.
 - Where a client has received management system consultancy from a body that has a relationship with a certification body, this is a significant threat to impartiality and mitigation of this threat is that the certification body shall not certify the management system for a minimum of two year following the end of the consultancy.
 - The certification body shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of the certification body.
 - The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy.
- 22.** The certification body shall take action to respond to any threat to its impartiality arising from the actions of other persons, bodies or organization.
- 23.** Carry out the certification in a restricted manner based on disclosures.
- 24.** Minimize the risks on the basis of clearly defined control points to ensure mitigation.