



QUALITY MANUAL

For

Pharmacovigilance Programme of India



Published By

Indian Pharmacopoeia Commission
National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare
Government of India

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RELEASE AUTHORIZATION

This Quality Manual is issued under the authority of

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Secretary-cum-Scientific Director

IPC (NCC-PvPI) Ghaziabad

And is the property of

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I. Abbreviations

ADRs	Adverse Drug Reactions
AEFI	Adverse Event Following Immunization
AIIMS	All India Institute of Medical Sciences
AMC	Adverse Drug Reaction Monitoring Centre
AIDS	Acquired Immune Deficiency Syndrome
BR	Benefit Risk
CDSCO	Central Drugs Standard Control Organization
CPWD	Central Public Works Department
CTP	Core Training Panel
CCTV	Closed-Circuit Television
E2B	Electronic Transmission of Individual Case Safety Reports
GoI	Government of India
GSR	General Statutory Rules
HCPs	Health Care Professionals
HIV	Human Immunodeficiency Virus
HR	Human Resource
ISO	International Organization for Standardization
IPC	Indian Pharmacopoeia Commission
IP	Indian Pharmacopoeia
ICSR	Individual Case Safety Report
IC	International Cooperation
IT	Information Technology
MoHFW	Ministry of Health and Family Welfare
MAHs	Marketing Authorization Holders
MvPI	Materiovigilance programme of India
NFI	National Formulary of India
NHPs	National Health Programmes
NACP	National AIDS Control Programme
NVBDCP	National Vector Borne Disease Control Programme
NCC	National Coordination Centre
Pv	Pharmacovigilance
PvPI	Pharmacovigilance Programme of India
PCP	Promotion, Communication and Publication
QA	Quality Assurance

QMS	Quality Management System
QRP	Quality Review Panel
QM	Quality Manual
QC	Quality Control
RNTCP	Revised National TB Control Programme
RTC	Regional Training Centres
SD	Signal Detection
SUSAR	Suspected Unexpected Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SRP	Signal Review Panel
SOP(s)	Standard Operating Procedure (s)
SMS	Safety Management System
TE	Training and Education
TB	Tuberculosis
UMC	Uppsala Monitoring Centre
WHO	World Health Organization
XML	Extensible Markup Language

II. Terms & Definitions

1. Adverse event

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

2. Adverse (Drug) Reaction (ADR)

A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. (WHO, 1972).

An adverse drug reaction, contrary to an adverse event, is characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment by the reporting or a reviewing health professional.

3. Benefit

An estimated gain for an individual or a population. See also Effectiveness/Risk.

4. Benefit - risk analysis

Examination of the favourable (beneficial) and unfavourable results of undertaking a specific course of action. (While this phrase is still commonly used, the more logical pairings of benefit-harm and effectiveness-risk are slowly replacing it).

5. Causal relationship

A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes B. In pharmacovigilance; a medicine causing an adverse reaction.

6. Causality assessment

The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according established algorithms.

7. CIOMS

The Council for International Organizations of Medical Sciences (CIOMS) is a body set up under World Health Organization and UNESCO. It has developed a series of guidelines on pharmacovigilance, drawn up by a committee of volunteers from Industry, regulatory authorities, WHO and others.

The main guidelines concern the international reporting form (CIOMS I); periodic safety update reports (CIOMS II); core data sheets (CIOMS III); benefit-risk assessments (CIOMS IV); practical issues in pharmacovigilance (CIOMS V); clinical trial safety data (CIOMS VI); and development safety update reports (CIOMS VII).

8. Cohort Event Monitoring

Cohort Event Monitoring (CEM) is a prospective, observational study of events that occur during the use of medicines, for intensified follow-up of selected medicinal products phase. Patients are monitored from the time they begin treatment, and for a defined period of time

9. Data mining

At the UMC, the use of an automated tool, based on Bayesian logic, for the scanning of the WHO database (VigiBase) in the process of detecting drug-adverse reaction associations: the BCPNN. Knowledge-detection is the preferred term for the process.

10. Effectiveness/ risk

The balance between the rate of effectiveness of a medicine versus the risk of harm is a quantitative assessment of the merit of a medicine used in routine clinical practice. Comparative information between therapies is most use ful. This is more useful than the efficacy and hazard predictions from premarketing information that is limited and based on selected subjects.

11. Formulary

A listing of medicinal drugs with their uses, methods of administration, available dose forms, side effects, etc., sometimes including their formulas and methods of preparation.

12. ICH

The International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals.

13. ICD

International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes.

14. Individual Case Safety Report

A report that contains information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient.

15. Pharmacology

Pharmacology is the science of drugs (Greek: Pharmacon-drug; logos-discourse in) . In a broad sense, it deals with interaction of exogenously administered chemical molecules (drugs) with living systems. It encompasses all aspects of knowledge about drugs, but most importantly those that are relevant to effective and safe use for medicinal purposes.

16. Pharmacovigilance

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

17. Regulatory authority

The legal authority in any country with the responsibility of regulating all matters relating to drugs.

18. Relative risk

The Probability of harm being caused; the probability (chance, odds) of an occurrence.

19. Serious adverse event or reaction

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- results in death
- results in life-threatening condition
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- causes congenital abnormality
- requires any intervention to prevent the occurrence of any of the above

To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", the following note of clarification is provided:

The term "severe" is not synonymous with serious. In the English language, "severe" is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) which is based on patient/event outcome or action criteria serves as guide for defining regulatory reporting obligations.

20. Side effect

Any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug.

21. Signal

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. The publication of a signal usually implies the need for some kind of review or action.

22. Spontaneous reporting

System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority.

23. SUSAR (Suspected Unexpected Serious Adverse Drug Reaction)

A serious adverse drug reaction whose nature, severity or frequency is not identified previously in the risk information provided to the clinical investigator's brochure (CIB) or on the drug label.

24. Unexpected adverse reaction

An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

III. Preface

This Quality Manual provides guidance for ensuring Good Pharmacovigilance Practices on monitoring, reporting, collection and recording/analysis of adverse drug reactions that support a Quality Management System. It is based on ISO 9001: 2008 standard for Quality Management System requirements and Good Pharmacovigilance Practices requirement as per the WHO Pharmacovigilance indicators. This Quality Manual shall be required for the NCC/AMCs to adopt best practices of Pharmacovigilance to improve patient safety. It is based on global standards and focuses on core principles of Pharmacovigilance. This Quality Manual shall be reviewed as or when required. This quality manual shall be distributed to all AMCs in the form of booklet, not including header and footer of master copy. The procedure laid down in the manual shall be adopted by the personnel engaged in PvPI activities in order to ensure Good Pharmacovigilance Practices.

IV. Authorization

The Safety/Technical Manager of the PvPI shall have adequate responsibilities and authority for technical operations of PvPI. He will be responsible to ensure that International standard criteria & requirements for the PvPI are met while performing its various technical activities as per the established documented procedures. In performing this responsibility properly he will be assisted by the Incharge of various divisions coming under the purview of NCC-PvPI.

The Quality Manager of the NCC-PvPI shall have adequate responsibilities and authority for planning, maintaining and documenting the quality system at par with the international standards. He shall ensure that the installed quality system is dynamic, continuous, suitable and effective in implementation. He shall contact with the competent authority for any matter to maintain the quality management system within the objectives of its activities.

The Quality Manager has also been authorized to coordinate all quality related activities within the PvPI and interact with individuals regarding all quality system related matters. Both Quality and Technical Manager will be responsible for each other functions in case one is absent.

The Safety/Technical Manager and Quality Manager of NCC-PvPI and their responsibilities are given at **Annexure-A**.

The changes in quality manual shall be approved and authorized by Secretary-cum Scientific Director.

V. Approval and Issue

The NCC-PvPI, has established a QMS to comply with International standard requirements. This Quality Manual addresses the NCC-PvPI commitment to quality of all its functional disciplines. This manual is the property of IPC, NCC-PvPI and it shall not be used directly or indirectly in any form that deemed to be detrimental to the interests of the PvPI.

This manual issued to all divisions of PvPI after the approval from competent authority. All authorized holders of this manual are responsible for its safe custody and the implementation of the quality management system in their respective division as described in this manual. The revised manual shall be circulated to the concerned division by the quality manager.

VI. List of Annexures

S. No.	Items	Annexure
1.	Role and Responsibilities of Quality Manager and Technical Manager	A
2.	NCC-PvPI Organogram	B
3.	Diagrammatic representation of the communication under PvPI	C
4.	List of PvPI SOPs	D
5.	Feedback form for stakeholders	E

1. Introduction to the PvPI Quality Manual

This manual conforms to the requirements of NCC-PvPI Quality Management Systems as per the current applicable International standards and guidelines on Good Pharmacovigilance Practices.

All personnel are committed to maintain the quality standard of Quality Manual. All staff share responsibility for identifying nonconformities or opportunities for improvement, recording these instances so that corrective or preventive actions can be taken.

In addition to the compliance of international standards, the manual also describes its commitment with all statutory and regulatory requirements applicable from time to time.

The manual shall be used by the PvPI for the purpose of developing the Quality Management System.

1.1 Overview of the Organization

The IPC is an autonomous institution under the aegis of Ministry of Health and Family Welfare, Government of India. The IPC is located at Sector-23, Raj Nagar, Ghaziabad, Uttar Pradesh, India. The mandate of the commission is to bring out IP, the compendium of the standard set out for drugs periodically. Besides publishing IP periodically, the IPC is vested with the duty of publishing the National Formulary of India (NFI) periodically to promote rational use of medicines and providing IP reference substances.

National Coordination Centre -Pharmacovigilance programme of India

The Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India initiated a nation-wide pharmacovigilance programme in July 2010, with All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre for monitoring Adverse Drug Reactions (ADRs) in the country to safe-guard Public Health. To ensure implementation of this programme in a more effective way, the NCC was then shifted from AIIMS, New Delhi to IPC Ghaziabad in April, 2011.

The main responsibility of NCC is to collect and monitor adverse drug reactions in Indian population. It aims to develop and maintain its own pharmacovigilance database for patient safety with respect to use of medicine in India so that recommendation(s) related to banning and suspension of drugs can be made to CDSCO based on reported Adverse Drug Reactions. NCC is operating under the supervision of Steering Committee and Working Group which recommends procedures and guidelines for regulatory interventions. With a view to establish a Centre of Excellence for Pharmacovigilance in India, NCC is collaborating with the WHO-Uppsala

Monitoring Centre which is based in Sweden and participating in International Drug Monitoring Programme.

The NCC has adopted a quality management system for the purpose of the effective implementation of PvPI.

Committees and panels under NCC-PvPI

The following committees and panels are constituted by the MoHFW, Government of India (GoI) to ensure efficient and smooth functioning of the programme.

❖ Steering Committee

PvPI is administered and monitored by the Steering Committee to supervise and guide the programme. The Committee was constituted by MoHFW, GoI in which DCG (I) shall act as a chairman.

❖ Working Group

It is constituted to review and approve major technical issues related to establishment and implementation of the programme and provide technical inputs to CDSCO for appropriate regulatory interventions.

❖ Quality Review Panel (QRP)

It is constituted to review quality and completeness of ICSRs. The panel also makes recommendations to NCC-PvPI on quality related issues of ICSRs, QMS and devises plans for follow up actions.

❖ Core Training Panel (CTP)

The CTP identifies trainers and zone wise Regional Training Centres (RTCs) for imparting training to the stakeholders. The CTP interacts with international agencies for participation and implementation of training programs related to Pharmacovigilance. The CTP also guides in preparing training modules.

❖ Signal Review Panel (SRP)

The Panel is constituted of experienced scientists, clinical and pharmacovigilance experts affiliated to government and non-government academic institutions, hospitals and pharmaceutical industries to collate and analyze information from ICSRs submitted to NCC. This panel assesses the results of the regular computerized screening of ICSRs in

NCC database for the occurrence of signals of possible importance to public health and drug regulation. It also suggests biostatistical methods to be followed in order to obtain the statistical significance of ICSRs.

Supporting documents:

- SOP for functioning of Quality Review Panel (SOP No. IPC/PvPI/QA/018)
- SOP for functioning of Core Training Panel (SOP No. IPC/PvPI/TE/003)
- SOP for Functioning of RTCs under PvPI (SOP No. IPC/PvPI/TE/002)
- SOP for operational functioning of SRP (SOP No. IPC/PvPI/SD/001)
- SOP for Functioning of SRP (SOP No. IPC/PvPI/SD/002)

1.2 Mission

To safeguard the health of the Indian Population by ensuring that the benefits of use of medicine outweigh the risk associated with its use.

1.3 Vision

To improve patient safety and welfare of Indian Population by monitoring the drug safety and thereby reducing the risk associated with use of medicines.

1.4 Objectives

- To create a nation- wide system for patient safety reporting.
- To identify and analysis the new signal from the reported cases.
- To analysis the benefit –risk ratio of marketed medications.
- To generate the evidence based information on safety of medicines.
- To support regulatory agencies in the decision making process on use of medications.
- To communicate the safety information on use of medicines to various stakeholders to minimize the risk.
- To emerge as a National Centre of Excellence for Pharmacovigilance activities.
- To collaborate with other national centres for the exchange of information and data management.
- To provide training and consultancy support to other national Pharmacovigilance centres located across globe.
- To promote rational use of medicine.

1.5 Scope

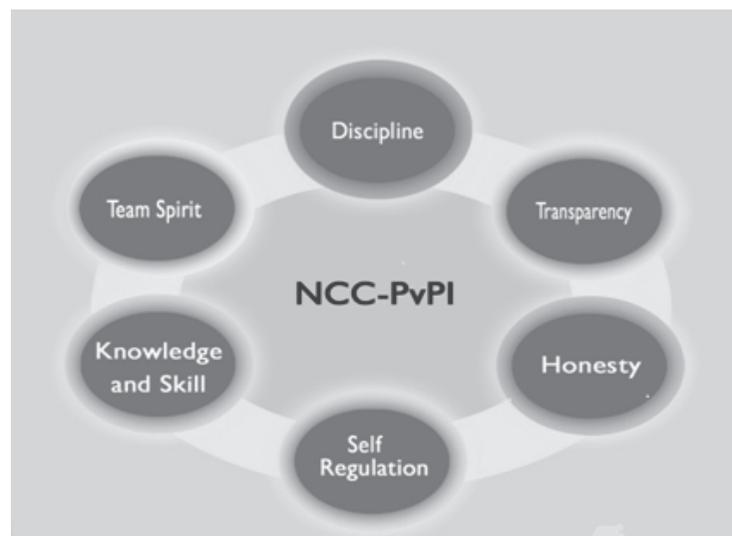
This document describe the quality parameter for ensuring good pharmacovigilance system as per the requirements of NCC-PvPI.

The document is intended for the use of the following stakeholders under PvPI:

- Staff and consultants in PvPI.
- Public Health Programs integrated with PvPI.
- Research Institutions engaged with PvPI.
- Staff and consultants in Indian drug regulatory authorities.
- Policy makers at all levels of healthcare, particularly those concerned with drug policy.

1.6 Core Principles

The staff working for PvPI should share the principles and values of the NCC, IPC in order to ensure a common understanding of ethics and integrity among all PvPI personnel. The NCC encourages the following guiding principles to be followed-



2 Quality Policy

We are committed to ensure patients safety through a transparent approach and high quality of services, focused on scientific innovation and rationality. We aim to be the centre of excellence in Pharmacovigilance by achieving global standards that fulfil the expectation of every stakeholder.

3 Organization

The Pharmacovigilance activities at NCC-PvPI shall performed by the qualified, trained and competent personnel under the leadership of Secretary-cum-Scientific Director.

3.1 Organogram

The organogram of NCC-PvPI is enclosed at **Annexure B**.

3.2 Organization policy

The policy of organization is based on the objectives and core principles of the Pharmacovigilance Programme of India in order to ensure the patient safety through a transparent and scientific approach.

3.3 Communication

Effective communication system has been established by NCC for improving the quality of work in PvPI and achieving the expected outcome. All stakeholders of PvPI are encouraged to provide constructive suggestions to the authority of NCC for further improvement. NCC-PvPI conducts periodic meetings to assess and review the progress of the programme. Most of the communications, in general take place via electronic mail, short message services, teleconference, website etc. Diagrammatic representation of the communication under PvPI is given in **Annexure C**.

Supporting documents:

- SOP for communication between PvPI and Stakeholders (SOP No. IPC/PvPI/CP/002)
- SOP for preparation and submission of progress reports (SOP No. IPC/PvPI/QA/010)

3.4 Personnel responsibilities

The job responsibilities of the personnel engaged in PvPI are defined in SOP No. IPC/PvPI/HR/002.

4 Infrastructure facilities and premises safety

4.1 Policy

The NCC-PvPI is equipped with sufficient space and excellent infrastructure to perform its work, to ensure quality, safety and efficacy of the services provided and to meet national safety regulations.

The NCC-PvPI design provides an efficient and safe environment for the NCC-PvPI staff.

4.2 Facilities

The facility has a three storied building, carpet floor areas & land measuring 26050 Square meter surrounded by a boundary wall. The building is maintained by Central Public Works Department (CPWD). The building has a number of well separated, ventilated rooms with proper furnishing, illumination, electricity, water & safety facilities. The ground floor covers Secretary-cum-Scientific Director chamber, Secretariat Office, National Coordination Centre, Analytical

Research & Development and Monographs Development Division. The Reference Standard Division, Quality Assurance and Central Instrumentation and chemical laboratory are situated on the first floor of the building.

The NCC-PvPI has sufficient space designated for specific use such as chamber of Officer-in-charge, Technical secretariat, Helpline, Vaccine pharmacovigilance, Integration with NHP, MAH Affair, SUSARs/SAE, Signal detection, Medicines benefit risk assessment, ICSRs processing, Quality assurance, Training and Education, Promotion Communication/Publication, Information technology, International co-operation, Mobile App-ADRs reporting, MvPI, storage facilities, washrooms, library and conference room and other supporting divisions etc. The library is well equipped with latest scientific journals and books of Pharmacovigilance. The library is modernized by adopting IT tools to access the e-journals/books.

In order to ensure the transparency and accountability of the system, CCTV Cameras and biometric attendance devices have been installed in the premises.

The campus is eco-friendly by maintaining the cleanliness, greenery, solar panels and rain water harvesting system.

4.3 Security

The security guards deployed at the main entrance and reception point of NCC-PvPI are responsible to restrict the entry of unauthorized person and perform watch and ward duties round the clock. They are also responsible for issuing the visitor pass/gate pass after consulting with the responsible person in the department.

4.4 Working Environment

Working areas are kept clean, dust free and are well maintained. A complete and thorough description of safety rules is available and all personnel are trained in safety management.

5 NCC-PvPI Structure

The various divisions of NCC provide technical, operational and administrative support to the PvPI activities to comply with the requirement of good Pharmacovigilance practices, as follows:

5.1 Operational Division

5.1.1 Safety/Technical Management System (SMS)

5.1.2 Quality Management System (QMS)

5.1.1 Safety/Technical Management System

The divisions working under the safety management system are as follows:

5.1.1.1 ICSRs Processing

The NCC-PvPI seeks ADR related information from the PvPI personnel at Adverse Drug reaction Monitoring Centres (AMCs)/ Health Care Professionals (HCPs) as per the requirement of current version of Suspected ADR reporting form. NCC also encourages the consumer to report adverse event by using the Medicine side-effect reporting form of their respective language and in such cases the authenticity of the reporter and medical relevance of information shall be confirmed by the PvPI Personnel.

The received ICSRs at NCC are subject to the quality and clinical review. During these review process multiple parameters such as report title, seriousness, primary source, patient information, gender, free text, reaction(s)/event, outcome, drug name, drug information, action taken, indication, time onset, causality assessment, case narrative and response to NCC are kept into consideration to generate meaningful data. In order to achieve the quality of ICSRs the following quality indicators are adopted.

- Verification of ICSRs with suspected ADR reporting form
- Quality review of ICSRs
 - Documentation grading and completeness of ICSRs
 - Clinical/Medical relevance of ICSRs
 - a. Listed and unlisted drug-ADR combinations
 - b. Drug-drug interaction
 - c. Causal relationship between the drug and event
 - d. Disease progression
 - e. Medical history

These indicators are regularly monitored for their concordance with the defined objectives and the activities established in the NCC-PvPI.

The following actions are taken based on above quality indicators:

- a) ICSRs provided with complete information - accepted as quality ICSRs
- b) ICSRs provided with incomplete information -accepted after upgradation
- c) ICSRs provided with least information-reverted back to reporter
- d) ICSRs provided with no information/duplicate ICSRs- Nullified

Supporting documents:

- SOP to fill suspected adverse reaction reporting form (SOP No. IPC/PvPI/QA/011)
- SOP to perform Causality Assessment (SOP No. IPC/PvPI/QA/012)
- SOP to enter data from suspected ADR reporting form to VigiFlow (SOP No. IPC/PvPI/QA/013)

- SOP for reporting and Processing Individual Case Safety Reports (SOP No. IPC/PvPI/QA/014)
- SOP for documentation grading and report completeness of ICSRs (SOP No. IPC/PvPI/QA/015)
- SOP for processing of Adverse reactions/Events reported to NCC-PvPI (SOP No. IPC/PvPI/MIS/002)

5.1.1.2 Marketing Authorization Holders (MAHs) Affairs

As per the amendments in Drugs and Cosmetic rules 1945 in schedule Y published in the para II sec 3 sub section (i) of the gazette of India notification GSR 287(E) dated 8th March 2016, Pharmacovigilance is one of the mandatory requirements for market authorization holders.

Therefore all the MAHs shall have to ensure that a Pharmacovigilance system is in place for ADR collecting, processing and forwarding the reports to the licensing authority. The system shall be managed by qualified and trained personnel and the Officer- in-charge of collecting and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of ADR reports.

The NCC-PvPI in coordination with the licensing authority i.e. CDSCO is engaged to ensure the Good Pharmacovigilance Practices of MAHs.

In order to facilitate the seamless management of ICSRs from MAHs, the NCC-PvPI adopts E2B XML format. To enhance the MAHs participation in PvPI, the NCC regularly conducts interactive sessions, acknowledgement to the submitted ICSRs and feedback to improve the quality of reports.

Supporting documents:

- SOP for Processing of ICSRs reported by pharmaceutical industries (SOP No. IPC/PvPI/IIP/001)

5.1.1.3 National Health Programmes (NHPs)

NCC-PvPI integrates with the National Health Programmes such as Revised National Tuberculosis Control Programme (RNTCP), National AIDS Control Programme (NACP), and National Vector Borne Disease Control Programme (NVBDCP) to monitor the safety of drugs used in their respective programs.

PvPI is associated with Universal Immunization Programme (UIP) of Ministry of Health and Family Welfare and Immunization Technical Support Unit (ITSU) to monitor the Adverse Events Following Immunization. The NCC-PvPI attempts to bridge the gap among AMCs, TB

and HIV treatment centres and State/District Immunization Officers. The NCC-PvPI conducts training and orientation programmes for the AMCs and National Health Programmes personnel in understanding the concept of Pharmacovigilance and ADR reporting methods.

Supporting documents:

- SOP for Processing and Communication of AEFI-ICSRs (SOP No. IPC/PvPI/NHP/001)
- SOP for Coordination between PvPI and NHPs (SOP No. IPC/PvPI/NHP/002)

5.1.1.4 SUSARs/SAE and Signal Detection (SD)

The ADR monitoring in Pharmacovigilance is a continuous process till the life period of a drug to update the drug safety information. The NCC plays an important role in identifying new safety signals from the reported ADRs and recommends to National Regulatory Authority i.e. CDSCO for appropriate regulatory interventions. The Indian population specific drug safety signals are identified from the reported ICSRs at NCC by applying case by case review process, biostatistical analysis and clinical/medical review.

Supporting documents:

- SOP for Operational Functioning of Signal Review Panel (SOP No. IPC/PvPI/SD/001)
- SOP for Functioning of Signal Review Panel (SOP No. IPC/PvPI/SD/002)
- SOP for Suspected Unexpected Serious Adverse Reactions Identification (SOP No. IPC/PvPI/SD/003)

5.1.1.5 Benefit-Risk Assessment

Benefit risk assessment involves procedures to make sure that products are developed, tested, manufactured, labelled, prescribed, dispensed, and used in a way that maximizes benefit and minimizes risk. Considering the importance of benefit risk assessment, PvPI has initiated the process of evaluation for benefit risk assessment.

Supporting documents:

- SOP for Benefit Risk Assessment (SOP No. IPC/PvPI/BR/001)

5.1.1.6 International Cooperation (IC)

The robust PvPI has been established under the aegis of NCC with the technical support, cooperation and coordination with the international partners like WHO, UMC etc.

The NCC-PvPI works/partners with other similarly placed international organizations of regulatory, research etc. to sustain the high quality standards of Pharmacovigilance. The NCC-PvPI also mutually exchanges the information with other countries through their visits vice-versa, organizing training/ meetings/conferences/workshops etc.

5.1.1.7 Information Technology (IT)

The PvPI adopts IT system for the collection, processing, recording, storage, and retrieval of ADR data, and has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process. The NCC uses IT/e-services such as website, e-mail, toolkit, mobile application, Helpline, Short Message Services etc. for disseminating the information to the stakeholders.

IT division is equipped with a backup and antivirus system on each computer and has procedures in place to meet national and international requirements for data protection and to restrict unauthorized access.

Supporting documents:

- Data integrity and backup (IPC/PvPI/IT/001)

5.1.2 Quality Management System (QMS)

The divisions working under the QMS are as follows:

5.1.2.1 Quality Assurance (QA)/ Quality Control (QC)

Quality of drugs safety data plays an important role as Pharmacovigilance is one of the component for ensuring patient safety. The drugs safety data collected through various stakeholders of PvPI requires mandatory information for analysis and decision making. Therefore quality data management and documentation plays a vital role in Pharmacovigilance.

The PvPI is committed to ensure the quality assurance system in compliance with applicable standard operating procedures.

Supporting documents:

- SOP for making SOP (IPC/PvPI/QA/001)

5.1.2.2 Training & Education (TE)

The training and education of the personnel is necessary to develop the skills and abilities to deliver better outcomes in pharmacovigilance. It is a planned process to improve the attitude, knowledge and skills of PvPI personnel and to improve the overall performance of the organization.

The training needs of personnel are identified by the Quality/Technical Manager /Officer- in charge PvPI, on the basis of the following:-

- (a) New job assignment
- (b) Change in the quality system/technical procedures
- (c) Transfer of an individual from outside/other division
- (d) Change in roles and responsibilities
- (e) Personnel performance rating on the present job
- (f) Recommendation given in performance appraisal
- (g) Evaluation of previously held training pertaining to technical and managerial skills
- (h) Training matrix of all the staff
- (i) Recommendation of any professional training (If applicable)

The NCC-PvPI conducts internal and external training to understand the operational and technical process and implementation of PvPI. Besides this, NCC provides an opportunity for the staff to participate in workshops, seminars, conferences etc to improve their knowledge and skills. The tentative training schedule is made available well in advance.

The regional training centres have been established under PvPI to impart training and education to the personnel engaged in AMCs of their respective zone. The PvPI training programs both at the level of NCC as well as RTCs are designed in such a way to enhance the technical competency of the personnel/trainee. The quality of training is ensured by evaluating pre and post assessment report and feedback of the participants. In order to ensure the harmonized pattern of training a standardized training module is in place.

The Training and Education division maintains the records of training for the personnel engaged in PvPI as follows:

- (a) Relevant academic and professional qualifications
- (b) Experience of technical staff
- (c) Personnel authorization

- (d) Participation in the Pharmacovigilance training and specialized training courses
- (e) Participation in Conferences, seminars, workshops etc.
- (f) Any other technical contribution

Supporting documents:

- SOP to conduct training under NCC-PvPI (SOP No. IPC/PvPI/TE/001)
- SOP for functioning of Regional Training Centre under PvPI (SOP No. IPC/PvPI/TE/002)

5.1.2.3 Promotion, Communication & Publication (PCP)

The NCC-PvPI has established a robust communication system for the stakeholders since it is vital to create awareness about ADR reporting, convey the risk due to medicines and build public confidence.

The NCC-PvPI is well connected with the stakeholders by following modes of communication:

- Newsletters
- Educational materials
- Website
- Dedicated e-mails, Short Message Services, Helpline number, IT tools etc.
- Conferences, teleconferences etc.

Supporting documents:

- SOP for drafting, publication, distribution and control of resource materials of PvPI (SOP No. IPC/PvPI/CP/001)
- SOP for communication between PvPI and Stakeholders (SOP No. IPC/PvPI/CP/002)

5.2 Supporting Division

The Supporting divisions working under NCC-PvPI are as follows:

5.2.1 Human Resources (HR)

Human resource ensures the engagement of qualified personnel for pharmacovigilance to achieve the goal of knowledge, attitude and practice and sense of team spirit, team work and inter-team collaboration.

In PvPI, the officers and staff are well qualified to perform their assigned duties. The required personnel are selected as per recruitment rules of the organization. They are fully competent in the field of their specialization.

The PvPI being a part of IPC has a clear cut policy regarding recruitment of personnel whose required qualification and experience for related field are clearly documented and are as per the requirement of Ministry of Health & Family Welfare, Government of India.

It is ensured that the supporting personnel engaged for PvPI are performing the duties as per their job description. A clear assessment system of training needs has been established for updating the skills of the staff.

All the staff of the PvPI carryout the assigned duties as directed by the senior authority. The PvPI maintains current job descriptions of all management, technical and support personnel involved in the PvPI work. The Job descriptions are dated and signed to demonstrate that the relevant person has read it and is in compliance to the agreement. They are being maintained in terms of current versions. An agreement is signed by all the personnel engaged in PvPI to maintain the confidentiality of the information. There is a procedure to document the performance of every individual staff working in PvPI on annual basis.

Supporting documents:

- SOP for the recruitment of contractual employee under NCC-PvPI (SOP No. IPC/PvPI/HR/001)
- SOP for the Job responsibility of employee under NCC-PvPI (SOP No. IPC/PvPI/HR/002)

5.2.2 Finance and Account

Finance and account division of IPC functions as per the by-laws of IPC.

5.2.3 Purchase & Procurement

The NCC-PvPI follows the policy and procedures as per the Govt. of India rules for purchase of the goods and services. The PvPI maintains effective control over the purchased items and services to ensure the quality of the work. Stores in consultation with Officer-in-charge and Technical/Quality Manager determines the quantity of the consumables to be purchased to run the PvPI efficiently. Repair and maintenance of building, furniture /fitting electricity, water sanitation and utility services and transportation is managed by the respective division.

6 Audits

6.1 Internal Audit

It is the policy of NCC-PvPI to conduct an internal audit for all activities to verify the continued compliance of system and operations as per international standards. The internal audit monitors all the functioning of NCC-PvPI at least once in a year; however additional audit may be conducted if required. The Quality Manager is responsible for planning and conducting of audits.

Audits are planned and conducted in such a manner that:

- a. PvPI management system elements and technical activities are verified for compliance.
- b. Trained and qualified personnel are engaged for the internal audit
- c. Auditors are independent to perform their activities.
- d. Quality Manager/Officer-in-charge PvPI ensures the schedule and procedure for audits.
- e. Audit is performed as per SOP No. IPC/PvPI/QA/007.
- f. Audit findings (observations and non conformances) are recorded in a designed and approved format.
- g. Performing the root cause analysis and taking the corrective actions within the stipulated period of time.
- h. Performing follow up audit activities to verify and record the effectiveness of corrective action implementation.

Audit records comprises of audit program (plan and schedule), audit notification, filled up check list, audit findings, root cause analysis, proposed corrective actions, details of corrective action taken, corrective action verification, implementation and preventive actions, if any are maintained by Quality Manager.

6.2 External Audits

It is the policy of NCC-PvPI to conduct an external audit for all activities to verify the continued compliance of system and operations as per international standards. The external audit monitors all the functioning of NCC-PvPI at least once in a year. The Quality Manager is responsible for planning and conducting of audits.

Supporting documents:

- SOP for Internal Audit (SOP No. IPC/PvPI/QA/007)
- SOP for ensuring the functioning of AMCs (SOP No. IPC/PvPI/QA/017)

7 Focus on Patient Safety

7.1 Policy

The NCC-PvPI is dedicated to promote patient safety by providing evidence based drug safety information to the regulatory authority, i.e. CDSCO and also committed to education and advocacy on Pharmacovigilance to the stakeholders.

7.2 Stakeholders satisfaction measurement

The NCC-PvPI is continuously seeking feedback from its stakeholders. The feedback thus received is reviewed and analyzed on continuous basis and is discussed in management review meetings. Feedback obtained from stakeholders is used to improve the quality system, technical activities and related services.

A nationwide helpline Toll free (1800-180-3024) facility is available for the stakeholders/ to provide assistance in ADR reporting.

The feedback form for stakeholders is given at **Annexure D**.

Supporting documents:

- SOP for receiving ADR from Healthcare Professionals and Consumers through PvPI Helpline (SOP No. IPC/PvPI/MIS/001)
- SOP for processing of ADR reported to NCC-PvPI (SOP No. IPC/PvPI/MIS/002)

8 Nonconforming Event Management

8.1 Policy

It is the policy of NCC-PvPI to ensure that all the work is carried out as per the procedures laid down in the National / International guidelines and in house quality system procedure like SOP. However, if any Nonconforming activity is evolved, the PvPI ensures that same is identified, documented, evaluated and discharged after taking proper corrective and preventive action of nonconforming events in all aspects of the quality management system.

Quality Manager is responsible for taking corrective & preventive action of any nonconforming work. In case evaluation indicates that nonconforming work can recur or the compliance of PvPI operations with its own policy and procedures are doubtful the corrective action in terms of conducting additional audit is promptly taken up.

Supporting documents:

- SOP for Handling of deviation (SOP No. IPC/PvPI/QA/004)
- SOP for Handling of Non-conforming work (SOP No. IPC/PvPI/QA/005)

8.2 Corrective Actions

It is our policy to plan, implement and monitor the corrective action without delay in case of any nonconforming work or deviation from policies and procedures laid down in the quality system and technical operations have been identified.

All nonconforming events related to ICSRs, audit reports, stakeholders complaints/feedback etc. are recorded, tracked, trends identified, and root cause analysis is performed. The appropriate corrective actions are taken and communicated to management.

The corrective action implementation comprises of the following steps:

8.2.1 Identification of Nonconforming activity

The nonconforming activities with the PvPI system can be identified through the control of nonconforming work, internal and external audit, management review, feedback from stakeholders and observation of supervisory staff.

8.2.2 Root cause analysis

The root cause for nonconforming work is investigated at various levels to take appropriate corrective actions and prevent further non-compliances in the system. The nature & extent of nonconforming work have also to be ascertained by collecting information from all sources such as stakeholder's requirement, type and nature of report, method and procedures, staff skills, training, consumables etc.

8.2.3 Implementation of corrective actions

The NCC-PvPI implements the corrective action plan to eliminate the problem and also to prevent its recurrence. The Quality Manager is responsible to initiate any amendment required in quality manual due to the nonconforming work observed.

8.2.4 Monitoring of corrective action

The effectiveness of the corrective action is monitored by reviewing its documented results. In case the results are not satisfactory, then the cycle of identifying a suitable corrective action, its implementation & effectiveness is carried out till a satisfactory result is achieved.

8.2.5 Additional audits

In case of recurrence of nonconforming work in some specific area an additional audit shall be ordered to investigate the reasons for such nonconforming work and recommend remedial measures so that such type of non-conformance may not occur in future. All the records are made in an appropriate manner.

Supporting documents:

- SOP for Corrective and Preventive action (SOP No. IPC/PvPI/QA/006)

9 Preventive action

The NCC-PvPI reviews the data and implements preventive actions allowing to anticipate eventual nonconforming events in its activities. A follow up of the actions implemented for improvement is ensured in the same way as described in S. no. 8 Nonconforming Event Management.

Preventive actions are taken to prevent the occurrence of any non-compliance or to reduce the frequency of non-compliance. It is a continuous process for further improving the Quality Management System. The identified preventive action is taken after mutual consultations by Quality Manager, Technical Manager & senior supervisory staff. The identified preventive action shall also be discussed in management review meeting.

The procedure followed for the preventive actions is exactly the same as in case of corrective actions and it also could be with respect to the Quality System, procedure and tools. All records of the preventive actions taken shall be maintained.

Supporting documents:

- SOP for Corrective and Preventive Action (SOP No. IPC/PvPI/QA/006)

10 Continual Improvement

10.1 Policy

It is the policy of NCC-PvPI to ensure the improvement related to the effectiveness of the management system by continuously applying the quality indicators. A management review meeting is performed annually to evaluate the PvPI quality management system, evaluation activities, corrective and preventive actions.

The NCC-PvPI develops an action plan of targets to be achieved every year and monitors the effectiveness of the actions undertaken.

The quality policy is reviewed for its continuous appropriateness / suitability and effectiveness during management review meetings. The achievement of established objectives is a specific concern of all the technical staff. Both are monitored and reviewed on regular basis. Information related to stakeholders complaints and feedback are analyzed and action taken are presented in management review meetings. Results obtained through internal quality control checks are brought to the management review and subsequent corrective and preventive actions are followed up. The records shall be maintained in an appropriate manner.

10.2 Management Review

The Officer-in-charge of PvPI shall be responsible to conduct the annual management review meeting. The meeting is chaired by Secretary-cum-Scientific Director and is attended by Quality Manager, Technical Manager, all Division Incharge and representative from technical / supporting division. This meeting reviews the progress and stock taking of NCC-PvPI. Also this meeting aims to address the current challenges and suggest for continuous improvement of the quality system.

In general, the review meeting takes account of the following:

- a. Suitability of policies and procedures
- b. Reports from Managerial and supervisory personnel
- c. Matters arising from the previous reviews
- d. Outcome of recently conducted internal audit
- e. Corrective and preventive actions
- f. Assessment by external bodies if any
- g. Stakeholder feedback and complaints
- h. Quality review
- i. Signal review
- j. Personnel training
- k. Amendment / review of documents
- l. Action Plan
- m. Financial and Administrative matters
- n. Recommendation for improvement
- o. Any other relevant matter with the permission of Secretary-cum-Scientific Director

The deliberation/suggestion emerged during the management review meeting are recorded in the form of minutes of meeting. The approved minutes shall be communicated to all concerned for the necessary action.

Quality Manager monitors the follow up action pertaining to individual responsibility and time frame, in the form of action taken report. The actions completed towards the task assigned are referred to the next review meeting for further evaluation.

Supporting documents:

- SOP for Management Review (SOP No. IPC/PvPI/QA/008)

11 Documents and Records

11.1 Policy

The NCC-PvPI ensures that documents and records are maintained as per applicable SOP.

11.2 Documentation Management

The following four levels of documents are applied to all divisions of PvPI:-

Level 1: Quality Manual

This addresses the PvPI policy and procedures pertaining to the relevant managerial and technical requirements in terms of documented quality management system.

Level 2: Standard Operating Procedures

This describes the operating procedure of a particular activity of the system. The list of all Standard Operating Procedures is given at **Annexure D**.

Level 3: Formats based on Standard Operating Procedures

The activity needs to be recorded in the specified format while following concern SOP.

Level 4: Other document/records:

It includes lists; forms, record files, record registers, log books, worksheet, charts, drawings, plans, check list etc. shall be indexed as per their usage.

11.3 Documents and Records Control

11.3.1 Document Control

The NCC-PvPI has developed well defined procedures to maintain & control all documents generated internally or externally which forms the part of management system. These documents comprise of general regulations, standard operating procedure & specifications, instructions, manuals, as well as drawings, software and other documents.

The master list of all the documents maintained and updated accordingly and each document has unique identification number. The master list provides information regarding revision status and the distribution of the documents.

A secure master file is maintained for all documents to prevent unauthorized access, loss or damage. A document control log is maintained to identify the current valid versions and their distribution. Reports maintained in the PvPI are legible, easily retrievable and stored in the suitable environment to prevent damage/loss of valuable information. All original reports are kept secured.

Quality Manager is responsible to retain the master copies of all the documents, whereas the controlled copies of documents are distributed to the concerned divisions based on their request. The Specimen signature of each employee of PvPI is maintained by NCC in order to ensure the authenticity.

All documents generated by the NCC contain the following information.

- a) Title of the document
- b) Document number
- c) Effective and review dates
- d) Revision number
- e) Page number including total number of pages in the documents; and
- f) Prepared, reviewed and approved by

Supporting Document-

- SOP for making SOP (SOP No. IPC/PvPI/QA/001)
- SOP for Specimen signature (SOP No. IPC/PvPI/QA/002)

11.3.2 Records control

The PvPI has established well documented procedure for identification, collection, indexing, access, filing, storage, maintenance and disposal as follows:

- a) The quality records include internal audit reports, management review records, training records, quality assurance records, corrective and preventive actions records etc.
- b) The technical record includes source documents, derived data and ICSR records, etc.
- c) The other record includes the identity of personnel responsible for the performance of the specific work, staff records etc.

It is ensured that the records are legible, stored and retained in such a way that these are

readily retrievable and also maintained in such an environment to prevent damage or deterioration of records. The retention period varies depending upon the types of records. However, the retention period for the records will not be less than three years from the date of their establishment. It is ensured that all records are held secured and in confidence with authorized holders.

The PvPI is also maintaining backup of e-records/data at NCC and secured by password protection to avoid unauthorized access.

In case an error occurs in any document, each is crossed (and not erased), made legible and the correction entered alongside with initial of the concern personnel.

11.3.3 Document approval and issue

All documents which are part of the PvPI are prepared, reviewed by concerned officers and approved by competent authority prior to issue. The responsibility for preparation, review, approval and issue of different levels of documents are given below:

Sr. No	Nature of document	Level	Responsibility			
			Preparation	Issue	Review	Approval
1.	Quality Manual	I	Quality Manager	QA Division	Officer-in-charge	Secretary-cum-Scientific Director
2.	Standard Operating Procedures	II	Concern Division	QA Division	Quality Manager/ Technical Manger	Officer-in-charge PvPI
3.	Formats	III	Concern Division	QA Division	Quality Manager/ Technical Manger	Officer-in-charge PvPI
4.	Record Files, Record Registers, Log Books, Worksheet, Charts, , Drawings, Plans, Check list	IV	Concern Division	QA Division	Quality Manager/ Technical Manger	Officer-in-charge PvPI

11.3.4 Documents changes

Changes in documents in the form of additions/deletion or alterations are reviewed and approved by the Officer-in-charge PvPI. The changes suggested by the technical staff may be considered by quality/technical managers for amendment if found appropriate.

In case of any error found in the documents which is going to affect the quality of work, NCC has the provision to amend/ correct such things immediately.

The revised document is issued within one month of the revision. The altered text is identified and recorded as per change control procedure if applicable.

Supporting Document-

- SOP for change control procedure (SOP NO. IPC/PvPI/QA/003)

11.4**Archiving**

The Quality Manager is responsible for proper archiving of documents and records. Documents and records are stored for a minimum period of three years. Reports for legal proceedings shall follow the legal procedure. The current version of the authorized edition of the document shall be made available at appropriate locations. The documents shall be reviewed at least every three years. If any significant change is required which impact the quality system that shall be reviewed as when required with prior permission of the Officer-in-charge. The Quality Manager shall ensure continuous suitability and compliance with applicable requirements.

The Quality Manager shall ensure availability of the amended documents in the location by replacing the previous copy, and the same shall be retained for reference purpose.

A copy of the obsolete documents is retained & maintained in the archive file for reference/legal purpose by the Quality Manager.

Supporting documents:

- SOP for making SOP (SOP No. IPC/PvPI/QA/001)
- SOP for change control procedure (SOP NO. IPC/PvPI/QA/003)
- SOP for Archiving of Documents (IPC/PvPI/QA/019)

Roles and Responsibilities

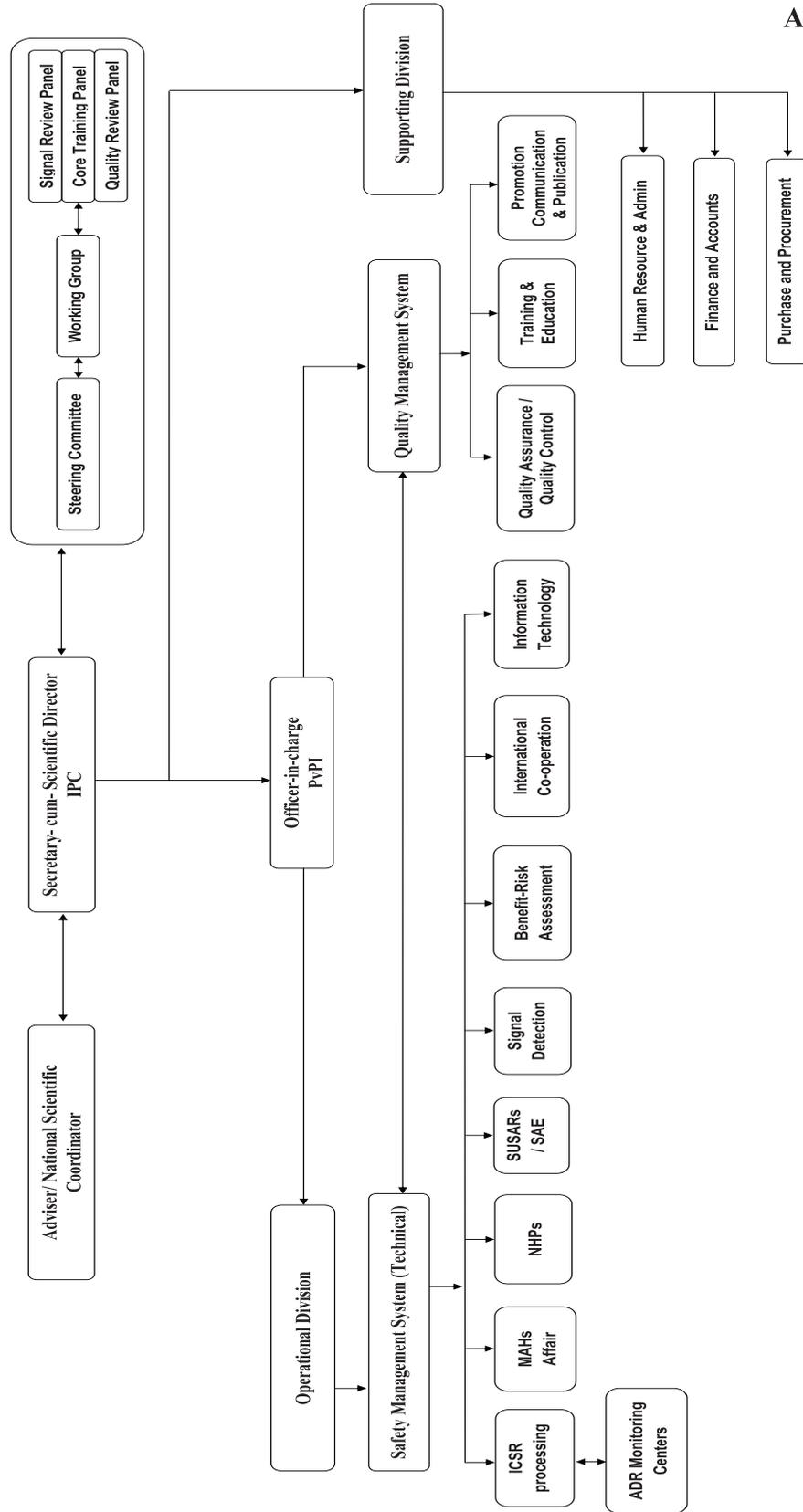
QUALITY MANAGER:

- To prepare and implement Quality Manual and SOP(s).
- To plan and conduct internal and external audits to ensure effective implementation of QMS.
- To evaluate and maintain the records of feedback from stakeholders.
- To handle queries related to QMS and maintain records.
- Timely intervention to rectify the non-conformance and corrective action.
- To organize management review meetings and maintain their records.
- To organize the training program as per schedule.
- To assign job responsibility for all staff members in consultation with the Officer-in-charge.
- Coordination with Technical manager for compliance of technical and quality requirements.
- Any other duties assigned by the Secretary-cum-Scientific Director from time to time.

TECHNICAL MANAGER:

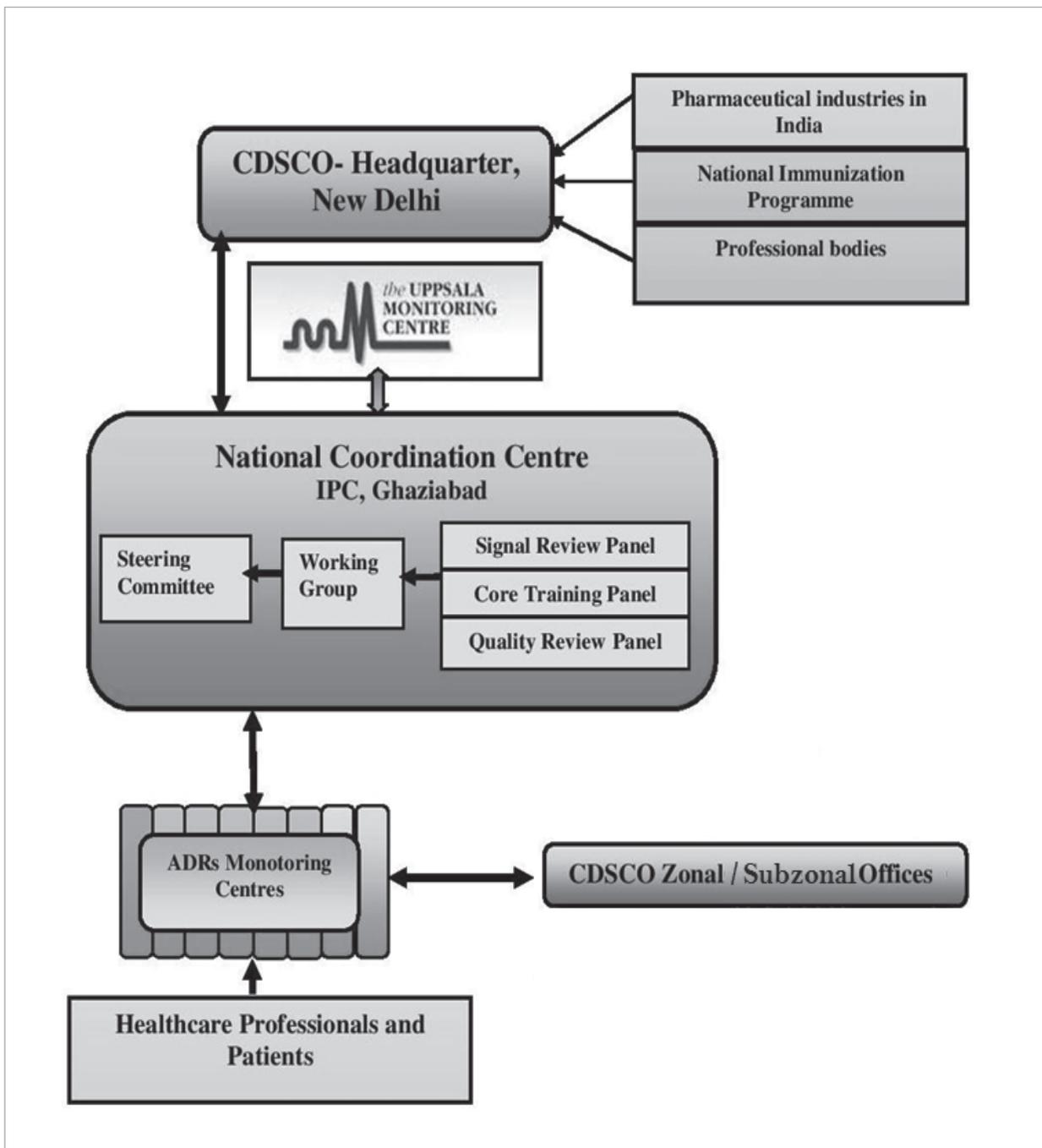
- Coordination with Quality Manager for maintaining QMS.
- Coordination with various division In-charge for timely completion of the assigned work.
- Ensuring processing of ICSRs as per SOP(s)/guidelines.
- Ensuring the drug alert and signal related activities.
- Ensuring the PvPI recommendations to CDSCO for appropriate regulatory interventions.
- Ensuring timely publication of resource materials of PvPI.
- To interact with Secretary-cum-Scientific Director for mobilizing the resources required for various technical/safety management system for the sustainability of PvPI.
- Any other duties assigned by the Secretary-cum-Scientific Director from time to time.

Organogram of National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI)



Annexure –B

Diagrammatic representation of PvPI's communication with the stakeholders



Master List of SOPs Division Wise**Annexure –D**

S No.	SOP Title	SOP Number
Quality Assurance (QA)		
1	SOP for making SOP	IPC/PvPI/QA/001
2	SOP for specimen signature	IPC/PvPI/QA/002
3	SOP for change control procedure	IPC/PvPI/QA/003
4	SOP for handling of deviation	IPC/PvPI/QA/004
5	SOP for handling of non conforming work	IPC/PvPI/QA/005
6	SOP for corrective and preventive action	IPC/PvPI/QA/006
7	SOP for internal audit	IPC/PvPI/QA/007
8	SOP for management review meeting	IPC/PvPI/QA/008
9	SOP for collection of ADR/AE reports at AMC	IPC/PvPI/QA/009
10	SOP for preparation and submission of progress reports	IPC/PvPI/QA/010
11	SOP fill suspected ADR reporting form	IPC/PvPI/QA/011
12	SOP to perform causality assessment	IPC/PvPI/QA/012
13	SOP to enter data from suspected ADR reporting form to VigiFlow	IPC/PvPI/QA/013
14	SOP for reporting and processing Individual Case Safety Reports	IPC/PvPI/QA/014
15	SOP for documentation grading and report completeness of ICSRs	IPC/PvPI/QA/015
16	SOP for documentation at AMCs	IPC/PvPI/QA/016
17	SOP for ensuring the functioning of AMCs	IPC/PvPI/QA/017
18	SOP for functioning of Quality Review Panel	IPC/PvPI/QA/018
19	SOP for archiving of documents	IPC/PvPI/QA/019
20	SOP for handling of medication error, lack of efficacy ICSRs	IPC/PvPI/QA/020
21	SOP for enrolment of AMCs under PvPI	IPC/PvPI/QA/021
Signal Detection (SD)		
21	SOP for operational functioning of Signal Review Panel	IPC/PvPI/SD/001

22	SOP for functioning of Signal Review Panel	IPC/PvPI/SD/002
23	SOP for Suspected Unexpected Serious Adverse Reactions identification	IPC/PvPI/SD/003
Training and Education (TE)		
24	SOP to conduct training under NCC-PvPI	IPC/PvPI/TE/001
25	SOP for functioning of Regional Training Centres under PvPI	IPC/PvPI/TE/002
26	SOP for functioning of Core training panel	IPC/PvPI/TE/003
National Health Programme (NHP)		
27	Processing & Communication of AEFI-ICSRs	IPC/PvPI/NHP/001
28	SOP for Coordination between PvPI and NHPs	IPC/PvPI/NHP/002
Communication and Publication (CP)		
29	SOP for drafting, publication, distribution and control of resource material of PvPI	IPC/PvPI/CP/001
30	SOP for communication between PvPI and Stakeholders	IPC/PvPI/CP/002
Human Resources (HR)		
31	SOP for the recruitment of contractual employee under NCC-PvPI	IPC/PvPI/HR/001
32	SOP for the Job responsibility of employee under NCC-PvPI IPC	IPC/PvPI/HR/002
Industries ICSRs processing & PSURs (IIP)		
33	Processing of ICSRs reported by pharmaceuticals industries	IPC/PvPI/IIP/001
Benefit Risk Assessment		
34	SOP for Benefit Risk Assessment	IPC/PvPI/BRA/001
Information Technology (IT)		
35	SOP for Data Integrity	IPC/PvPI/IT/001
Miscellaneous (MIS)		
36	SOP for receiving ADR from Healthcare Professionals and Consumers through PvPI Helpline	IPC/PvPI/MIS/001



Pharmacovigilance Programme of India (PvPI)

National Coordination Centre

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Government of India

SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311

E-mail: pvpi.ipc@gov.in; ipclab@vsnl.net, Web: www.ipc.gov.in

No. MM/YY/No (Filled by NCC-PvPI)

Feedback Form for Stakeholders

PvPI appreciate your effort to complete this feedback form. Your honest feedback will help us to strengthen the programme and enable us to improve our standards of monitoring medicine safety.

(Please tick (✓) the appropriate box)

Doctor	Nurse	Pharmacist	Patient	Others (Please Specify)

- All medicines can cause side effects/Adverse Drug Reactions (ADRs). Do you think this is an important health concern?
 Yes No
- Have you experienced/noticed side effects/ Adverse Drug Reactions (ADRs) after use of medicines?
 Never Very Commonly Some times
- When experienced/noticed any Adverse Drug Reaction (ADR) what did you do?
 Nothing Informed Nurse/Doctor
 Informed Drug Company/Manufacturer Informed ADR Monitoring Centre
- Have you ever heard about Pharmacovigilance Programme of India (PvPI)?
 Yes No
- Are you aware that the mission of Pharmacovigilance Programme of India (PvPI) is to monitor Adverse Drug Reactions (ADRs) and promote safe use of medicines?
 Yes No
- Are you aware about PvPI helpline (**1800-180-3024**) (Toll free) to report any suspected Adverse Drug Reactions (ADRs) after the use of medicines?
 Yes No
- Have you ever attended any awareness programme regarding reporting of suspected side effects of medicines/ Adverse Drug Reactions (ADRs) after use?
 Yes No
- Are you aware about specifically designed format of PvPI for reporting Adverse Drug Reactions (ADRs)?
 By Healthcare Professional By Patients/Consumers/Relatives of Patient/Care givers (available in different languages at PvPI website - www.ipc.gov.in)
 Through ADR Mobile App

- 9. Are you aware of Adverse Drug Reactions (ADRs) Monitoring Centre in your region?
 Yes No
- 10. Would you like to participate in medicine safety initiatives of PvPI?
 Yes No
- 11. Have you seen any medicine safety promotional materials prepared by PvPI?
 Yes No
If yes, Did you find it useful?
 Yes No
- 12. Have you ever interacted with any PvPI personnel?
 Yes No

if Yes, Please share your experience:

a) Does he/she provide any value addition in medicines safety?

.....
.....

b) What role do you expect from him/her to improve the medicines safety?

.....
.....

Your comments/suggestions to improve our services:

.....
.....
.....

Personal details:

Name:.....
Address: Name of premises/building/village.....
Road/street.....Area Locality.....
District..... State..... Pin.....
Email:Phone/Mobile No.:.....

Date:

Signature

Kindly send feedback to pvpi.ipc@gov.in; ipclab@vsnl.net

Thank you for your feedback.
Your assistance in completing this form is greatly appreciated.



About the Institution & Programme

Indian Pharmacopoeia Commission (IPC), Ghaziabad is an autonomous institution under the aegis of Ministry of Health & Family Welfare (MoH&FW), Government of India. We at IPC, strive hard to achieve its mission – “To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.” The vision of IPC is – “To promote the highest standards of drugs for use in human and animal within practical limits of the technologies available for manufacture and analysis.”

Since 2011, IPC is function as National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI). The mission of PvPI is to safeguard the health of Indian population by ensuring that the benefit of use of medicines outweighs the risk associated with its use. The programme is an important initiative of MoHFW for improving patient safety & welfare of Indian population by monitoring drug safety and thereby minimising the risk associated with use of medicines. It also aims to bolster the regulatory mechanism in India by utilising the drug safety database for identifying signals and thereby providing support for appropriate regulatory intervention. The programme seeks support from all stakeholders including the physicians, pharmacists, patients, pharmaceutical industry and consumers for strengthening the PvPI.



Indian Pharmacopoeia Commission

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let us join hands with PvPI to ensure patient safety

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