

QUALITY MANUAL OF THE IP COMMISSION

Introduction

Quality

Quality is totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Quality Assurance

Quality Assurance is a managerial tool to set up the activities for ensuring quality in the processes by which products are developed.

Scope of Quality Assurance

- Quality Assurance aims to prevent defects with a focus on the process used to make the product. It is a proactive quality process.
- Establish a good quality management system and the assessment of its adequacy.
- Periodic conformance audits of the operations of the system.
- Prevention of quality problems through planned and systematic activities including documentation.
- Everyone on the team involved in developing the product is responsible for quality assurance.



The Indian Pharmacopoeia Commission (IPC) is maintaining quality management system through Quality Assurance Department (QA). The Quality Assurance Department is playing a vital role in the maintenance of quality standards.

The purpose of the quality assurance department is to maintain the quality System of the Indian Pharmacopoeia Laboratory at Indian Pharmacopoeia Commission and ensure its compliance as per ISO/IEC17025:2005, WHO prequalification, ISO Guide 34:2009(E) and adherence to the laid down system and procedures at IPC.

Objectives of Quality Assurance Department

- To ensure the full compliance and implementation of quality parameter which developed through in-house standard operating procedure and other controlled documentation system as per NABL/WHO and GLP specification.
- To **review raw data** generated for the IPRS development, NDS analysis, MISC sample and regulatory samples.
- To Conduct **Internal audit program** for all departments of IPC as per schedule.

The objective of audits is to enhance the effectiveness and efficiency of the internal activities.

Audits and reviews should be performed in accordance with written procedures and checklists.

- To maintain **calibration schedule and preventive maintenance** record and to ensure that calibration of all instrument/equipment shall be done as prevailing Standard Operating Procedures.
- To **issue new logbooks** for various activity as when requested and maintain their records.
- To **revise and prepare new SOP's** and provide training to the staff after their revision and preparation.

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- Preparation, review and maintenance of quality documents such as **Quality Manual**.

 - To **issue controlled worksheet form and format's related to Repeat Analysis form, CAPA form, Deviation** (planned/unplanned) form, **Change control form** related to SOP/personal/location, **Incident event form, Out of Specification form, Calibration form** for various analytical instruments.
 - To make all the laboratory staff aware to the requirements of ISO/IEC 17025:2005, ISO/IEC 17034:2016, ISO/IEC 17043:2010 by conducting regular training and interactions.
 - Issuance, review, maintenance and archival of test reports of laboratory.
 - Regular participation in Proficiency Testing and **Inter Laboratory Comparison Program** and maintain their records.
 - Inter Laboratory Comparison purpose ILAC G:13, ISO/IEC 17043:2010.
 - Evaluation of the performance of laboratories for specific tests or measurements and monitoring laboratories continuing performance.
 - Identification of problems in laboratories and initiation of actions for improvement which for example may be related to inadequate test or measurement procedures, effectiveness of staff training and supervision or calibration of equipment.
 - Establishment of the effectiveness and comparability of test or measurement methods.
 - Provision of additional confidence to laboratory customers.
 - Identification of inter laboratory differences.
 - Education of participating laboratories based on the outcomes of such comparisons.
 - Evaluation of the performance characteristics of a method often described as collaborative trials.
 - Assignment of values to reference materials and assessment of their suitability for use in specific test.

- To provide relevant **training to internal staff** for upgrading technical knowledge and skills of staff required in the development of standards and monographs.
 - Training is essential for direct and indirect measurement staff and personnel responsible for operation, calibration, interpretation of data, and equipment maintenance.
 - Trainings given to staff for the principles and details of the methods used, technical details and potential problems of the processes in which they are involved.
 - Training helps the staff in order to provide knowledge of the overall quality system and its objectives.
 - Training can be provided through, on-the-job training, technologist certification programs, participation in inter comparison programmes.
- To provide **trainings to government analysts, Bench chemists, Stake holders, Drug inspectors and Assistant Drug inspectors** to enhance their skills and knowledge.
 - IPC is regularly conducting training to enhance their skills and knowledge for better understanding of techniques used for quality control of drugs as per regulatory requirements.
 - To update their skills as well as output, hands on training on modern analytical instruments like- HPLC, ICP-MS, LC-MS/MS, GC-MS/MS, Autotitrator, KF Titrator, Potentiometer, etc.
- To assist in research projects of Pharma students and research scholars.
- Strive for continual improvement related to laboratory functions through personnel involvement at all levels.

The other Safety measures handled by the Quality Assurance Department

- Monitoring environmental conditions under which products are manufactured/stored
- Monitoring of air and water systems to prevent contamination– Air Handling Units
- Monitoring of humidity
- Monitoring of personnel
- Feedback and follow-up

Quality Assurance Essential at all Stages

