



Value added course

Quality Assurance & Quality Control

Modules

- Quality Assurance and Quality Management concepts: 3 hrs. (5 Hrs)
- ICH Guidelines: 7 hrs
- Quality by design (QbD): 5 hrs.
- Calibration and Validation: 12 hrs.
- Preparation of SOPs- 3 hrs.

SEMESTER

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COURSE DURATION

30 HRS

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2025-2026

Course objective

- Understanding Definition and concept of Quality control, Quality assurance and GMP Understand the Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines.
- Understanding Definition, overview, elements of QbD program, tools.
- To Study about general principles of calibration, qualification and Validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Calibration of Dissolution apparatus, Qualification of UV-Visible spectrophotometer.
- To Study regarding Preparation of basic SOPs for instrument handling and maintenance.

Course outcome

- Students get knowledge about Definition and concept of Quality control, Quality assurance and GMP
- Students understand overview, elements of QbD program, tools
- Students understand general principles of calibration, qualification and Validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Calibration of Dissolution apparatus, Qualification of UV-Visible spectrophotometer.
- Students understand how to prepare basic SOPs for instrument handling and maintenance

COURSE COORDINATOR

DR. RAHUL HAZARE

NAME OF DEAN

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