



PI 003

COURSE DESCRIPTION:-

This course provides students with a comprehensive knowledge about the pharmaceutical quality control and quality assurance, principles of Good Manufacturing Practices (GMP). It exposes students to all aspects of validation, calibration, inspection and the requirements for manufacturing facilities. It also provides students with a review of the process engineering, technology transfer, personnel management, training and hygiene, premises and contamination control, documentation and auditing, process deviation with emphasis on risk management, complaint handling and product recall theory. Moreover, the vision about designing a quality product and its manufacturing process to consistently deliver the intended performance of the product to meet patient needs is discussed by applying Quality-by-Design and six sigma principles.