SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

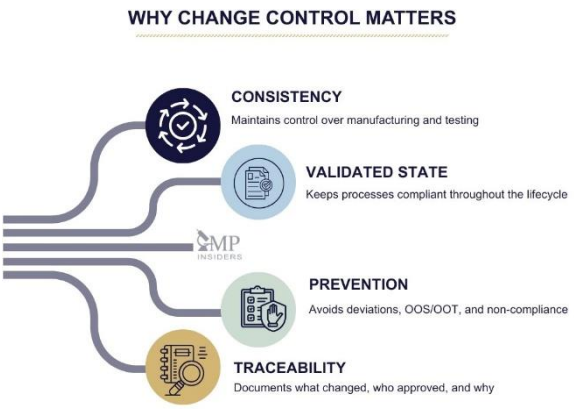
UNIT 2

COURSE NAME: QCSH

TOPIC: GOOD MANUFACTURING PRACTICE

Case Study 1: Inadequate Change Management in API Manufacturing

An API manufacturer producing a Sartan API faced issues when receiving substandard starting materials from suppliers. They attempted to adjust specifications and add purification steps based on small-scale experiments but failed to properly validate changes at full scale, leading to potential impurities and a FDA Warning Letter for inadequate change control. Lessons learned include the need for thorough risk assessments, full-scale validation, and quality unit approval before implementing changes. To avoid this, companies should use comprehensive change management systems with pre- and post-implementation monitoring.



Case Study 2: Combining Lean Manufacturing with GMP in Pharmaceuticals

An Australian pharmaceutical company experienced a bottleneck in its manufacturing process. By applying lean manufacturing principles alongside GMP, they identified inefficiencies and resolved the issue through process optimization while maintaining compliance. Challenges included balancing efficiency with strict quality controls, but solutions like streamlined workflows led to improved production without compromising safety. Outcomes included enhanced operational efficiency and sustained GMP adherence.

Case Study 3: Nutraceutical Manufacturer Achieving GMP Certification

A mid-sized nutraceutical manufacturer in Houston implemented GMP through standardized procedures, raw material verification, batch documentation, and staff training. This led to passing a GMP audit, with achievements including improved product consistency and reduced defects. Benefits were decreased customer complaints, higher efficiency, and increased customer satisfaction, demonstrating how GMP certification enhances market trust and operations.

Case Study 4: FDA Warning Letter Remediation in Healthcare Products

A healthcare company in Ohio received FDA Warning Letters for compliance issues. Through a remediation project, they integrated improvements into SOPs, trained staff, and monitored effectiveness, addressing quality systems, CAPAs, and complaint protocols. Challenges involved overhauling processes post-citation, but results included restored compliance and updated procedures to prevent future violations.

Case Study 5: Cross-Contamination in Solid Oral Dosage Facilities

Multiple firms were cited for cleaning deficiencies in non-dedicated equipment, leading to cross-contamination via residues in ductwork, filters, and surfaces. Issues included incomplete logs, improper disassembly, and lack of validation for cleaning limits. Lessons emphasize identifying all hazards, detailed procedures with visuals, and ongoing monitoring. Prevention involves automating cleaning, frequent reevaluation, and thorough training to ensure no visible residues or microbial risks.