

What are the 4 types of validation in pharmaceutical manufacturing?



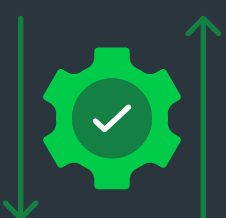
Prospective Validation

- Performed before commercial manufacturing, this approach tests and documents processes to ensure consistent product quality.
- It includes: risk assessment, process characterization, and validation protocols to identify and resolve issues early, reducing risks to quality and compliance.



Retrospective Validation

- This method uses historical data to validate existing products and processes.
- While it avoids production disruption, regulators recommend combining it with prospective approaches for critical processes.



Concurrent Validation

- This method validates processes during routine production, allowing for immediate market delivery.
- It's ideal for time-sensitive products, but requires strong monitoring and carries more risk than prospective validation.



Revalidation

- Revalidation ensures that changes to processes, equipment, or materials don't affect product quality.
- Triggered by changes, time-based reviews, or quality issues, it maintains control and quality throughout the lifecycle.