

■ Pharmaceutical Manufacturing

OVERVIEW

Pharmaceutical Manufacturing introduces the complex processes of manufacturing, packaging, and transporting small molecule drugs. Governments highly regulate drug manufacturing to ensure patients receive safe and effective medications. Pharmaceutical Manufacturing provides you with the knowledge to understand how to get a small molecule drug from the production line to the patient, and remain in regulatory compliance.

Five Takeaways:

1. Diagram the key steps of small molecule drug production.
2. List the main ingredients that make up a small molecule drug and the purposes for each.
3. Explain how regulators ensure manufacturing quality control through the supplier, production, packaging, and shipping validation.
4. Compare and contrast the four most common pharmaceutical formulations: tablets, capsules, suspensions, and emulsions.
5. Describe the pharmaceutical supply chain considerations including the prevention of drug tampering and counterfeiting.

AGENDA

Chemical Synthesis

- Advantages of small molecule drugs
- Small molecule drug ingredients
 - Active pharmaceutical ingredient (API)
 - Excipients
- Small molecule drug characteristics
- Types of chemical synthesis
 - Organic: linear and convergent
 - Stereoselective: R and S enantiomers

Purification

- Process and goals of purifying API
 - Crystallization
 - Distillation
 - Chromatography: ion exchange, reverse phase, size exclusion
- API production regulations
- Supplier validation purpose and requirements

Formulation

- Formulation defined
- Key formulation goals
- Characteristics of dosage forms
 - Tablets, capsules, suspensions, emulsions

Packaging

- Fill and finish purpose and methods
- Packaging purpose, process, and regulations
- Tamper resistance components
- Counterfeit protection methods
- Anti-counterfeit technologies
- Supply chain
 - Cold chain management
- Shipping validation