Setting Up A Pharmaceutical Manufacturing Process and Supply Chain:
A Complex & Lengthy Undertaking

Biopharmaceutical companies begin setting up the manufacturing supply chain for a medicine years before that medicine is even approved for use by patients. This includes determining how to safely and efficiently manufacture the medicine, meeting all the regulatory requirements and developing plans for getting the medicine to patients, and incorporating robust risk management and business continuity plans to ensure supply network security.

Initial Development of Manufacturing Plans

Designing the manufacturing process to ensure consistency and reliability is a complex activity. Manufacturing plans address operations from the receipt and manufacturing of materials to production, packaging, labeling, relabeling, storage and distribution, as well as related quality control and testing systems.

Build the Supply Chain, Including Suppliers

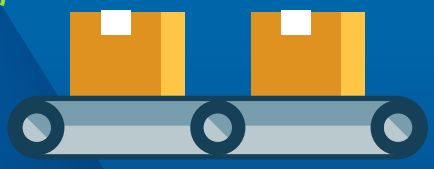
As large-scale manufacturing processes are developed, companies develop plans for sourcing all the materials needed, which may be sourced in-house or through qualified vendors and suppliers. Manufacturers also develop risk management plans to ensure redundancy in suppliers in the event of supply disruption.

Scale Up Manufacturing Process

As clinical trials progress and assuming they show positive results, scaling up the manufacturing process to meet rigorous FDA standards at a commercial level is complex and costly. Building quality into the manufacturing process is a key focus in product and process design, including scaling up production.

Build New Facility or Expand Capacity

Building a new facility or expanding an existing facility to make commercial quantities of medicines requires substantial planning and resources. Building a new facility can cost up to $2 billion and take 5 to 10 years. Expanding existing facilities, transferring a single product to a new manufacturing site or retrofitting an existing facility for a new product can take several years.



It can take **5 to 10 years** to set up a new manufacturing facility, and even longer to onshore an entire manufacturing network.

Comply with Regulations and Submit for Inspections

FDA regulations help ensure that medicines for use by patients meet quality standards that help protect the public health. FDA also reviews information about the manufacturing process as part of drug applications and during pre-approval and surveillance inspections. Manufacturers must register with FDA and list the drugs they manufacture. FDA relies on this information to plan for and conduct surveillance inspections at finished drug and API sites. To comply with product security regulations, all facilities within the supply network implement security plans.

Making changes to even one element of a supply chain can take years to implement and have significant costs.

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