Delivering treatments to patients: The medicines manufacturing journey

Manufacturing includes all the operations and the quality controls that are required to produce and distribute an Active Pharmaceutical Ingredient (API) and medicinal product. It is a highly regulated process: at each step, quality assurance confirmation ensures that the product has been manufactured and tested in accordance with marketing authorisation applications, regulations and commitments. Once all requirements are met, a final certification can be given to release the product for wholesale distribution.

Manufacturing facilities must operate to strict standards and are regularly inspected by competent authorities. Besides the unproductive time during cleaning, each facility is often shut down for 2-8 weeks each year to ensure maintenance, equipment qualifications and the implementation of innovations, e.g. for sustainability. Local regulatory requirements are part of the global manufacturing process. This means that the same manufacturing process delivers the same product to patients living in different parts of the World.

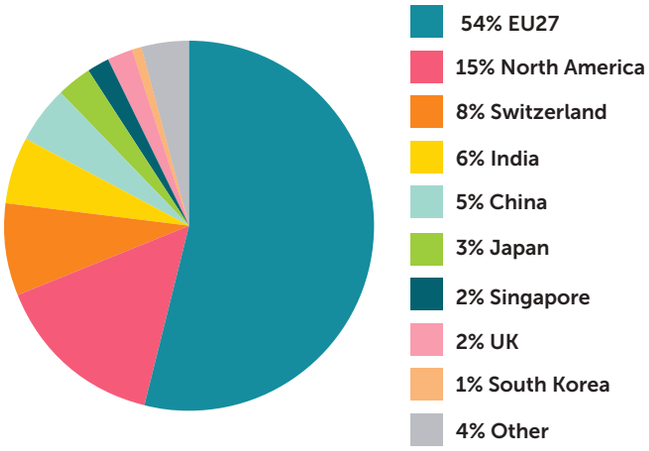
European manufacturing by the research-based pharmaceutical industry in figures

Today, the EU-27 is a leading location for the manufacturing of innovative medicines and related active ingredients, contributing to a trade surplus of 158 billion euros in 2023[1] and continued supply to patients. The changing policy environment may put this contribution at risk.

€363 billion (EFPIA total): The value of pharmaceutical production in Europe in 2022[2]

€158 billion: Trade surplus of medicinal and pharmaceutical products in 2023[3]

64% of APIs are manufactured in Europe (EU-27, Switzerland, UK)[4]



Innovative manufacturing is key to continue to meet patients' needs

Manufacturing enables access to medicines

The research-based pharmaceutical industry is constantly making investments in innovative manufacturing technologies such as continuous processing, automation, modular/mobile manufacturing for all medicines including vaccines, biologics, and advanced therapy medicines.

These innovations help improve supply reliability, meet regulatory requirements, as well as facilitating the green and digital transitions.

1,2,3 EFPIA, The Pharmaceutical Industry in Figures, 2024, https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf
4 EFPIA survey conducted in April 2021. Number of APIs (biological and chemical) sourced or manufactured per region of origin (irrespective of value/volume). A total of 16 EFPIA member companies submitted their input to the survey referring to in-patent and off-patent medicines
5 Deoxyribonucleic Acid
6 Physical separation of a chemical substance of interest from foreign or contaminating substances
7 Bulk materials include any materials that are dry, granular, powdery, or lumpy in nature

The Manufacturing process: Continuously optimised by implementing innovations

efpia

Our Commitment

Developing and manufacturing **high quality** and **greener medicines**.

Ensuring a stronger **European voice** while being at the forefront of developing and implementing **innovative products and processes**.

Defining a strategic vision to **proactively prevent medicines shortages** caused by disruptions to global manufacturing and supply chains.

Raw materials:

These are usually commercially available and sourced from plants, organic and inorganic compounds, oil, or DNA[5]. Many are sourced from the bulk chemical industry from suppliers all over the world, with the pharmaceutical industry representing a minor customer.

Starting material:
(12–28 weeks)

Some API starting materials may be commercially available; others may be manufactured/ modified for the specific use and require complex chemical transformations. For biotech products, a working cell bank is created from the master cell bank.

API manufacturing:
(1–10 weeks)

Manufacturing of the Active Pharmaceutical ingredient (API) from API starting materials is conducted in a carefully controlled manner which is critical to the production of high quality, safe, and efficacious medicinal product. API manufacturing may require many chemical and purification[6] steps. Each of these steps may be performed in a dedicated facility, and in a continuous or batch manufacturing mode. For many products, especially biological, manufacture may be in a sterile environment. Cleaning is necessary after each manufacturing cycle and may take additional 1-3 weeks.

Excipients, containers, and packaging materials added:

Usually commercially available from the chemical or food industry. They can also be designed and manufactured specifically for pharmaceuticals. Quality is controlled by adherence to pharmacopoeia or internal standards. Major changes in demand may take between 1–12 months to implement.

Pharmaceutical products:
(1–10 weeks)

These are manufactured from the API with excipients towards 'bulk'[7] material and further processed into containers or devices. Conditions to ensure sterility are applied when required (e.g., for injectable products).

Devices used:
(as applicable)

Devices (e.g., inhalers, pre-filled syringes, on-body injectors) may be used for better patient experience. Where medical devices are required, they are manufactured and controlled to predefined specifications.

Medicinal product:
(1–2 weeks)

The packaging step prepares the final drug product to be delivered to patients. This step is applied to comply to country specific rules, including labels, packaging, and specific content for each country, including leaflets. Repackaging might occur, e.g., if the product is needed in another country or there is a change in the leaflet.

Distribution to patients:
(1–4 weeks)

The finished product gets delivered to different owners (e.g., distributors, wholesalers, pharmacies or directly to local health authorities), ensuring all Good Distribution Practices are respected. The distribution chain of medicinal products needs careful maintenance to ensure their quality, potency, and purity.

Call to action

Promote a **policy environment that fosters R&D in Europe** – the first step to locating advanced manufacturing in the bloc.

Streamline and harmonize **regulatory requirements** to support innovation.

Build a collaborative, best-practice led approach to **sustainable manufacturing** to address environmental challenges.