

# THE VALUE OF ACTIVE PHARMACEUTICAL INGREDIENTS



## What are APIs?

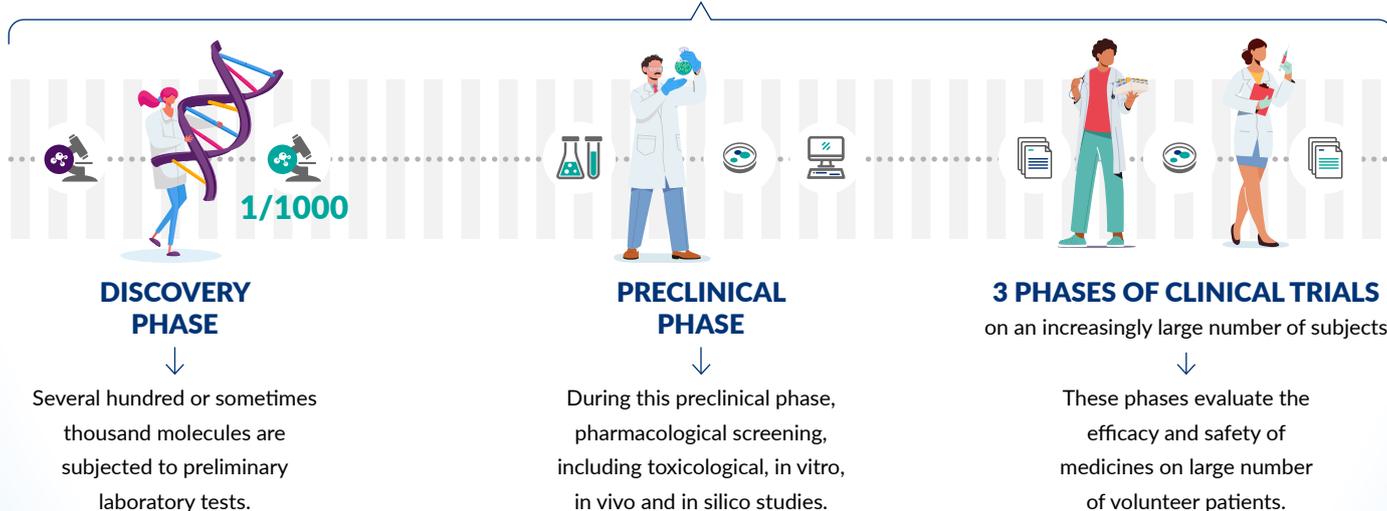
**APIs** (Active Pharmaceutical Ingredients) are **responsible for the therapeutic effect** of formulated pharmaceutical products (medicines),

They are produced using **highly technological industrial processes**, both during the R&D and commercial production phases.

## How is a medicinal product developed?

### 5 PHASES - 10 YEARS

The development of a new pharmaceutical specialty is long and costly and can last up to ten years.



At the end of this selection process, Only one in ten molecules remain that can proceed to **Clinical Phases 1, 2 and 3** subject to prior authorisation by the competent national authorities, and very few of them make it to the end of the full selection process (screening and clinical trials).

## A medicinal product must



Demonstrate its therapeutic activity



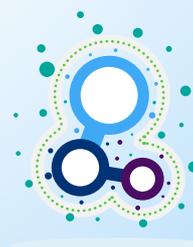
Have a good delivery system



Be absorbed once delivered or be effective where required



Reach its target(s)



Perform its action and be subsequently eliminated

# How is an Active Pharmaceutical Ingredient produced?

APIs are produced according to **Good Manufacturing Practices (GMP)** defined by Health authorities. The entire system is controlled by very strict regulatory procedures and enforced by inspections.



A **registration with Eudralex** certifying that the company works **in accordance** with the requirements of the **EU legislation** on GMP.



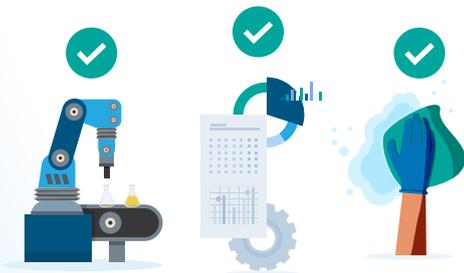
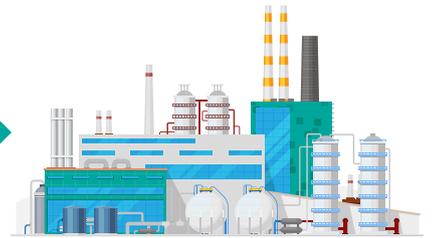
A plant that has the **adequately trained personnel, premises and equipment** for the production and the handling of each and every product.



**Quality systems and processes** that guarantee the proper functioning of the equipment and the **consistency and quality** of the APIs produced.



It is crucial for the API manufacturer to have a **cutting-edge Research & Development (R&D) facility**, enabling the **transition from laboratory scale to pilot plant** and then **to full industrial scale**. To achieve this, an **excellent level of technology** is needed.



GMP standards require from manufacturers, inter alia, the **validation of their equipment, processes, analytical methods and cleaning methods**.



Strict **environmental, health and safety (EHS) standards** are required to operate manufacturing plants.



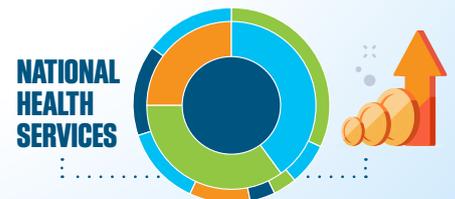
**“Gold standards”** are applied to meet excellence in **industrial safety, environmental protection and health & safety at work**.



At the expiry of its patent the **active ingredient** can be used for the production of **generic and biosimilar drugs**,



allowing **access to affordable healthcare** to a **wider patient population**, including in lower-income countries,



and **reducing the cost for health services** and insurers thus **freeing up resources for innovative therapies**.