

THE FUTURE OF EUROPEAN API MANUFACTURING



Active Pharmaceutical Ingredients (APIs) are essential in the development of pharmaceuticals as they deliver the curative effect of formulated medicines



Pharmaceutical companies mostly outsource the process development and manufacturing of their medicines, relying on partnerships with API producers and CDMOs (Contract Development and Manufacturing Organisations).

API producers are specialised in tailor-made drug development and manufacturing services. A pharmaceutical company can therefore begin with a concept and be guided all the way from pre-formulation and formulation development, through to clinical trials and commercial production.

Setting solid bases for the future

with a healthy growth rate for the next years foreseen at 4.5 to 6.0%



The past

Until recently, the trend for API producers lay in the production of APIs for generics and new chemical entities (NCEs) for **small and large molecules** that will be branded by pharmaceutical companies through CMO contracts.



The last decade

During the last decade, many new important medicines were discovered and developed. The production processes and advanced technologies required by these new medicines were mainly developed by European API manufacturers, consolidating their role as essential actors and partners in the pharmaceutical value chain.

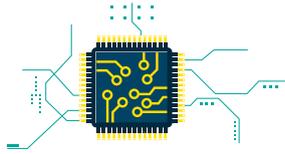


The future

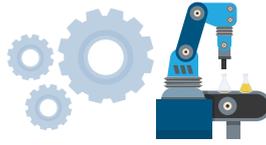
Pharmaceutical companies are investing in new and more efficient products and European API producers will therefore increasingly be involved in developing new processes for New Chemical Entities (NCEs).

The Contract Development & Manufacturing activities will significantly grow in many European companies, thanks to large pharmaceutical companies and new advanced players trusting European companies to be the most technologically and scientifically skilled partners.

What will be needed for future medicines?



Cutting-edge technologies to adapt to the new types of medicines being developed



Highly specialised and innovative manufacturing processes are indispensable to meet exacting demands



Continuously investment in innovation by API manufacturers

API manufacturers will be **indispensable partners of big pharmaceutical companies** in the development of future medicines and vaccines

What can we do?



Partnerships in R&D

Innovation is only possible in partnerships and if European API manufacturers can rely on multi-disciplinary **R&D teams who can integrate traditional chemistry with new technologies** such as flow chemistry, biocatalysis, solid chemistry, mechanochemistry, biotechnology, physics, mathematics, and computer sciences.

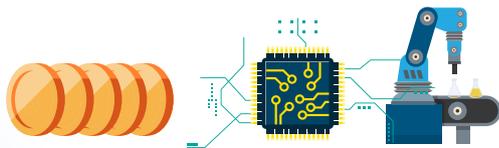


Targeted reshoring

Targeted reshoring projects that will respect the strictest environmental regulations. They will aim to significantly reduce the consumption of energy, **to actively work towards the development of green chemistry**, within a high-level fully integrated and controlled quality framework.

Supporting the EU health system's open strategic autonomy

To guarantee an uninterrupted access to essential medicinal supplies, be it existing or new, the EU authorities should support the growth of API manufacturing in Europe.



European API producers consistently invest in Innovation, striving to be at **the cutting edge of technological processes**.



They now need support from the EU authorities in **making sure their investments will not go to waste** in an environment where their competitiveness and sustainability will be undermined.



Key policy enablers

A regulatory global level playing field that will have all **global players respecting the same rule book**, applying the highest safety, environmental and social standards to all global suppliers of the pharmaceutical value chain



The full respect of the quality system is a distinctive feature of European procedures and the target, in a global market, will be that all manufacturers apply a homogeneous system – whatever the country they operate in.

Only then can we ensure a sustainable autonomous pharmaceutical supply chain for Europe's future.