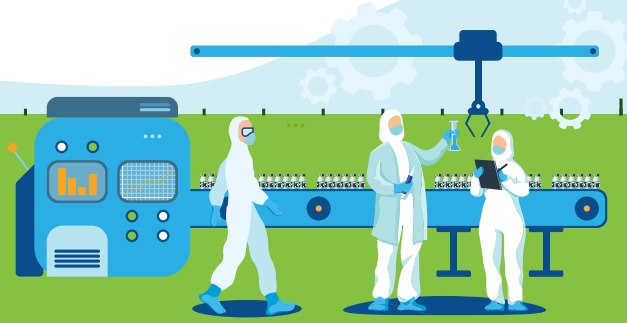
Vaccines Manufacturing



On average, it takes between **12-36 months* to manufacture a vaccine.**

Vaccines are complex biological products with lengthy manufacturing and control processes. Quality controls are applied all along the manufacturing process and represent up to 70% of the manufacturing time. Quality assurance ensures that vaccines are produced following the highest standards. [1] **All components, manufacturing steps, controls tests including reagents and standards, distribution steps comply with good practices such as Good Manufacturing Practices (GMPs), Good Laboratories Practices (GLPs) and Good Distribution Practices (GDPs).**

Raw material reception

2 weeks on average
(it can range from several days to a few months)
Raw material are either used in key production steps as fermentation, purification or as an integral part of the vaccine. Up to 160 raw materials could be used to produce some vaccines.

Active ingredient manufacturing

12 months
Generation of the antigen** (active ingredient) is the most critical step in the production of high quality, safe and efficacious vaccines.

Coupling & Formulation

2 weeks
During the formulation, the antigen is coupled with stabilizers, preservatives, adjuvant to enhance the immune reponse, facilitate vaccines administration & ensure vaccine stability in time.

Filling

8 months
Vaccines are filled aseptically, in a vial or a syringe, to endure sterility. Vials are closed using sterile stoppers and crimped to maintain sterility. Unstable liquid vaccines are lyophilized. During this step, water is removed from the liquid to allow stability. In this case, the vaccine will have to be reconstituted just before injection.

Packaging & lot release

18 weeks
Due to the diversity and complexity of regulatory requirements, across EU Member States and globally, vaccine syringes or vials are each time labelled and packed in a country-specific format (label, leaflet, carton). Following quality assurance confirmation that the product has been manufactured and tested in accordance with ad hoc procedures, a final authorization is given to release the product for distribution.

Shipment

2 weeks (up to 4 weeks in case of cross region transfer)
Maintenance of the cold chain for vaccines (temperature: +2C to +8C) is essential for preservation of most vaccines.

Distribution

Finished product is delivered to distributers, wholesalers, pharmacies or directly to local health authorities, ensuring all Good Distribution Practices are respected.

- Testing done by manufacturer
- Testing done by the exporting country
- Testing done by the importing country

* Complex multivalent vaccines can have production lead times of more than 36 months.

** Antigen is a live (e.g., viruses and bacteria) or inactivated substance capable of producing an immune response.

[1] World Health Organization. Immunization Standards. Vaccine quality. Available at: http://www.who.int/immunization_standards/vaccine_quality/en/. Accessed April 8, 2016