IFPMA DCVMN

THE DEVELOPMENT AND MANUFACTURE OF VACCINES TO PROTECT GLOBAL HEALTH

Key stages and timeline to bring vaccines to market

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KEY STAGES AND TIMELINE TO BRING VACCINES TO MARKET

01 Research & antigen discovery

- Intensive research around the antigen (the active component) and antigen identification.
- Genetic sequencing can provide access to the pathogen's genetic information thus helping to identify antigens.
- Vaccine candidate is evaluated for safety and efficacy using in vitro and in vivo testing.

02 Pre-clinical development

- Safety studies are conducted (in depth testing of the vaccine candidate's safety in laboratory and animal models).
- No testing on humans in this phase.
- Adjuvant(s)[1] for the formulation of the vaccine candidate may be selected.

03 Clinical development

- If the vaccine triggers an immune response, it is tested in human clinical trials.
- Small-scale process development (delivery system definition and first GMP-level batches tested for safety).
- Testing in human clinical trials in 3 phases:
  - Phase I: small number of individuals
  - Phase II: larger number of individuals
  - Phase III: thousands of people

04 Regulatory review & approval

- Documentation submission, evaluation and potential approval by competent regulatory authority.
- The regulatory authority may conduct its own testing.
- In case of a positive outcome, the regulatory authority grants the license to market the vaccine.

05 Manufacturing scale-up

- The manufacturing processes is established and optimized.
- Ensuring the products meet the necessary regulatory requirements (including GMP).
- Large scale production of enough vaccine doses for national vaccination programs.

06 Post-license monitoring & quality control

- Following its market entry, the product is tracked and monitored.
- Post-marketing safety and efficacy are monitored during a vaccine's whole life.
- Phase IV trials may be conducted.
- The impact and safety of the vaccine is monitored over a long timeframe.
- Any side effects or issues reported following vaccination are assessed.

STANDARD TIMELINE TO BRING A VACCINE TO MARKET: 10-15 YEARS ON AVERAGE

1-5 YEARS	1-4 YEARS	5-7 YEARS	1-2 YEARS	+/- 24 MONTHS	THROUGHOUT THE ENTIRE LIFECYCLE

ACCELERATED TIMELINE TO BRING COVID-19 VACCINES TO MARKET: 1-2 YEARS

6 MONTHS[2]	6 MONTHS	1.5 YEARS	6 MONTHS	3-6 MONTHS	THROUGHOUT THE ENTIRE LIFECYCLE

The successful accelerated development and manufacturing of COVID-19 vaccines was an exceptional achievement enabled by various factors such as intense international collaboration among various stakeholders, rapid sharing of pathogens and data, reliance on innovative technology platforms, and use of regulatory agilities and convergence.

[1] Adjuvants: ingredients of some vaccines that help to promote a better immune response; they can also reduce the amount of virus needed for the vaccine production.

[2] However, extensive previous research and insights around vaccines and possible diseases that could cause a pandemic were leveraged during this time.
GMP: Good Manufacturing Practice.

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A focus on the manufacturing chain

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A FOCUS ON THE MANUFACTURING CHAIN

- Vaccine manufacturing involves 6 key steps, potentially each step can be performed in different sites in different countries.
- A vaccine typically travels through several different sites before being ready for shipment.
- A vaccine undergoes up to several hundred quality control tests during its manufacturing journey.

Raw material reception

All incoming raw materials are checked for conformance with the quality specifications.

Bulk antigen manufacturing

The active ingredient of the vaccine (the antigen) is manufactured. This is the most critical step in the production of high quality, safe and efficacious vaccines.

Formulation

The active ingredient is mixed with other ingredients (such as stabilizers, preservatives, adjuvants) to improve the immune response and ensure product stability.

Filling

The vaccine is filled into the final container (a vial or a prefilled syringe).

Packaging

The vaccine in the final container is labeled in accordance with regulatory requirements and packed, ready for shipping to the customer.

Lot release

Quality assurance confirms the product has been manufactured and tested in accordance with the correct procedures. The national regulatory authority gives final authorization to distribute the vaccine.

05

Manufacturing scale-up

- Quality control represents up to 70% of the full manufacturing time

- Testing is done by different stakeholders:
  - Manufacturers
  - Exporting country
  - Importing country

R&D: Research and development; PDPs: Public-private product development partnerships