

# Seasonal Influenza Vaccine Production Process

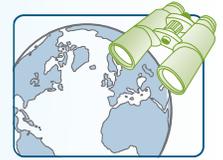
## Surveillance

Year Round

- The seasonal influenza vaccine protects against the 3 most prominent virus strains circulating in a given year, which must first be identified before production can begin each year.
- Ongoing global surveillance is key to

predicting which 3 strains will circulate each influenza season.

- Scientists around the world submit samples to the World Health Organization and its reference laboratories, such as the Centers for Disease Control, which analyze and identify the circulating strains.

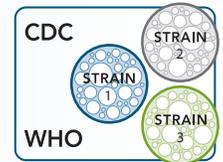


## Strain Selection

January-March

- Based on the surveillance, WHO makes a strain recommendation in February for the Northern Hemisphere and in September for the Southern Hemisphere.

- In the U.S., the strains are submitted to the Food and Drug Administration (FDA) to recommend which 3 to include.
- WHO coordinates seed virus distribution.



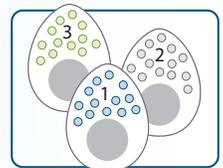
## Bulk Manufacturing and Production<sup>a,b</sup>

January-July

- Millions of specially-prepared chicken eggs are used to produce the vaccine. Throughout the year, fertilized eggs are delivered to the manufacturer. Each egg is injected with 1 strain.
- Each virus strain is produced separately, and later combined to make 1 vaccine.

- The eggs are incubated for several days to allow the virus to multiply. After incubation, the virus-loaded fluid is harvested.

[Click here to see sanofi pasteur's Bulk Influenza Vaccine Manufacturing Process](#)



## Purification and Testing<sup>a,b</sup>

June-October

- The virus fluid undergoes multiple purification steps and a special chemical treatment to ensure the virus is inactivated, or "killed."<sup>c</sup>
- The virus is split by chemically disrupting the whole virus.

- Manufacturers test the vaccine concentrate to determine amount and yield of the virus to ensure concentrate is adequate for immunization.

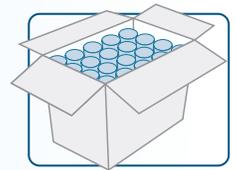


## Formulation, Filling and Packaging

July-December

- Viral fragments from all 3 strains are collected from different batches, and combined upon completion of quality control tests.
- Quality control tests are performed on all 3 strains for purity, sterility and potency in each step of the production process.

- Manufacturers begin filling the doses into vials and syringes, which are then sealed and carefully inspected before labels are applied to show the vaccine batch, lot numbers, and expiration date.
- Each lot must be specifically "released" by the FDA before manufacturers can ship supplies.



## Shipping

August-November; Beyond as needed

- Vaccine shipments typically begin in August or September and continue into November.
- With the CDC's<sup>d</sup> support, partial shipments are sent early in the season to all customers to ensure broad access for high-risk patients.

- Depending on viral yields and virus activity, additional doses may be released and distributed into December and beyond to support late-season immunization.



## Vaccination

October and Beyond

- The CDC recommends an annual influenza immunization for anyone who wishes to reduce their risk of contracting influenza: children 6 months through 18 years of age; adults 50 years of age and older; pregnant women; and anyone with chronic health conditions such as asthma, chronic

- obstructive pulmonary disease (COPD), heart disease, and diabetes.
- Immunization may begin as soon as vaccine becomes available and continues through the influenza season, which typically ends in March.
- Immunity develops approximately 2 weeks following vaccination<sup>e</sup>.



<sup>a</sup>To ensure safety and purity, vaccine is produced in a clean environment where quality control experts enforce strict standards, continuously monitoring the process; <sup>b</sup>The majority of time for Bulk Manufacturing and Production and Purification and Testing is dedicated to testing and approval.; <sup>c</sup>This process makes it impossible to contract influenza from the vaccine upon administration; <sup>d</sup>Centers for Disease Control and Prevention; <sup>e</sup>Children younger than 9 years of age receiving vaccination for the first time need 2 doses 1 month apart.