



# Sampling in vaccine formulation

Si Yang 司阳, Manager of Aseptic Manufacturing, Novartis Vaccines  
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# Company profile

## Novartis vaccines and Tianyuan Biopharm



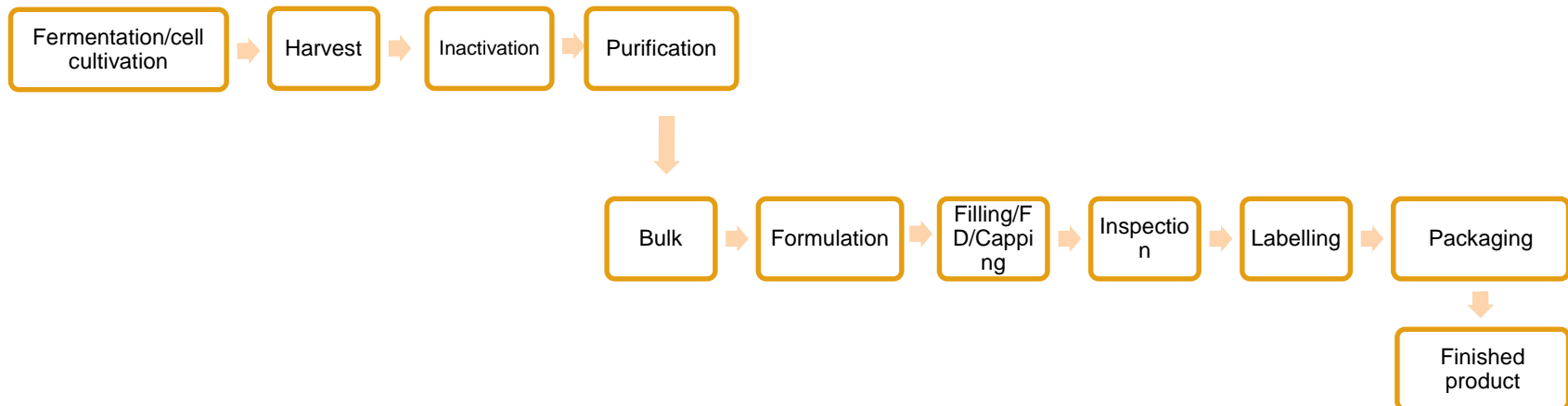
- World's fifth leading vaccine manufacturer and second leading influenza vaccine manufacturer. Produces over 800 million vaccines yearly that reach more than 100 countries around the world. An average of 25 people per second are inoculated with a Novartis vaccine. As a leader in scientific innovation, Novartis Vaccines seeks to help more people through constant innovation in products and technologies.



- Zhejiang Tianyuan biopharmaceuticals: one of China's leading vaccine manufacturers. Tianyuan is devoted to providing high-quality vaccine products to people in China and the rest of the world in order for them to achieve a healthy and high-quality life.

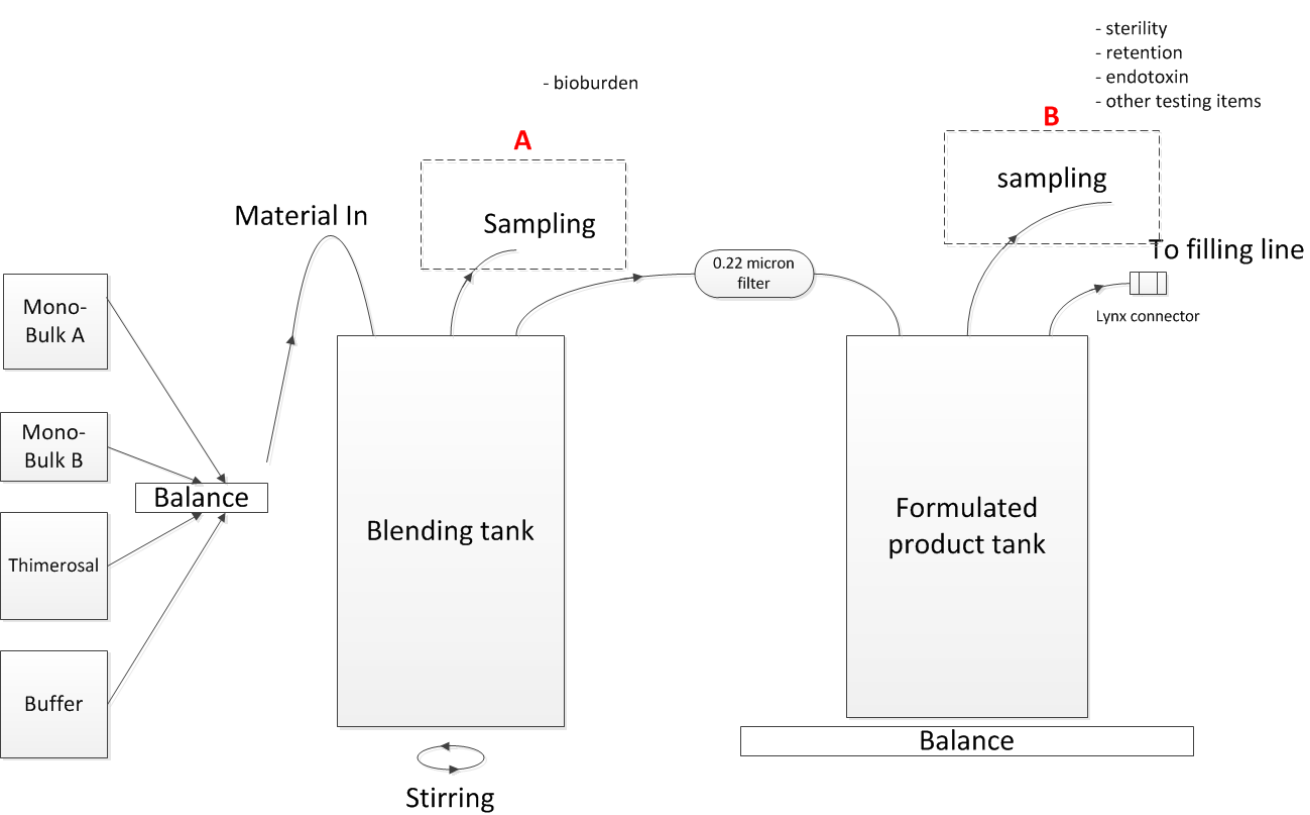
# Vaccines

- Vaccines: vaccine is a biological product that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins.
- General process flow of vaccine manufacturing :

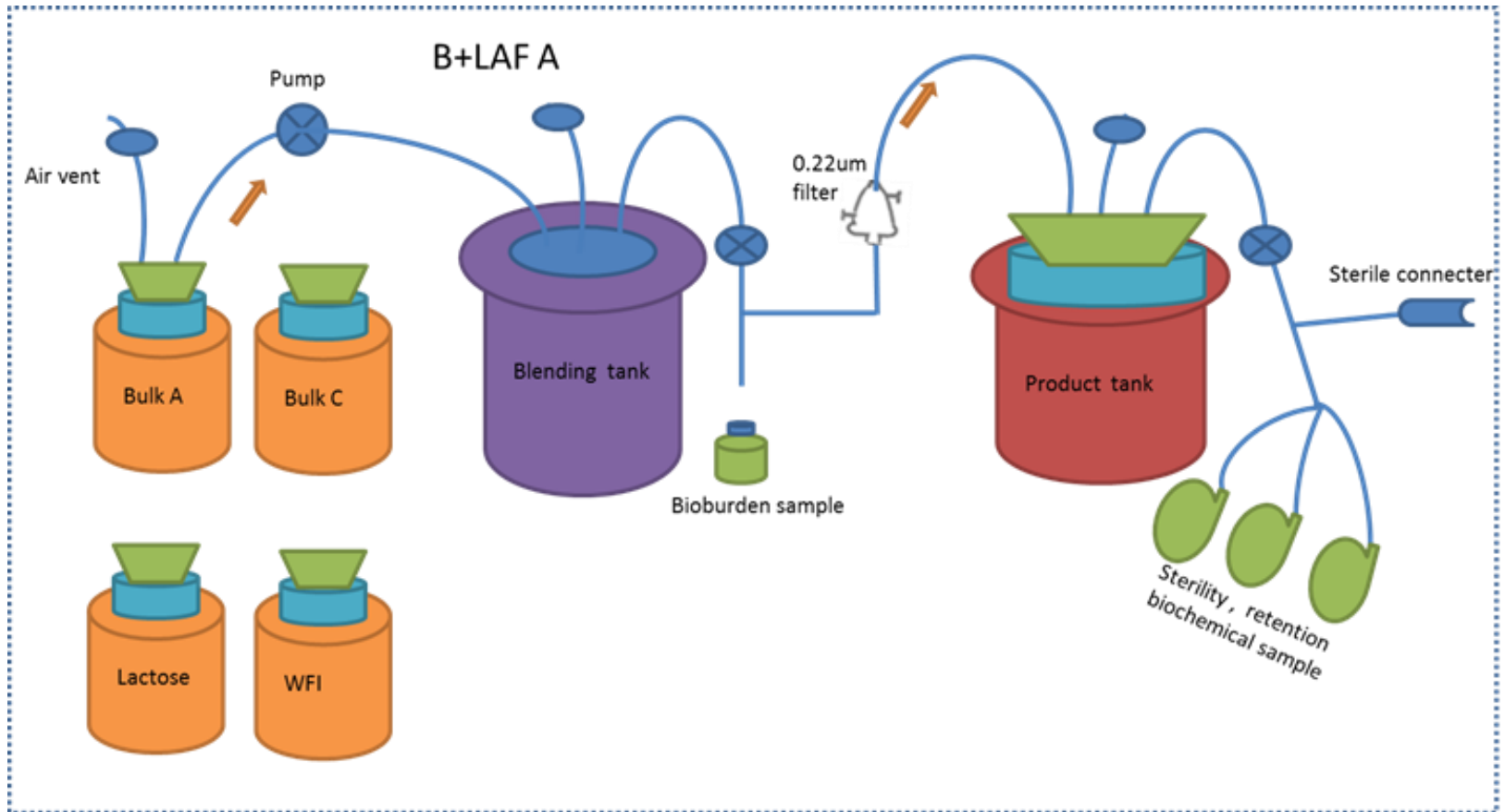


# Schematics of formulation system

## Process flow and challenges



# Proposed new way of sampling



# Improvement of sampling

*From open sampling to closed system sampling*



## Before change

- Open manipulation under LAF A

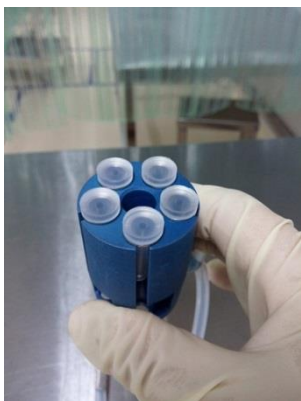
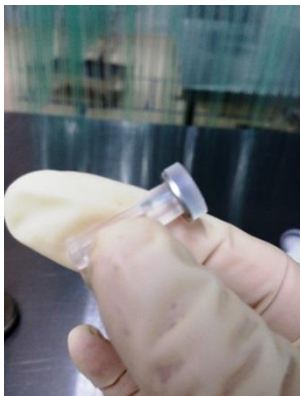
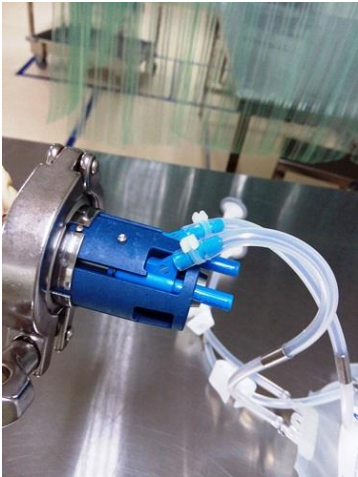
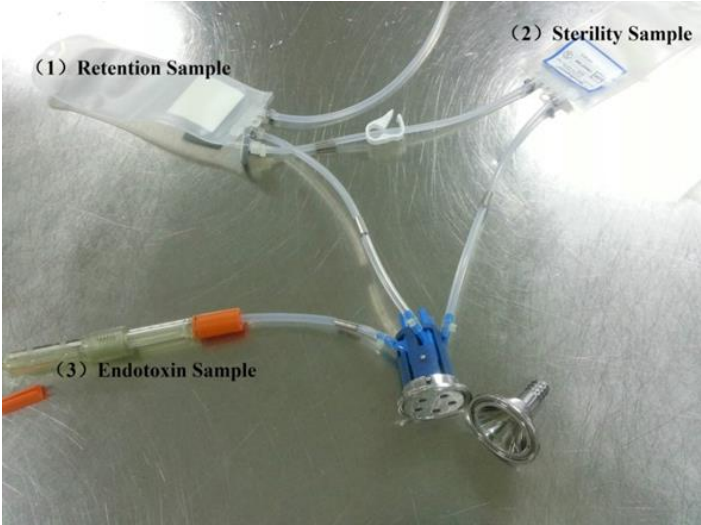
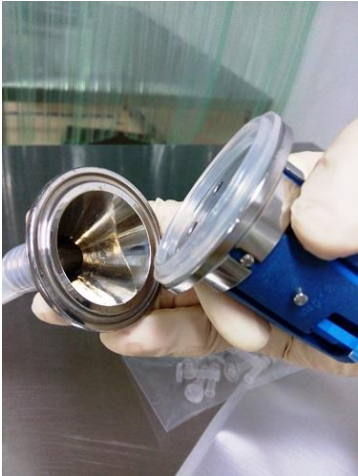


## After change

- Close system operation under LAF A

# Set-up

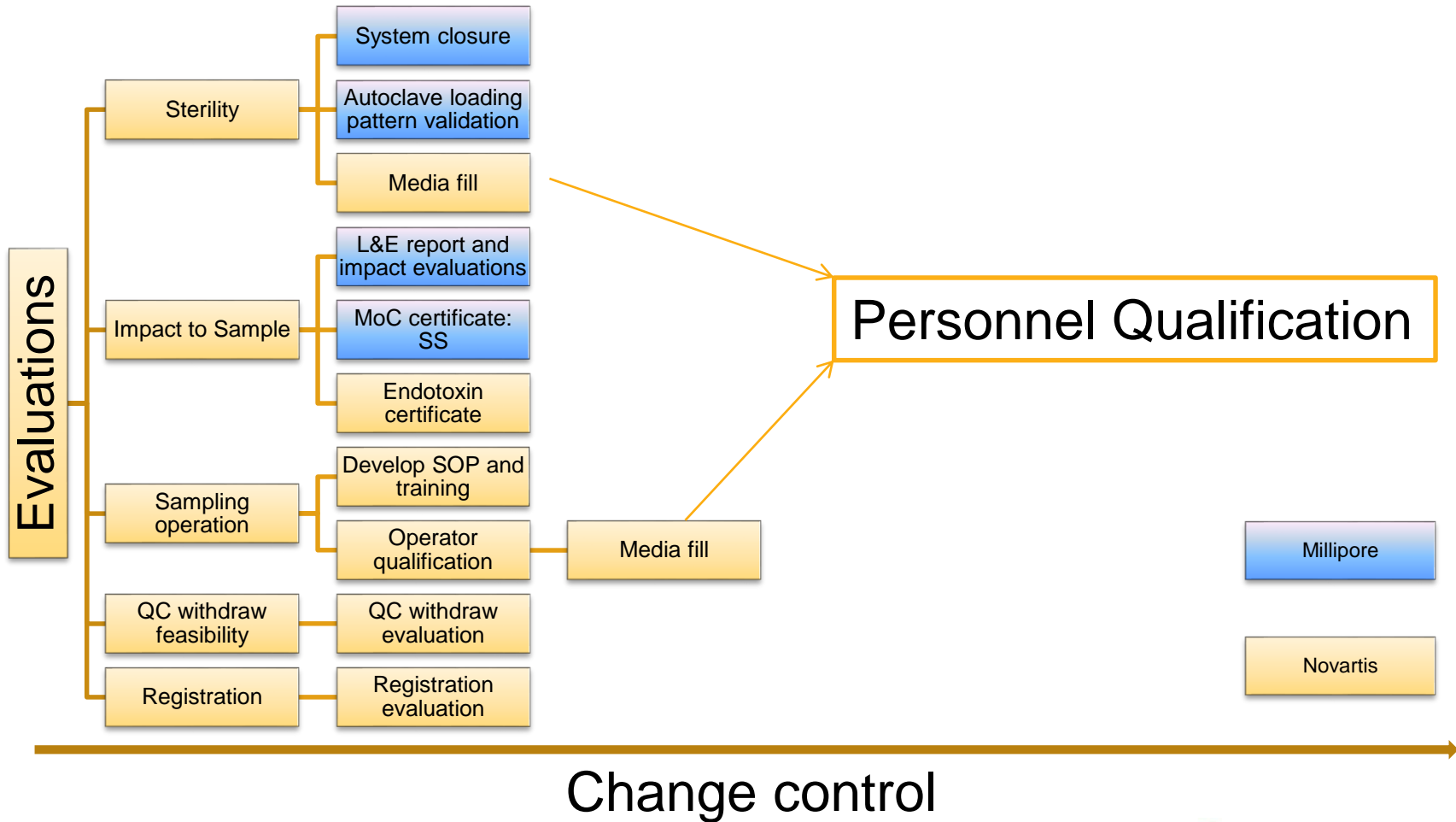
## set-up of the system



# Implementation of the change

## *Some considerations in change control*

### ■ Change control management





# Some to-do and not to-do

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## ■ To-do

- Wear glove during assembly
- assemble under LAF hood protection
- Put unused sampling tubes in sealed bag
- Disinfect surface before transferring to clean bench

## ■ Not to-do

- Not touch the product contact surface
- Not put product contact surface on table

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- Contact: 司阳 [yang.si@novartis.com](mailto:yang.si@novartis.com) +86-133-2571-1866

**THANKS**