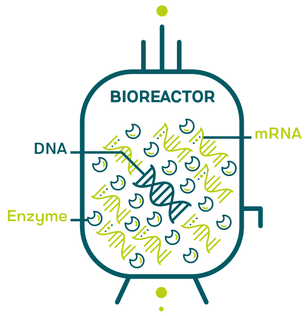
BNT162
Manufacturing process

Introduction

Our COVID-19 vaccine consists of a short segment of genetic material, called messenger RNA, that provides instructions for a human cell to make a harmless version of a target protein or antigen, which activates the body's immune response against the SARS-CoV-2 virus. mRNA can be produced at large scale in a short manufacturing cycle, which is unique to BioNTech and allows for a scale-up of manufacturing aimed at a worldwide supply.



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Step 1:
mRNA production for BNT162

To manufacture mRNA at a large scale, we use biochemical reactions, similar to those occurring in every cell of the human body. This reaction can be replicated with a bioreactor in a so called in-vitro transcription (IVT). This enzyme-based process "translates" a DNA template into mRNA. Due to the highly specific and effective enzyme RNA polymerase, more than 500 mRNA copies can be produced with one DNA strain.

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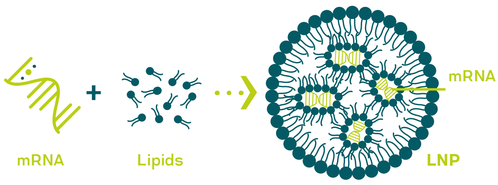
Step 2:
Drug substance purification and concentration

Following the mRNA production in the bioreactor, the mRNA is purified by a separating process and product-related impurities, including the DNA templates, are removed by using a proprietary purification process. After purification, the mRNA solution is concentrated. In a final step, the drug substance is filtered to remove any potential microbial contamination.



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Step 3:
Formulation

The mRNA in the drug substance needs to be appropriately formulated to ensure the delivery of the RNA to the particular target cells and is critical to protect the encapsulated mRNA from degradation after injection into the human body. Therefore, the mRNA is combined with a mixture of lipids to form lipid nanoparticles (LNP). The lipids in the BNT162-mRNA formulation are selected to deliver the drug substance to lymphatic cells to induce the immune response against the SARS-CoV-2 virus protein. The LNPs in the solution give the vaccine a slightly turbid appearance.

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Step 4:
Fill & Finish

The final manufacturing step is a sterile filtration and filling of the vaccine into vials. The vials are labelled and undergo a strict quality control before packaging. About 200 multi-dose vials fit in one carton and can then be shipped to the sites where individuals will potentially be vaccinated. On site, the mRNA-LNP formulation will be diluted with saline to adjust the concentration prior to the intramuscular injection.