



BIONTAINER

by BIONTECH



A sustainable solution to vaccine access in Africa



The learnings of the global COVID-19 pandemic: public health requires a globally coordinated effort and a better preparedness to address new challenges.



However, there is still a lack of global access to vaccines: Africa produces less than 1% of the human vaccines it uses.

(Source: <https://www.nature.com/articles/d41586-021-01048-1>).



BioNTech believes that mRNA is a powerful new drug class that is a scalable, innovative technology to help address the global challenge of vaccine access. We aim to make this technology globally accessible.

The challenge

Establishing GMP production for mRNA-based vaccines is complex and time-consuming

Technical solutions for manufacturing sites must **comply with internationally harmonized GMP standards**

Complex mRNA manufacturing encompassing 50,000 steps that have **highest quality standards**, including about 40 quality control tests for each manufactured vaccine batch to ensure safety and efficacy

transferring process and keeping the systems up-to-date and employing **highly qualified personnel**

The solution

Turnkey package that includes modular production units, GMP-compliant set-up and personnel training

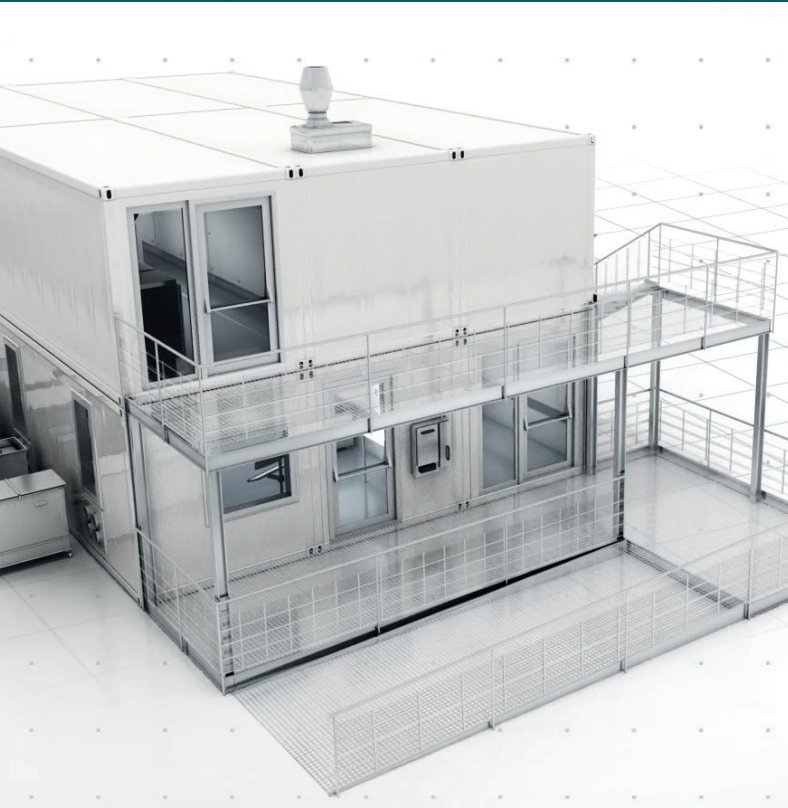
Container-based **"Plug & Play" approach with modular design, standardized equipment and software components** to support rapid set-up of fully functional mRNA manufacturing facility

The **GMP process implementation and maintenance will be facilitated** by validation packages, automation, digital solutions, as well as **local and global quality control**

BioNTech will initially staff the BioNTainers and train local employees to hand-over the site in the mid- or long-term

As a decentralized solution, BioNTainers aim to offer **greater independence and faster vaccine supply within the African Union** and support the **development of talent** as well as an **emerging biotechnology industry**

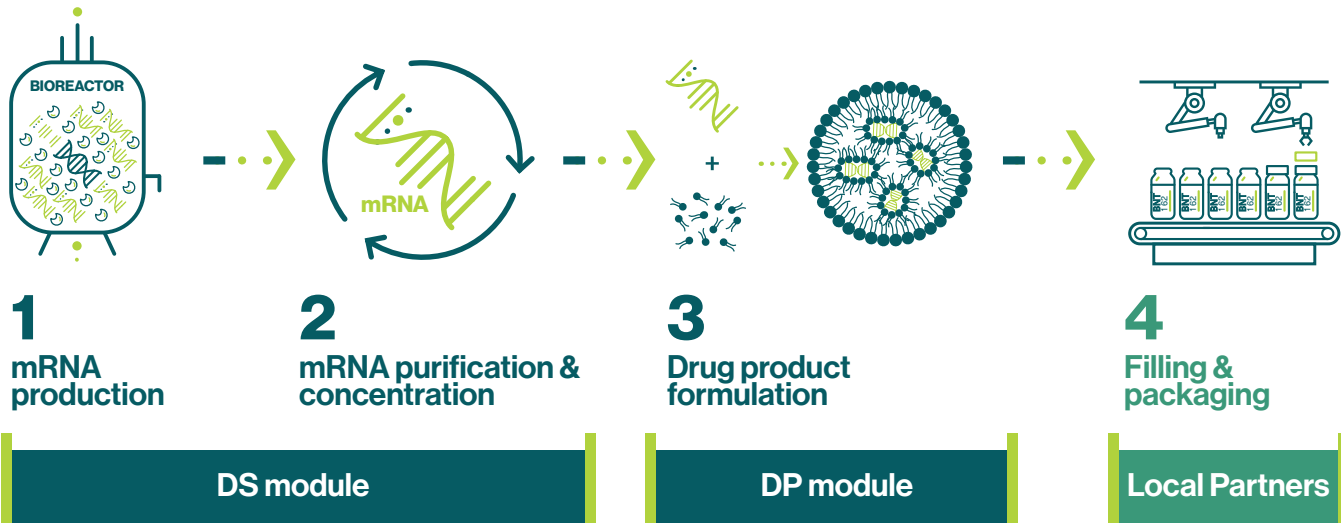
BioNTainers as a solution to promote sustainable local vaccine production in the African Union



Scope	12 containers
Structure	6 containers = 1 module > 1 drug substance (DS) module > 1 drug product (DP) module
Container size	ISO sized (2.6m x 2.4m x 12m)
Shipment	Shipped via freighter, truck and train
Production volume	E.g. approx. 50 million doses of the Pfizer-BioNTech COVID-19 vaccine
Production	BioNTech jointly with local support
Quality control	BioNTech jointly with local support
Local infrastructure	E.g. logistics, quality control labs, quality assurance set-up, warehousing, cold and frozen storage
Technical autonomy	Fully self-sufficient
Value offering	Single to multi-drug production & clinical trials

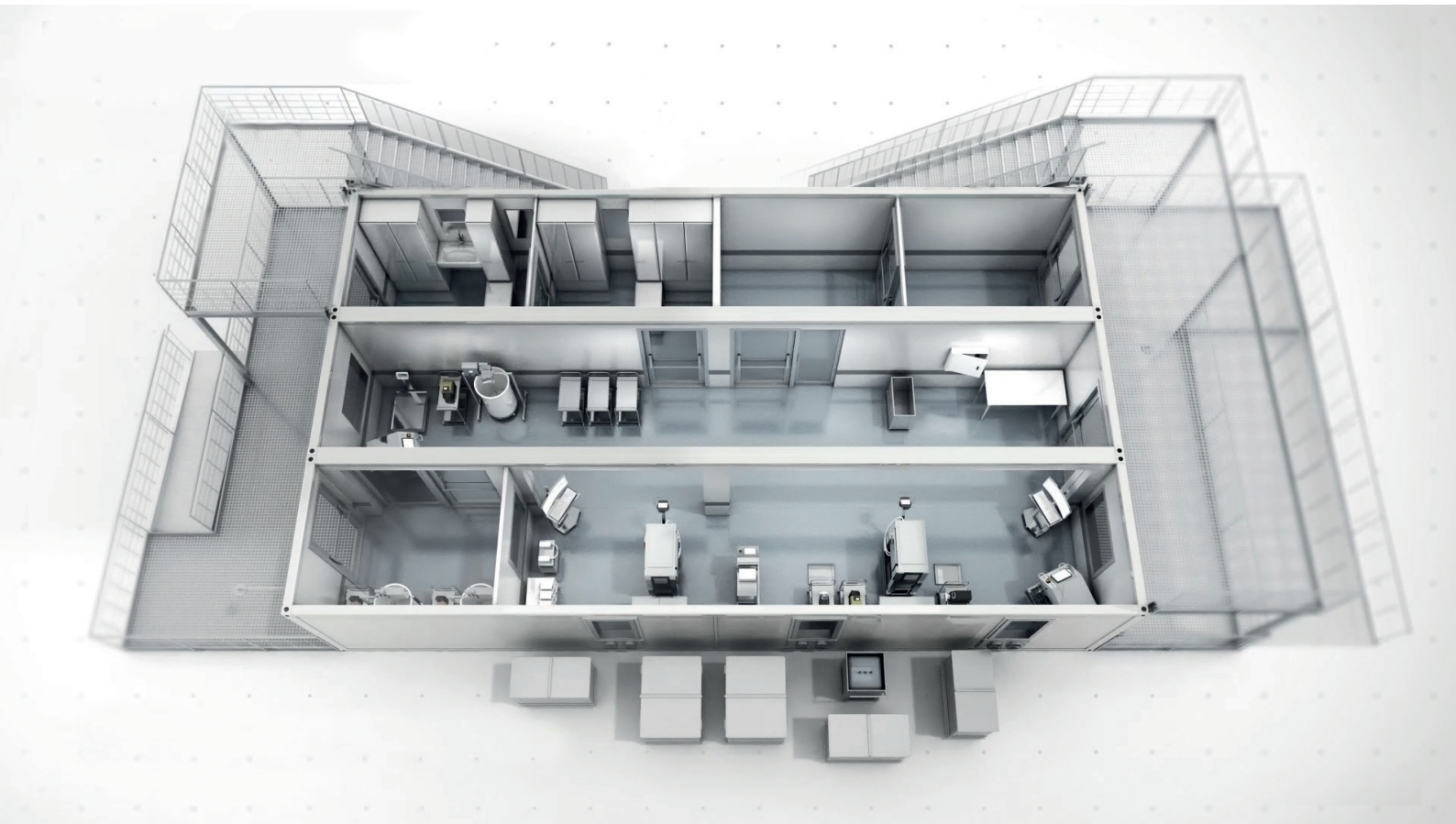


Overview of mRNA vaccine manufacturing process

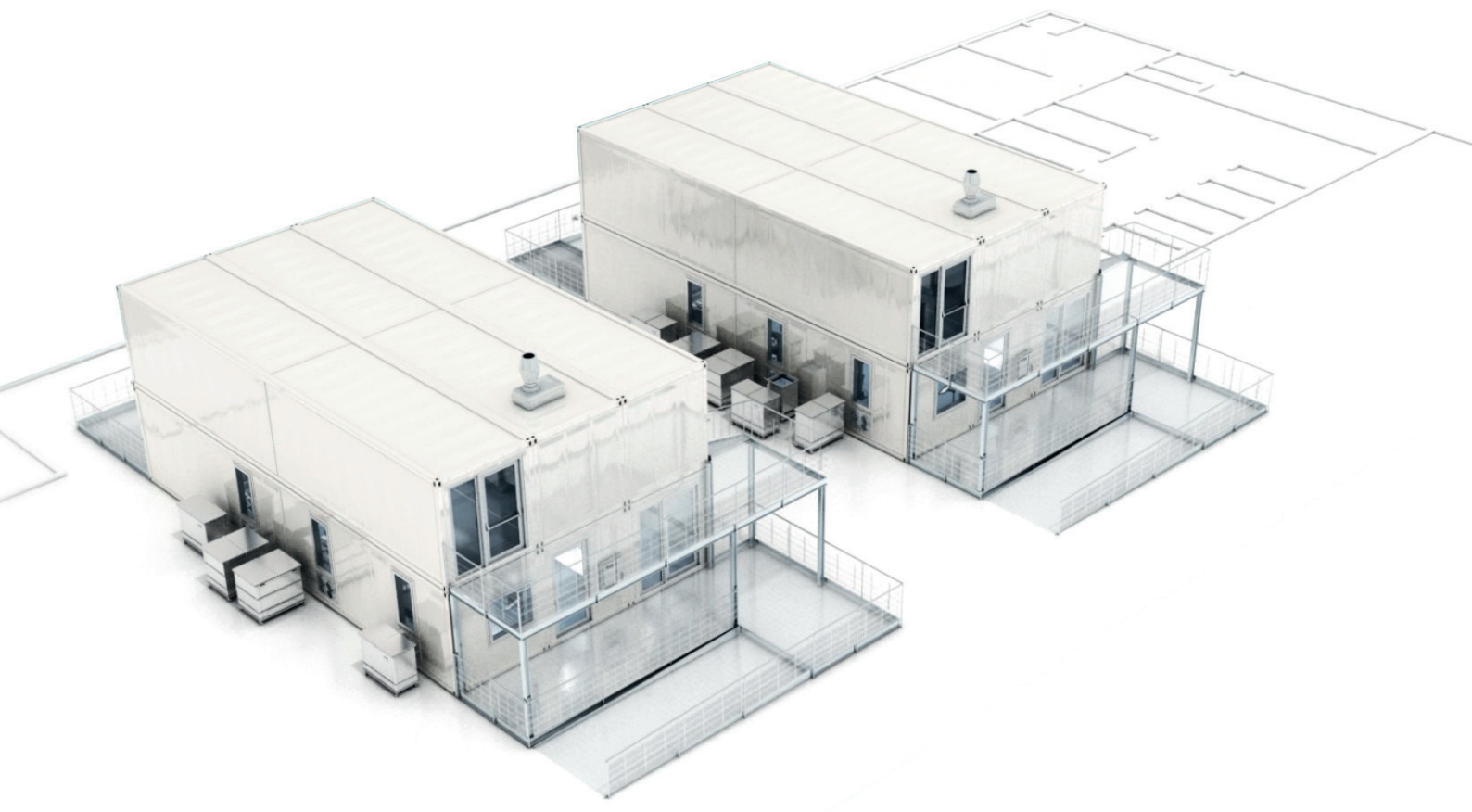


6 containers = 1 BioNTainer for Drug Substance

6 containers = 1 BioNTainer for Drug Product



How BioNTech's solution is being set up



1

Manufacturing of modules and procurement of process equipment coordinated at BioNTech's innovation center in Marburg. In parallel, construction of production hall in target location

2

Shipment and delivery of containers and equipment to target location after testing to verify functionality

3

Set-up at target location where infrastructure is provided on-site (e.g. power and water supply, labs for quality control and assurance, warehousing, cold and frozen storage)

4

Local qualification runs to ensure GMP-compliant vaccine production; training of local employees

5

Start of production