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Software-optimized production processes for BioNTech

Algorithms for manufacturing mRNA-based pharmaceuticals

Back in 2019, BioNTech was far from a household name. Nowadays, however, the pharmaceutical company from Mainz is world-famous for developing and producing Comirnaty®, a COVID-19 vaccine. The company's original aim was to develop personalized mRNA-based treatments to fight cancer – a goal that it continues to pursue to this day. Since 2016, a research team at the Fraunhofer Institute for Industrial Mathematics ITWM has collaborated with BioNTech to optimize the planning, management and documentation of their production processes. This work culminated in the development of two software platforms, one for vaccines and one for cancer treatments, which help organize and optimize the production processes at BioNTech today. These systems are in use and are continuously adapted and improved as situations and requirements change.

In just a few short years, BioNTech has grown from a small pharmaceutical company to an internationally active business with a global production network as well as value creation and supply chains that extend across the world. The company, which started out by developing individualized mRNA-based cancer drugs, managed to develop a vaccine against COVID-19 in record time. Manufacturing individualized medicines and producing hundreds of millions of vaccine doses requires detailed planning, coordination and management of the production processes involved. Working in collaboration with BioNTech, Fraunhofer ITWM in Kaiserslautern developed two software platforms that make it possible to implement planning and management processes for both cancer treatment and vaccination applications, and to adapt them to new requirements. "This isn't possible with commercially available software, it calls for a solution that uses flexible mathematical methods and models – a tailor-made solution that is not only specifically designed for the processes at BioNTech, but can also optimize them. In the long term, the software platforms will also help to more clearly distinguish the products according to the different regulatory requirements of the approval authorities, as well as supporting the automation of the processes." So says Dr. Heiner Ackermann, a researcher at Fraunhofer ITWM and the High Performance Center Simulation and Software Based Innovation in Kaiserslautern. At the beginning of the partnership with BioNTech, the processes underwent detailed analysis, modeling, and structuring, based on information supplied by the pharmaceutical company. "First of all, we had to apply a structure to BioNTech's specific requirements and translate this into the language of

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mathematics,” explains Dr. Ackerman, who has been the project manager responsible for developing and optimizing the software platforms since December 2016.

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Complex pharmaceutical processes, diverse challenges

This was no easy task, especially given the diverse challenges associated with such complex pharmaceutical processes as producing individualized cancer drugs. These challenges can stem from the particular difficulties posed by bioprocesses such as fluctuating process times and higher reject rates, for example, due to defective tissue samples. “Deviations and fluctuations in the process time crop up frequently in bioprocesses, but it is still necessary to maintain the utmost quality standards. The methods of producing individualized medicines are different from established processes in the pharmaceutical industry. Every step must be carried out extremely carefully and on an individual basis for each cancer patient, and the batches are also considerably smaller than in conventional processes. Ultimately, this makes the granularity of the mathematical model an important factor,” explains Dr. Ackermann.

Country-specific regulations

At the same time, in view of the extensive country-specific regulatory requirements for both cancer treatments and vaccine development, manufacturers need customized scheduling processes so that they can update their production plans in an optimal way. These schedules may provide important information such as the dates that each individual patient will receive their treatment.

BioNTech also relies on a network of external service providers to produce Comirnaty®. Each of these contract manufacturers specialize in certain process steps. To manage this network, it is necessary to make adjustments to account for the regulatory requirements of the various countries and the limited shelf life of the intermediate products. Furthermore, when developing vaccines, product variants must be considered during the production planning stage, for example, to account for the raw materials required, contractual partners, capacities and batches, production machines and locations.

Software with star quality

While these challenges present a considerable obstacle, the software platforms developed by Fraunhofer ITWM can tackle and ultimately overcome them. Now, at BioNTech, the softwares are central tools for planning, managing and documenting production. They also ensure long-lasting, stable production processes for the manufacturing of vaccines and individualized mRNA-based cancer treatments. “The solutions optimally support production planning and are used on a day-to-day basis,” says Dr. Ackermann. The platforms will be gradually expanded and adapted to developing requirements, as well as being integrated into BioNTech’s IT systems. “Thanks to our successful collaboration with the Fraunhofer ITWM team, BioNTech has acquired tailor-made solutions

that provide vital support in high-stakes situations. We will continue to use the software-optimized processes in other areas in the future,” says Dr. Oliver Henning, Senior Vice President Operations at BioNTech.

For more information on the High Performance Center Simulation and Software Based Innovation, see:

[Website for the High Performance Center Simulation and Software Based Innovation \(leistungszentrum-simulation-software.de/en.html\)](https://leistungszentrum-simulation-software.de/en.html)

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Fig. 1 BioNTech COVID-19 vaccine vial

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