Software-Optimized Production Processes at BioNTech

Since the Mainz-based company developed the first broadly approved vaccine against COVID-19, the name BioNTech has been widely known. The real concern of BioNTech SE is the development of individualized therapy for cancer patients. For both use cases – the production of the individualized cancer drugs as well as the Corona vaccine – researchers of the Fraunhofer ITWM have developed a software platform, with which the production process can be controlled more effectively.

The production of individualized drugs is complex from both a technical and organizational perspective and differs fundamentally from established processes in the pharmaceutical industry. Individualization raises a variety of novel issues and requires new approaches to production organization and planning. For example, all steps must be carried out individually for each patient. For many years, this was not the focus of established solutions for production planning.

Customized Solution

To develop a platform that plans and coordinates these processes is the task of the team around Dr. Heiner Ackermann, head of the department "Optimization – Operations Research". First, the previous knowledge of the scientists at BioNTech had to be combined with that of the ITWM researchers. "Finding a common language, a common understanding of processes, was an essential part of our work," says Ackermann. Modeling, structuring, and analyzing data and processes followed. The end result was software that could be used to plan and organize the manufacturing processes of the individual drugs, and which provides a completion forecast for the respective patients.

The researchers at Fraunhofer ITWM continuously adapt the software to the changing requirements of vaccine production.

Automated Processes for Increasing Production Figures

Several of BioNTech's oncology product candidates are already in advanced stages of development and will soon enter pivotal trials. Production for commercial distribution is already being prepared today. This also has an impact on the planning processes: They sometimes need to be adapted and expanded, particularly with regard to greater automation. Preparations for this are already underway. "With a few hundred patients, manual intervention in the process is still possible. This will no longer be possible with several 10000. Automated processes and additional decision support options may be required there," says Ackermann, describing the advantages of an automated planning process.

Whether cancer therapy or vaccine production – the Fraunhofer ITWM and BioNTech develop software to improve the planning, coordination, and documentation of complex production processes.

And Then Came Corona

With the onset of the Corona pandemic, BioNTech is also using its expertise on mRNA-based anticancer drugs to develop a vaccine. "I learned from a newspaper article that BioNTech was planning to develop a vaccine. Shortly thereafter, the company inquired about working with us on new software solutions. That's when chaos briefly broke out for me, but of course we got to work," Ackermann looks back.

The manufacturing process for the vaccine is much less complex than that for the individual cancer drugs. The critical issue here is production capacity for the hundreds of millions of vaccine doses required. The solution is for BioNTech to work with contract manufacturers who specialize in certain process steps.

The Fraunhofer ITWM and BioNTech have established software that allows the company to plan, coordinate, and document the production network and the individual process steps. "Now we are working on adapting the platform to the ever-changing requirements. As the production process evolves, we are also developing the platform. In some cases requirements change on a weekly basis, but this is a challenge that we're coping very well with," says Ackermann, describing the ongoing collaboration.

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