

TECHNOLOGY TRANSFERS FOR THE COVID19 VACCINE SUPPLY

Four steps to success

In order to increase production capacities for medicinal products, the manufacturing processes and the accompanying analytics can be transferred to other organisations. A so-called technology transfer is required in order to establish pharmaceutical products at a new production site. This process includes the transfer of know-how, the procurement of equipment or raw materials where necessary, and a series of trials to establish the manufacturing process and ensure the safety and comparability of the medicinal product produced. These transfers, among other things, are the current bottleneck in the supply of COVID-19 vaccines.

Production capacities can be increased by expanding the production facilities on the one hand and by integrating additional production sites on the other. In order to avoid restricting production through conversions, the integration of further production sites within and outwith the company remains as an essential instrument. This is achieved through process transfers, in which the process is transferred from a "Sending unit" to a "Receiving unit".

1. Selection of a suitable contract development and manufacturing organisation (CDMO)

The selection of a suitable partner or CDMO is essential for a rapid and successful transfer. The availability of suitable manufacturing facilities and laboratories plays an essential role here, as does the CDMO's experience with biotechnological production processes. It is also important for the total production capacity available at the CDMO to be high enough that the number of transfers, and therefore the organisational workload, can be kept low.

2. Focus on all resources

The sending company is equally critical in contributing to fast, efficient transfers. The manufacturing process must be robust so that it can be easily standardised. In addition, a CMC and transfer strategy with an appropriate documentation package in place allows all resources to be fully focused on technical implementation. Furthermore, any transfer must be drawn up on the basis of risk in accordance with ICH Q9 – if well founded, risk-based decisions can significantly speed up projects.

3. Standardisation as the key

The keyword for speeding up a process transfer - already an essential guiding principle when it comes to COVID vaccines - is standardisation. The manufacturing processes for mRNA-based vaccines can easily be standardised in terms of the manufacturing process and the accompanying analytics. The individual process steps fall back on proven partial steps and are put together in a modular fashion. Complex, efficient cooperation is also essential in order to be able to rapidly adapt the processes in view of SARS-CoV2 variants.

However, standardisation can lead to supply bottlenecks. The process owner can provide valuable start-up assistance to the CDMO by providing scarce raw materials and coordinating laboratory capacity.

4. Building expertise with the right partner

An experienced partner/supplier can massively accelerate the implementation of a tech transfer and contribute to its success, for that matter. Particularly when the partner has a lot of experience in transfers, especially for similar processes and molecules, and can draw on both strategic know-how and detailed expertise in the specific areas.

The first step is to find a suitable CDMO and to develop a comprehensive CMC and transfer strategy in order to pool resources for technical implementation, as well as to simplify process transfers by means of standardisation, to anticipate supply bottlenecks in the process, and finally to further build expertise by choosing a suitable partner.



Expert

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