BIO DEUTSCHLAND
Biotechnologie-Industrie-Organisation Deutschland e. V.

Success factors

for biotechnological vaccine production in Germany

Introduction

The fight against the pandemic rests, among others, with a group of medical biotechnology entrepreneurs in this country. For over 30 years, they have formed the link between science and the pharmaceutical industry in Germany. Most of them have worked in research themselves. In order to apply their discoveries and make them accessible to patients, they have founded start-ups and steadily advanced their research and development. The pandemic has deservedly brought them into the spotlight, and they are showing what they can do. In this way, biotechnological innovations are quickly making an important contribution to the fight against coronavirus infections.

In the view of innovative biotechnology companies and the firms that make up BIO Deutschland, the sector association of the biotechnology industry, the following factors are critical for vaccine production success:

1. Specialised knowledge and expertise:

Knowledge of the biological processes that ultimately lead to the vaccines we are discussing today is highly specialised – for both vector vaccines and messenger RNA (mRNA) vaccines. The latter approach is entirely new. BioNTech's mRNA vaccine is the first COVID-19 vaccine ever approved in the western world. It is also the first time an mRNA agent has ever been approved.

Biotech vaccines, such as those with an mRNA agent, are comparatively new technologies that have been developed and advanced as an innovative approach for some time now. In the early stages of the pandemic, large-scale production processes were already in place for them, but there weren't enough large-scale facilities with an established supply chain for the raw materials and excipients needed for such quantities. It is not only the ribonucleic acid itself, but also the excipients, i.e. plasmids, vectors, enzymes, bacterial strains, cell lines or lipids, that are produced biotechnologically. This requires not only expertise and suitable production facilities, but above all, experts and sufficient quantities of accessible raw materials.

2. Scale:

A large proportion of medical biotech companies are currently in clinical phases with product developments that are still far from being officially approved. Scaling up to industrial quantities requires a good deal of expertise, time and investment. The facilities for this are also specific and need to be financed, built or converted, approved and run. So far, investments in large-scale biopharmaceutical production have been very tentative, despite many requests. For their part, banks with their financial instruments are not prepared for innovative biotech companies or their development and production concerns. Such companies (still in product development without existing revenues) do not fit into the typical approach.

For this reason, many biotech companies work with contract development and manufacturing organisations (CDMOs), and establish extensive networks here (e.g. CureVac). Alternatively, they take over a manufacturer and integrate it into the company's operational structure (e.g. BioNTech Innovative Manufacturing Services GmbH – BioNTech IMFS). The third possibility is that companies scale up their production themselves (e.g. CureVac with the construction of its own industrial production facility in Tübingen and BioNTech with the takeover of Novartis' Marburg plant). However, all these paths take too long when a pandemic breaks out and are also not without difficulties.

3. Supply chains:

According to their own statements, BioNTech and CureVac are working with manufacturer networks and what are often completely new supply channels for them. These supply chains are not yet fully developed and must first prove their viability. Decentralised production can replace central scaling to a large extent, but poses greater challenges in formulation, completion and bottling, as well as in transport.

Also, the “weakest link” in the chain always determines the speed of production. Often, it is either urgently needed substances with low profit margins or those that are based on specialised biotechnological expertise (see above) that become scarce, such as plasmids, vectors, enzymes, bacterial strains and cell lines. No link in this value chain was previously designed for such large quantities. With innovation, other links in the value chain have become relevant and in greater demand. In addition, approval processes are not harmonised within Europe, and CDMOs with several production plants have to reapply for approval in each member state. There are also consequences when typical supply chains are disrupted, e.g. due to government decree (Defense Production Act, etc.), the closing of borders or the deliberate patronage of domestic companies.

4. Stockpiling:

Biotech companies, which usually work on a smaller scale, are not used to or cannot afford to stockpile. Some vaccine manufacturers have already taken a high risk by pre-producing large quantities without knowing whether the vaccine will work and, of course, before final approval has been granted. Pre-orders and purchase guarantees can only cover part of the costs. The production of products that are still required for vaccine production – e.g. plasmids – is often assumed by biotech companies, which in turn cannot produce these important components in advance at their own expense.

5. Security – the need for protection in a pandemic situation:

Production, delivery, storage and, of course, research and production data must be protected – from criminals in the real world and in cyberspace. Not only must the companies at the core of production, such as manufacturers of active pharmaceutical ingredients (APIs), be safeguarded, but also suppliers.

6. Improvement possibilities:

- Uncomplicated, rapid approvals for biotechnological processes, products and facilities, as well as the best possible support from public agencies and policymakers.
- Purchase guarantees for suppliers or financial support for vaccine manufacturers, enabling comprehensive stockpiling to cushion risks and thus ensure sustainability for production setup (capex) and maintenance of operations (opex).
- Harmonisation of production licensing procedures across Europe.
- Ensuring access to raw materials within the EU, e.g. by supporting European suppliers.
- Amending financing options for production expansion, including for companies that are still in the product development phase, and significantly improved depreciation allowances for investments in plants.
- Basic political support for a strong biotech industry in Germany (ecosystem for innovation financing, secure protection of intellectual property, scaling improvements, skilled labour, targeted funding of disruptive approaches, despite the risks involved).
- Better planning security for entrepreneurial decisions through suitable political actions.
- Direct political involvement in biotechnology issues and decisions over the course of the pandemic and beyond.
- Creation of a sustainable pandemic concept for Germany and Europe.

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