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Novartis' Contract Manufacturing Contribution To Biotech

by

Scrip speaks to Global Biotech Cooperations, the contract manufacturing team of Novartis Operations, about their strategic direction and contribution to biotech innovation.

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The biotech field continues to be one of the most exciting in life sciences, with new modalities and innovative technologies bringing more effective, promising treatments to patients in need. Manufacturing these products can be complex, capacity limited, and high levels of expertise required.

In an exclusive interview with Scrip at BIO International 2023, Dr. Harald Oberegger, global head of business development for Novartis' contract manufacturing team, Global Biotech Cooperations, discussed the benefits of a contract manufacturing organization (CMO) team in Novartis Operations, their broad offer and role in contributing to biotech innovation.

Q Scrip: What prompted Novartis to form Global Biotech Cooperations, and can you tell us about the founding of the contract manufacturing organization?

A Oberegger: Over the years, Novartis has built up a unique, global development and manufacturing network, with end-to-end capabilities and cutting-edge technologies.

Our medicines reached around 743 million patients in 2022. For years, to serve even more patients, we have also been providing contract manufacturing services for specific technologies like microbial, building a solid customer base over the last 20 years. In the past 2-3 years we have received more requests for other, newer technologies like cell and gene therapies and RNA as well. These emerging technologies may represent both an opportunity and a challenge for some companies, struggling to get the required capacity and the best quality to bring their medicines to patients in the right timeframe. Our driver to form Global Biotech Cooperations (Novartis' contract manufacturing unit) was to act more strategically as a contract manufacturer, providing external companies access to our manufacturing and development network. Combined with our regulatory and logistical strengths, we believe we can help other companies in bringing more innovative products to patients in need.

Q Scrip: How does the contract manufacturing business fit into Novartis' overall strategic direction?

A Oberegger: We have a flexible and agile manufacturing network of more than 35 production facilities globally, complemented by an external network of strategic partners. We produced more than 72 billion treatments across our global production sites in 2022. Across our network, we continue to adapt our manufacturing capabilities to facilitate our shift toward making more specialized medicines. Patient health and safety is fundamental to us. We cannot deliver on our purpose if we do not provide safe, high-quality medicines. Additionally, we continue to reduce emissions, water consumption and waste sent for disposal in our own operations, in line with our targets.

This vision will not change; we are steadfast in our commitment to making available both our increased capacity in our biotechnology and cell and gene sites, as well as leveraging our highly regarded capabilities in these areas – our skills, assets and people – to help more patients.

Q Scrip: What does Novartis offer in comparison to other CMOs?

A Oberegger: We aim to be a trusted partner for companies in manufacturing their medicines, at good quality and with competitive pricing. Bringing medicines to market may be challenging today, with specific manufacturing technology difficulties, quality issues, complex regulatory pathways and constant logistical tasks. We can support with our teams' extensive knowledge and long-standing experience in overcoming those challenges.

There are a number of key benefits of Novartis acting as a large CMO. We can deliver high quality medicines in a sustainable manner, and offer many different technologies – such as mammalian, cell and gene therapy, fill and finish – under one quality system. Additionally, our financial stability and commitment to capacity allows reliable long-term cooperations. We can also offer a stable and sustainable global supply chain, as we have long standing relationships with a network of global suppliers.

Q Scrip: What stages of manufacturing is the company focusing on, and for what types of drugs?

A Oberegger: We offer our global development and manufacturing network with end-to-end capabilities (drug substance to drug product and final dosage forms) for technologies or drugs such as mammalian and microbial fermentation in all scales; drug product filling and packaging and logistical services; specific DNA and RNA, both m-RNA and siRNA manufacturing expertise; and cell and gene therapy manufacturing capabilities in the US and Europe.

Q Scrip: Can you comment on your contract manufacturing deals?

A Oberegger: Building on our proven success in partnering with other companies to support production of vaccines and therapeutics for COVID-19, we have signed many deals covering various technologies like microbial, mammalian, cell and gene therapies, fill and finish, and mRNA manufacturing. Some of these can be found on our website under [contract manufacturing news](#).

Q Scrip: What's next for the organization?

A Oberegger: We are living in very exciting times. The biotech and cell and gene space has seen rapid development over the last few years, and we are open to continue building other successful partnerships in these areas. Besides that, Novartis has invested in a viral vector facility in Slovenia and will further invest in mammalian large scale manufacturing in Kundl (Austria) and Singapore, as well as further expanding our development and manufacturing capabilities. All this is to improve our operations, create value for our business and improve the lives of millions of people around the world.