Sandoz Biosimilars
Quality, Heritage and Excellence through Novartis Manufacturing
High-quality biologics

Development and manufacturing at Novartis

Biologics, including biosimilars, are changing healthcare systems – improving and extending the lives of millions of patients worldwide.

Novartis has a world-leading portfolio and pipeline of reference biologics and biosimilars.

Novartis develops and manufactures these complex molecules to industry-leading quality standards on a large scale, ultimately helping transform patients’ lives:

- 10 sites on three continents
- Over 5,000 employees
- ‘End-to-end’ technical development and manufacturing capabilities, i.e. producing biologics in a single location – from raw materials to packaged medicines.
- Investing in state-of-the-art technologies and facilities at global locations that will expand technical capabilities in process development, devices and manufacturing.
Heritage in manufacturing

70 years of biotechnology expertise

Novartis – through its Sandoz division – has been at the forefront of the biotechnology revolution for over seven decades, and the pioneer and global leader in biosimilars since a center for the manufacture of penicillin was founded in Kundi, Austria in 1946.

Novartis is the global leader in the development and manufacturing of recombinant biotechnological medicines, producing more than 25 different recombinant proteins for the Sandoz division and other leading companies.

In 1996 the first biosimilar development program was initiated by Sandoz, resulting in the launch of the world’s first biosimilar 10 years later (Omnitrope® in the EU, 2006). Sandoz markets biosimilars in 86 countries around the world, with a total of more than 340 million days of patient experience.

References:
2. Periodic Safety Update Report 10 (Somatropin; Sandoz internal report), Data on file: 14 Nov 2016
Producing biologics under one roof

‘End-to-end’ technical capabilities

Access to and operation within the Novartis network enables optimal coordination and utilization of facilities. The result is a streamlined transfer of medicines from development to packaging. These ‘end-to-end’ technical capabilities ensure the reliable development and manufacture of industry-leading quality biologics.

The Novartis development and manufacturing functions

<table>
<thead>
<tr>
<th>Drug Substances</th>
<th>Drug Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td>Technical</td>
</tr>
<tr>
<td>Development and Manufacturing</td>
<td>Development and Manufacturing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Packaging and Devices</th>
<th>Analytical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Development and Manufacturing</td>
<td>Research &amp; Development and Quality Control</td>
</tr>
</tbody>
</table>
Novartis facilities operate in full compliance with Current Good Manufacturing Practice (cGMP) regulations, which are an integral part of the comprehensive quality assurance system for biologics.

The Novartis manufacturing facilities for recombinant medicines are regularly inspected by local and international health authorities, such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and many others.

Novartis, through the Sandoz Regulatory Department, pioneered the regulatory pathway for biosimilars in the US and EU and has a proven track record of medicine approvals.

Quality at every stage of the process ensures each medicine fully meets requirements.

The Novartis sites are dedicated to developing and manufacturing industry-leading quality biologics. All sites meet international quality and regulatory requirements and all activities are carried out by highly experienced personnel in a fully cGMP-compliant setting.

Three of these sites are state-of-the-art facilities that develop and manufacture Sandoz biosimilars: Kundl and Schafftenau in Austria, and Mengeš in Slovenia with plans to expand in to other worldwide locations.
BioInject at Schaftennau, Austria

At the frontier of manufacturing biologics

BioInject is a cutting-edge facility that manufactures pre-filled syringes and devices for Sandoz biosimilars and Novartis reference biologics. The facility has the capacity to fill 18,000 syringes per hour and package 100 per minute.

The facility provides ‘end-to-end’ technical development and manufacturing capabilities with quality-control processes at each stage of the process, from analysis to storage.

BioInject will play an important role in driving the next wave of biosimilar and reference biologics growth at Sandoz and across the Novartis group – helping address an unmet medical need and broaden patient access to biologic medicines.