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 **SANDOZ**
Biopharmaceuticals

a Novartis company

BIOTECH MANUFACTURING SOLUTIONS

4 YOUR SUCCESS



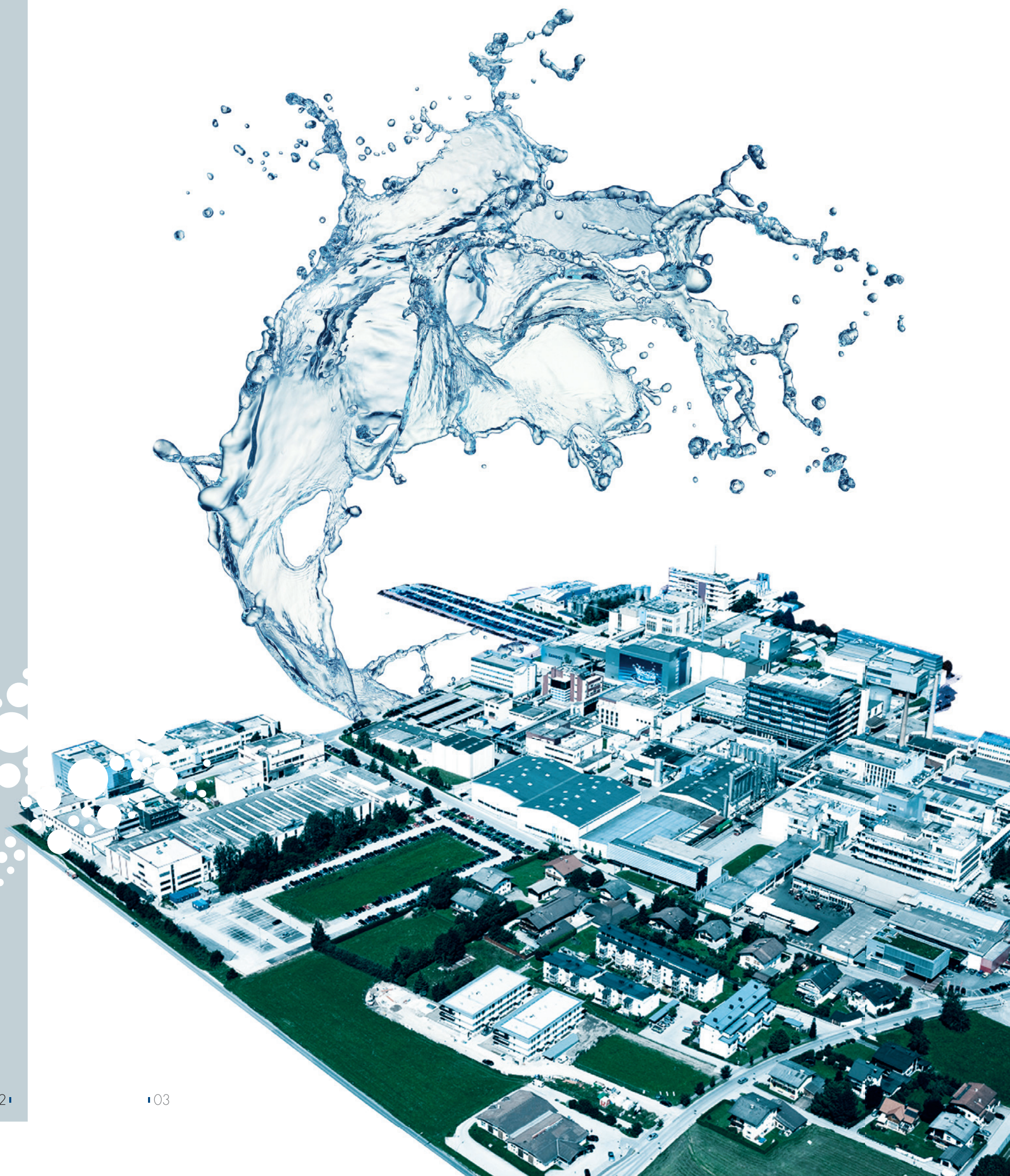
For your advantage: Experience. Quality. Reliability. Productivity. Based on these values, Sandoz has long been recognized as a global leader in the development and cGMP-compliant production of recombinant biotechnological products, specializing in the two major manufacturing technologies - microbial (peptides/proteins) and mammalian cell culture (monoclonal antibodies/glycosylated proteins).

LEADING THE WAY IN RECOMBINANT TECHNOLOGIES

The comprehensive know-how is based on more than three decades of experience in the development and production of recombinant products serving customers worldwide. Building on this expertise, you have broad variety of integrated services: innovative expression systems, process development, scale up, production of recombinant products derived from microbial systems and mammalian cell culture.

Sandoz has a substantial and highly successful track record of top-level partnerships spanning several decades, geographies and technological areas. We are currently manufacturing more than 30 different recombinant products for well-known pharmaceutical and biotechnology companies located in the US, Europe and Japan.

What can we do for you?



EXPERIENCE QUALITY RELIABILITY PRODUCTIVITY
4 YOUR SUCCESS



A comprehensive development team is available to support process development, process optimization and process characterization studies.

EXCELLENCE IN DEVELOPMENT AND PROCESS TRANSFER

The Sandoz lab development groups, which are located in Austria and Slovenia, fully understand what it takes to successfully execute large scale manufacturing processes. Dedicated teams use integrated development approaches at all process stages from cloning to downstream process development to ensure the optimal combination of innovation and process economics.

In addition, dedicated pilot plant facilities up to 150L scale are available for both microbial and mammalian cell culture products. These facilities are operated by a highly customer-focused team with extensive expertise across analytical development, technology transfer and scale-up.

With its proprietary N^{PRO} fusion technology, Sandoz has developed a novel expression system for peptides and proteins that ensures controllable autoproteolytic cleavage, resulting in an authentic N-terminus. This effective and high-yield expression technology offers you a highly cost-competitive option for manufacturing peptides and proteins.

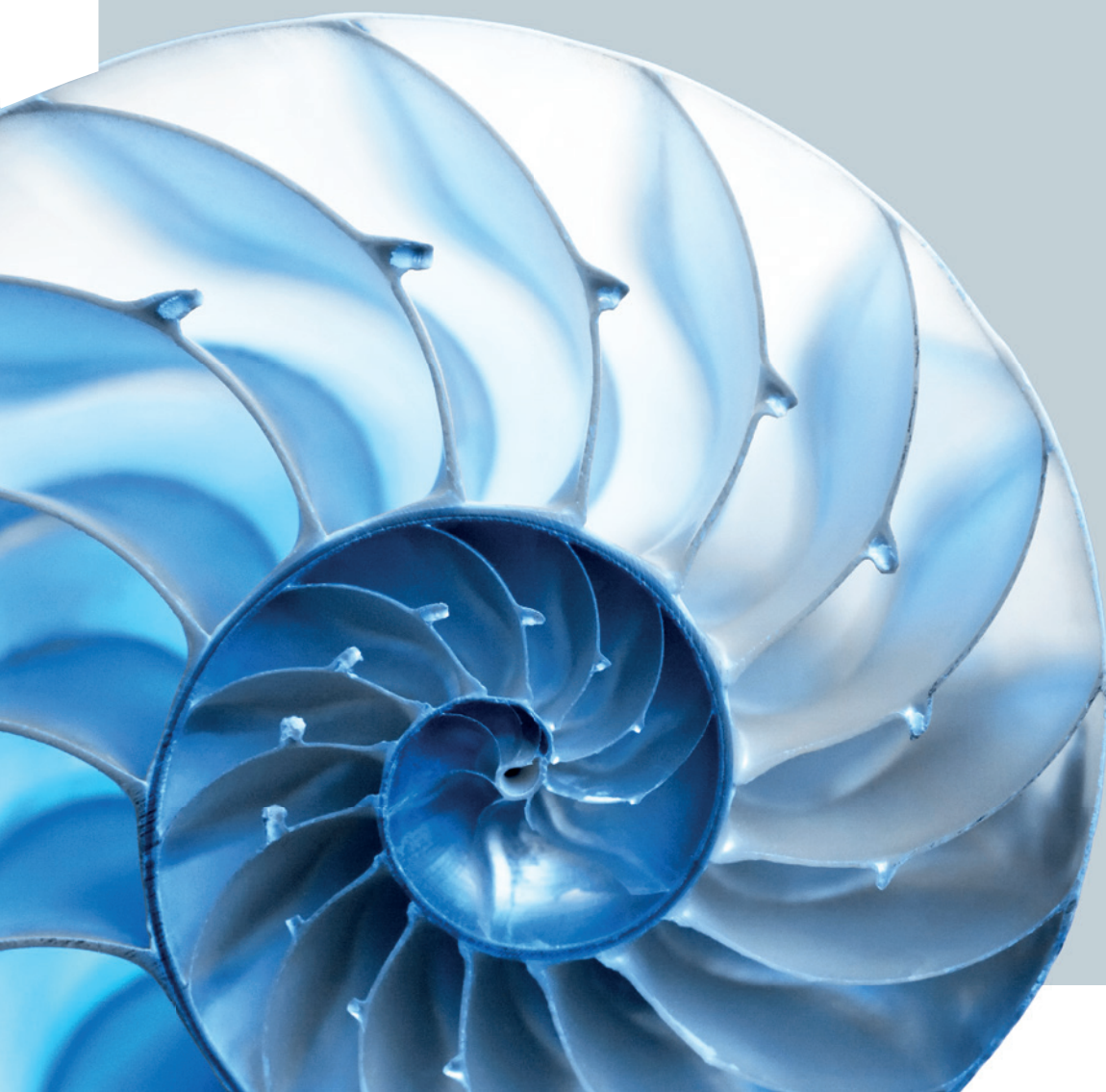
You have the tasks. Sandoz has the resources, the facilities, the systems - and the right people to make the most of them. For your success.



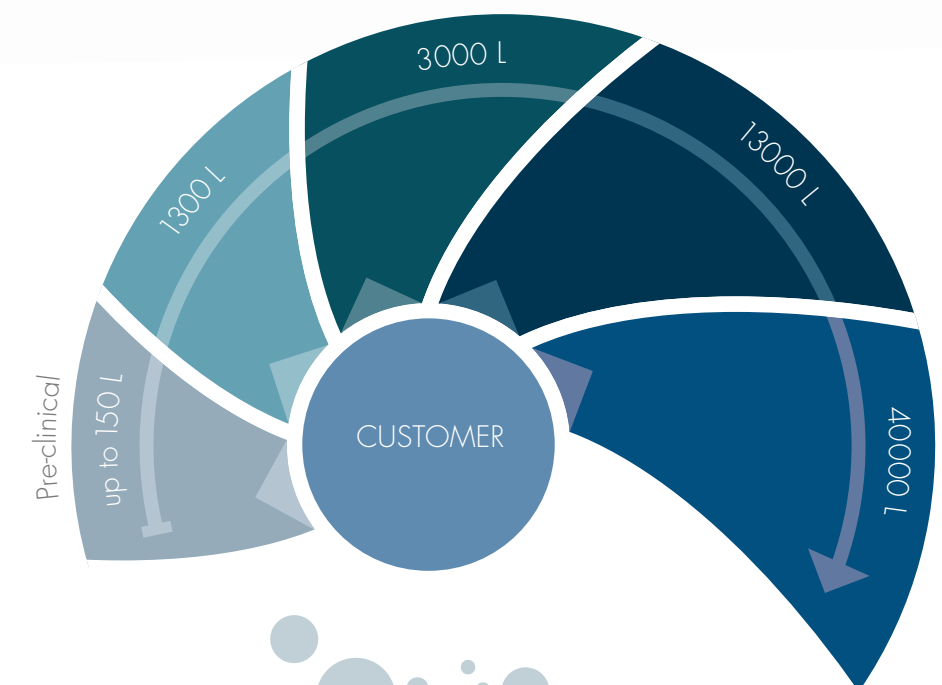
As our partner you get access to leading global technology in development as well as large-scale production capacity. Sandoz provides you with the flexibility you need to successfully develop and produce innovative recombinant products that address unmet medical needs and transform patients' lives.

WORLD-CLASS IN MICROBIAL MANUFACTURING

Sandoz has four cGMP manufacturing lines in Kundl, Austria that are available for both clinical and commercial scale manufacturing of your microbial-based products. We offer customized solutions with our ability to handle increasing demand levels quickly and efficiently without the need for costly and time-intensive site transfers.



SCALABILITY MICROBIAL
MAIN BIOREACTOR VOLUME



Various state-of-the-art manufacturing facilities are available in Austria and Slovenia to manufacture clinical and commercial material at required quantities. The facilities meet all international quality and regulatory requirements.

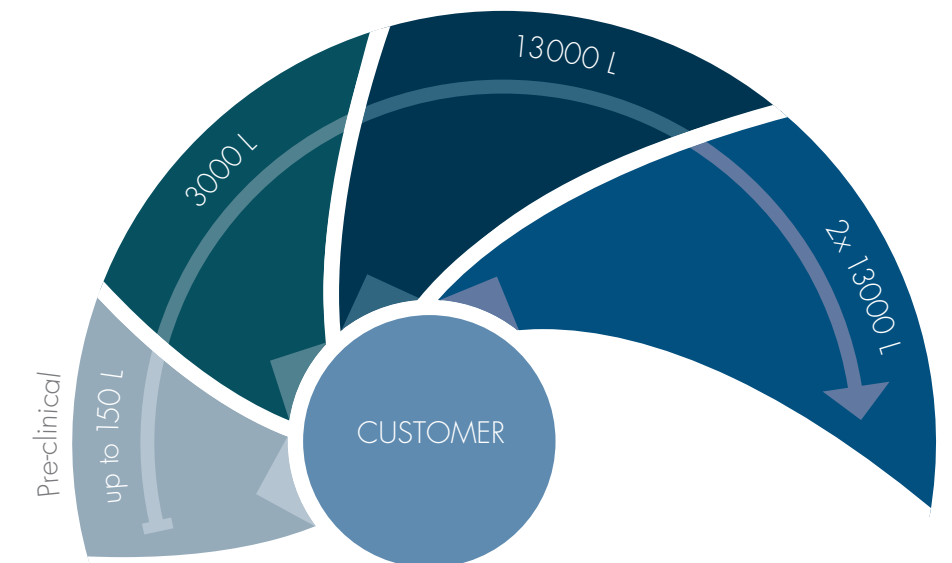
NEW HORIZONS IN CELL CULTURE MANUFACTURING

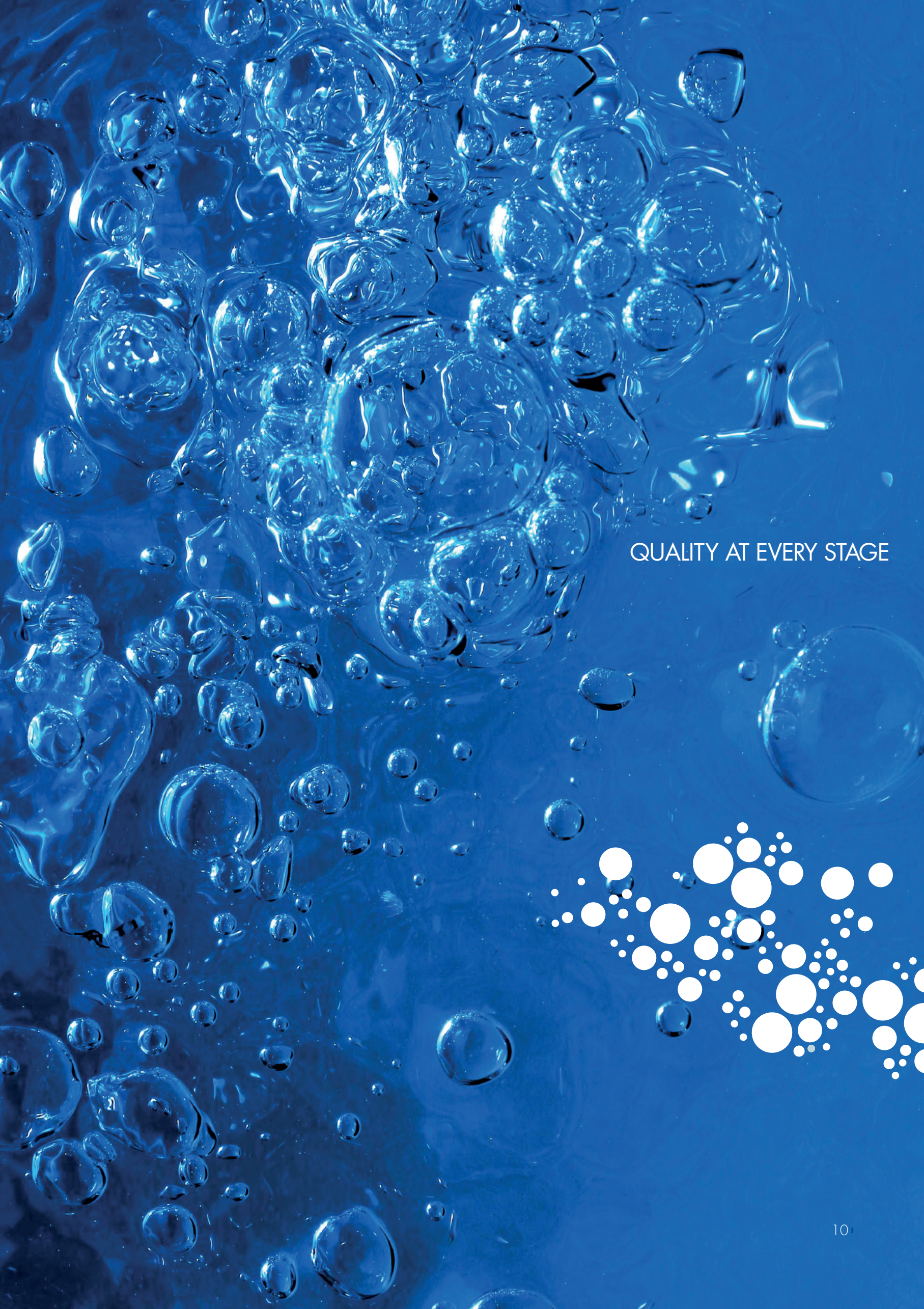
All manufacturing activities are carried out by highly experienced personnel in a fully cGMP-compliant setting and all facilities are designed as multipurpose plants. The flexible design of production capabilities and our fully integrated service offering allows to choose the optimal scale for different phases of development, as well as for subsequent commercial manufacturing, on a case-by-case basis.

This set-up offers you solutions that are not just cost-efficient, but fully optimized across the board.



SCALABILITY MAMMALIAN
MAIN BIOREACTOR VOLUME





QUALITY AT EVERY STAGE

Quality is the top priority at Sandoz and the shared responsibility of all associates. The facilities operate in full compliance with cGMP regulations, which are an integral part of the Sandoz comprehensive quality assurance system for biopharmaceutical products.

QUALITY AND REGULATORY COMPLIANCE

Additional advantages for you: Sandoz fully complies with the rigorous internal quality standards applied by the worldwide Novartis Group across all its facilities. The Sandoz manufacturing facilities for recombinant products are inspected and approved by local and international health authorities (e.g., FDA, EMEA, PMDA).

The Sandoz Regulatory Department is highly experienced in the field of recombinant proteins with a proven track record of approved products. A dedicated regulatory manager is available to support your CMC filings. Quality at every stage of the process ensures that the product fully meets all your requirements.

We believe partnership is for the long term. And for your sustainable success.

