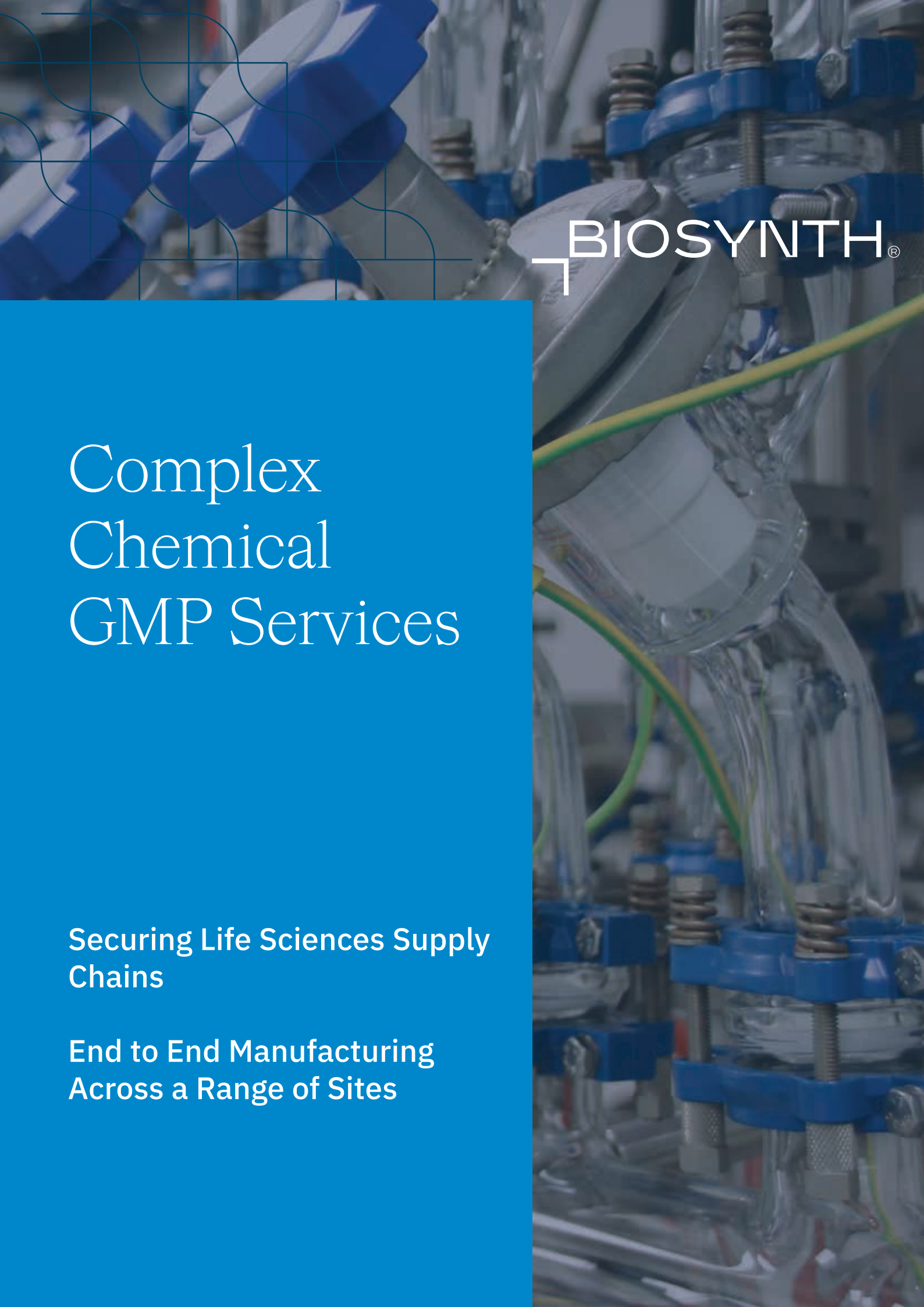

BIOSYNTH®

Complex Chemical GMP Services

Securing Life Sciences Supply Chains

End to End Manufacturing Across a Range of Sites

GMP Manufacturing Services

With our state-of-the-art GMP facility and specialist complex chemistry expertise we are uniquely positioned to support you with the development and manufacture of your product to GMP.

At Biosynth, we understand that your needs may change, and we work as a partner with you. Whether this be for your GMP development or supporting scale up and validation we can undertake the whole service or the separate parts you need. We have experience in manufacturing and developing for a range of applications, including APIs, foodstuffs, excipients, process materials, adjuvants and more.

Manufacture

- Development
- Optimization
- Technical transfer
- GMP manufacture

Analysis/QC

- Analytical development
- Technical transfer
- QC testing and release
- Stability testing

Regulatory & QA

- Oversight
- Documentation
- Support in submissions

Filling, Packaging, Warehousing

- Custom filling
- Flexible packaging and labeling options

GMP Manufacturing Facility

Our state-of-the-art GMP plant in Switzerland performs pilot and production runs at a range of scales up to 100 L as well as small scale API manufacturing. Biosynth has a flexible facility that can be adapted to different process designs and scales, which enables clinical batches and bulk production by the same experienced team.

Our warehouse and processing capabilities and qualifications allow us to store, package, and ship the GMP products we manufacture. Key Features of our GMP Facility:

- GMP Class D (ISO 8) cleanroom facility for organic synthesis of APIs
- Chemical hoods for organic synthesis of small-scale amounts (mg to several 100 g batch size)
- GMP plant for production (1 – 10 kg batch size, 100 L maximum)
- 40 L and 80 L pressure filter for Hydrogenation reactors up to 50 L
- Freeze drying capability of up to 60 L

The plant is GMP, PMDA and ISO 9001:2015 compliant.

Expertise

The GMP team at Biosynth are experts in complex chemistry, in particular the synthesis of carbohydrates and nucleosides, with unique skills in optimizing and troubleshooting production and analysis, as well as broader chemistry expertise.

How We Operate

Dynamic and Flexible Partners
The route from your needs to a cGMP product involves strategic and tactical considerations. We work as your partner to deliver what you need when you need it, being ready for the next stage or phase when business requirements, budget or data demands allow it.

High Quality Analysis
Our analytical capability is a key part of our service, with in-process control (IPC) and final product testing. GMP batch release testing of each API is performed in our Swiss quality control laboratory. We work with you to transfer in, develop, qualify and validate methods as appropriate for your stage of development.

Regulatory Expertise and Guidance
We are experienced with the development and validation of many API processes that have been through various stages of regulatory approval. We are proud to have an excellent inspection record and seek to continually improve. We offer a regulatory filing assistance service, whether it is for preparation or review of CMC or DMF filings.

For more information visit
www.biosynth.com/complex-chemicals

sales@biosynth.com **www.biosynth.com**

Global Locations

Switzerland
United Kingdom
Slovakia
India

Unites States
China
Ireland
South Korea

The Netherlands
Austria
Japan

About Biosynth

Securing Life Sciences Supply Chains - where Chemistry meets Biology, Products meet Services and Innovation meets Quality, Biosynth is at the Edge of Innovation.

With an unrivaled research product portfolio of over half a million products and end to end manufacturing services, we are science led and customer focused to solve problems, taking pride in delivering products and projects that others cannot. Our expertise and capability runs across Complex Chemicals, Peptides and Key Biologics all from one trusted partner.

sales@biosynth.com **www.biosynth.com**