



**From Research Products
to
Pharmaceutical & Diagnostic Solutions**

Company history timeline



2009 - New logistics and QC

2004 - Urs Spitz becomes CEO

2017 - Extended GMP facilities

1985 - Production plant

2016 - EU hub, Bratislava

1966 - **Biosynth** is established by Hans Spitz

2011 - Expanded synthetic laboratory

2019 - **The two companies merge to become Biosynth Carbosynth**



2006 - **Carbosynth** is incorporated

2008 - QM System. Established Carbosynth H-K and China synthetic labs

2009 - Acquisition of CMS Chemicals

2010 - Set up LLC in San Diego. Opened a sourcing office in India and established a manufacturing JV with Carbotang

2012 - QC lab expansion. Addition of clean room

2015 - Apin and Sequoia research products acquisition

2017 - Acquisition of Glycomix. Synthetic laboratories expanded

2018 - New bioscience division created

2020 - New sales office in Tokyo

Our two divisions

Delivering the best solutions to our customers

Pharmaceutical & Diagnostic Products Division

- APIs
- Pharmaceutical ingredients
- Diagnostic reagents
- R&D projects
- Custom synthesis



R&D Products Division

- Biochemicals for life science research
- Fine chemicals for organic synthesis
- Novel probes for pharmacological targets
- Original reagents introduced, based on review of scientific literature and customer feedback
- Global distribution
- 20.000+ products in stock



Top product segments

7000+ Carbohydrates

- Monosaccharide building blocks
- Oligosaccharides
- Polysaccharides
- Glycoconjugates

700+ Enzyme Substrates

- Chromogenic
- Fluorogenic
- Chemiluminescent

2400+ Nucleosides

- Natural and functionalised
- Sugar nucleotides

Detergents

- Digitonin
- n-Octylglucoside (OG)
- n-Octylthioglucoside (OTG)
- Dodecyl β -D-maltopyranoside (DDM)

Reducing Agents

- Dithiothreitol (DTT)
- Dithioerythritol (DTE)
- Tris-(2-carboxyethyl)phosphine HCl (TCEP)

Anticoagulants

- Sodium polyanetholesulfonate (SPS)

Culture media products

- Sodium pyruvate
- Antibiotics/Antimicrobials

Products for microbial testing

- Precipitating enzyme substrates
- Dyes
- Inhibitors

Phospholipids

- 4-Nitrophenylphosphorylcholine

Natural Products

- Rare and often unique phytochemicals
- High quality
- Multiple applications

Bioscience Products

- Cutting-edge, high-quality biomedical research tools
- Established biochemicals and reagents
- Controlled drugs including cannabinoids and steroids

Niche Fine Chemicals

- Peptide reagents
- Click chemistry

Our top level services

- **GMP manufacture**

- **CDMO**

The partner for carbohydrate-based APIs

- Qualified Clean Room labs, production and filling
- GLP QC facility
- Unrivalled expertise in carbohydrate, nucleoside and other areas of organic chemistry

- **Custom synthesis**

- **Route scouting**

- **Custom QC/QR**

- **Custom filling and packaging**



Our plants and production capabilities

Staad, Switzerland

- mg to kg
- GMP manufacturing
- APIs and advanced intermediates
- Catalogue products 100s kg to 10s mt
- Contract manufacture

Compton, UK

- mg to 100s of grams
- Custom synthesis, FTE
- Catalogue products

Bratislava, Slovakia

- mg to kg

Beijing, China

- mg to kg
- Catalogue products

CarboTangJinan, China

- 100s kg to 10s Mt
- Advanced intermediates
- Contract manufacture

Suzhou, China

- mg to kg



R&D labs and small scale production

Compton, UK

Staad, Switzerland

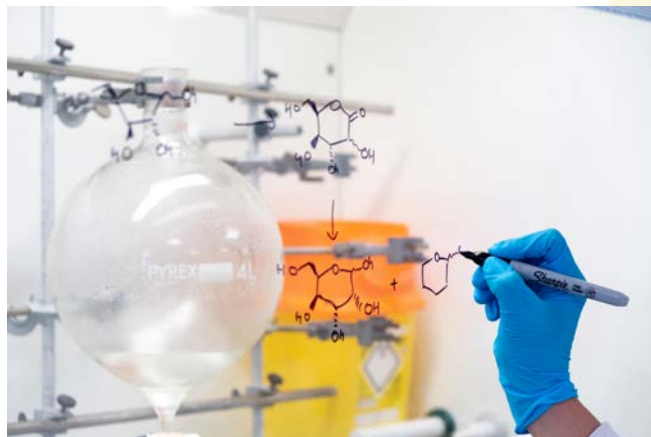


State-of-the-art synthetic labs

- Interchim, Biotage and Companion systems
- Preparative HPLC
- Size exclusion chromatography - Buchi MPLC
- CEM microwave synthesis system
- Multi-stage short path and thin film distillation
- Lyophilisation
- 20L scale equipment



Synthetic chemistry team



Project Skills

- **Route evaluation:** identification of efficient route of synthesis in terms of costs and number of steps
- **Synthetic route development:** existing methodology's & optimization of routes
- **Complex multi-step reaction schemes**
- **High purity complex products**
- **Small-scale and pilot** - including cGMP APIs
- **Large scale synthesis**
- **Final step synthesis**
- **Purification**
- **Optimisation and scale-up**

Experienced Chemistry Teams

- **Carbohydrates**
- **Nucleosides**
- **Enzyme substrates**
- **Fluorinations**
- **Peptide chemistry**
- **Natural product synthesis**
- **Phosphates** (phosphinates, phosphoramidites, phosphonates etc)
- **Heterocyclic chemistry**
- **Medicinal chemistry**

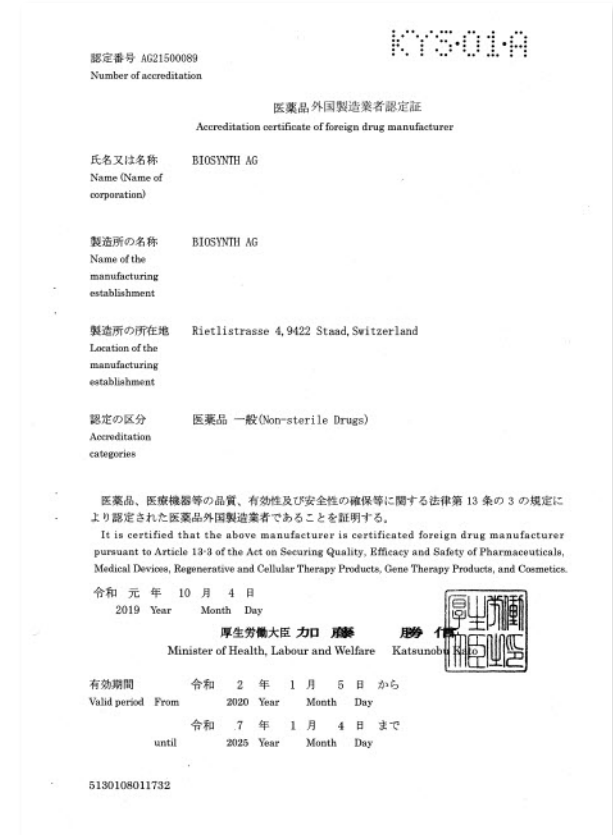
Quality and Compliance



ISO 9001:2015

GMP

PMDA



Good Manufacturing Practice

GMP plant



- CDMO
- Process development
- Analytical development
- Route scouting
- Pilot manufacturing
- Scale-up
- Management of outsourcing
- Regulatory support and DMF filing

API production

Portfolio Examples

- **Histamine dihydrochloride**
 - Manufactured at Biosynth as an API since 2008
 - Approved by PMDA, Swiss Medic, EMA
- **5-Aminolevulinic acid hydrochloride**
 - Manufactured at Biosynth since 2005
 - Approved by SwissMedic, EMA
- **5-Hydroxytryptamine creatinine sulfate monohydrate**
 - Synonym: Serotonin creatinine sulfate
 - Uses: veterinary applications

API production

Case study

A reference substance in a diagnostic procedure was unexpectedly declared to be an API.

This **regulatory challenge** created a major problem for a customer.

Solution

We developed and validated a small-scale manufacturing process. Along with the required analytical methods and full documentation, a DMF was submitted and gained regulatory approval.

Extensive and versatile quality control

Chemical techniques available

- Chromatography (HPLC, GC, TLC, IC)
- NMR 400 Mhz
- ICP-MS
- FT-IR
- ICP-OES
- Specific rotation
- Elemental analysis
- Titration
- Water content (Karl Fischer)
- Melting point
- pH value
- TOC
- Loss on drying
- Sulfated ash
- Conductivity
- Refractive index
- UV spectroscopy

Biological assays

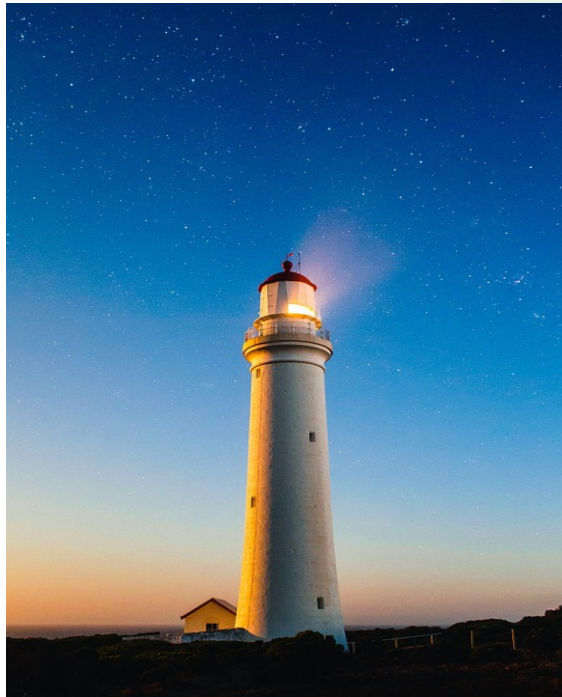
- Enzymatic activity
- Microbial growth
- Performance tests
- DNase/RNase activities
- SDS-PAGE
- Endotoxin testing



Innovation is our DNA

We continuously invest in ambitious new developments of reagents for diagnostic assays and in the optimisation of existing methods.

Our portfolio of patents proves it.



ALDOL® Indicators

Chromogenic & fluorogenic probes

RUG®

Highly sensitive *E. coli* detection

STAADIUM™

Novel enzyme-activated inhibitors

AquaSpark®

New chemiluminescence substrates and probes



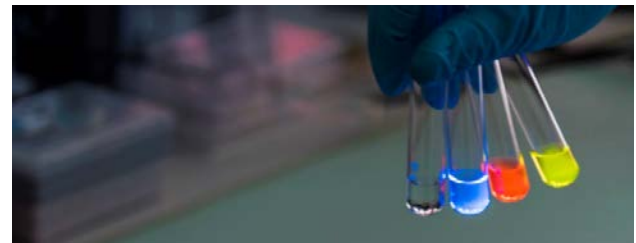
Innovation

Experts in microbiology

- We run a **biosafety level two microbiology lab** (pathogenic organisms)
- **Large collection of microorganisms**
- We constantly develop and **improve diagnostic reagents**
- We hold numerous **patents** in the field and
- We provide **firsthand technical support**

Applications

- **clinical microbiology**
- **industrial microbiology:** food and environmental applications



References

What auditors and customers say

“Customer satisfaction resides in the center of business processes”. *ISO 9001 Auditor’s Report*

“The quality of the material and the customer service is excellent”

“We never question the quality of products from Biosynth”. *Customer statements*

“During the review of the Quality Records it was observed that Biosynth had a clear understanding of how to maintain and control their records”. *Customer Audit statement*

“The manufacturer commands a high level of expertise in synthetic chemistry and operates the necessary equipment”. *Customer GMP Audit comment*

“I have seen several chemical companies and this one is the cleanest, most high-tech, and well-organized, with highly effective and efficient processes as SOPs. **This is what the industry standard should look like**”. *Visitor statement*

Biosynth Carbosynth products in the scientific literature

Our products are widely used by scientific community and cited in peer-reviewed, high impact journals

Recent examples:

Takashi Nishiyama, Tominari Kobayashi, Suljid Jirintai, Shigeo Nagashima, Putu Prathiwi Primadharsini, Tsutomu Nishizawa, Hiroaki Okamoto (2019). **Antiviral candidates against the hepatitis E virus (HEV) and their combinations inhibit HEV growth in *in vitro*.** *Antiviral Research* **170**,104570

Gwenyth L. Day, Michelle L. Bryan, Scott A. Northrup, Douglas S. Lyles, Marlena M. Westcott, John H. Stewart (2019) **Immune Effects of M51R Vesicular Stomatitis Virus Treatment of Carcinomatosis From Colon Cancer.** *Journal of Surgical Research* **245**, 127-135



Thank you!



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