

# Experienced hands for your recipes Custom Synthesis

Elena Schaller,  
an enabler in custom synthesis



Pharma Ingredients & Services. Welcome to more opportunities.  
Custom Synthesis | Excipients | Active Ingredients

 **BASF**  
The Chemical Company

## Experience for your complete peace of mind



**“With our recognized expertise and strong track record as a service provider for the pharmaceutical industry, we fully support the needs of the world’s leading – as well as emerging – pharmaceutical companies.” ...**

... says Dr. Elena Schaller, Head of Pilot Plant at BASF Custom Synthesis. BASF has considerable know-how and industrial experience in handling complex chemistry at lab, pilot and full manufacturing scale. Our unrivalled network of experts in across BASF R&D and within Custom Manufacturing organizations are dedicated to supporting you throughout the entire life cycle of your products.

## Global reach with local care

With more than 50 years’ experience in the custom synthesis of APIs, BASF is one of the leading custom manufacturers of small molecules for the pharmaceutical industry. Our goal is to provide high-quality and cost-effective services to our partners, when and where they are needed. Our expertise allows you to focus on your core competencies while we ensure that your supply chain is efficient and reliable.

## Dedicated support helps you achieve your goals

Your dedicated project manager will ensure that all aspects of your project are taken care of, from analytical and process development to manufacturing and supply. We keep our processes agile, our multi-functional teams responsive and our labs and production facilities ready to respond to any challenge, big or small.



We combine our portfolio of services to meet your unique outsourcing needs

Project management

A single contact for the entire life cycle of your project provides clarity, efficiency and consistency. Your project manager will coordinate all BASF experts working on your behalf, to deliver full transparency and the right results, at the right time and the right price.

Process development – your road to success

We offer expertise in route scouting, process optimization, up-scaling, development of unit operations and particle engineering.

Analytical development – precision where it counts

Our dedicated team provide analytical validation services and support your analytical development needs from early development to full-scale production.

Regulatory services – benefit from our expertise

We maintain more than 60 Drug Master Files with regulatory agencies in Europe, the USA and Japan. Our experts offer support for your regulatory submissions (INDs, NDAs, CMC sections and more).

Manufacturing: multi-purpose facilities – one standard

Our plants can handle from g/kg to multi-ton scale production under cGMP and complex, hazardous processes, allowing us to meet the most challenging requirements.

Complete peace of mind  
Reliable supply from a trusted partner  
Process development and analytics  
Excellence in regulatory & quality services



Flexible, multi-purpose manufacturing capabilities



BASF manufactures active ingredients and advanced intermediates in Evionnaz (Switzerland), Saint-Vulbas (France) and Minden (Germany). All our sites are regularly inspected by the FDA and local regulatory agencies.

Kilo lab (cGMP-compliant)

Our kilo lab can produce small quantities of APIs and intermediates up to the kilogram scale.

Pilot plant (cGMP-compliant)

Our pilot plant is designed to handle complex, multi-stage chemical processes. We scale-up and produce your APIs and intermediates up to 1,000 liters. Robust safety systems are in place for hazardous and toxic substances.

Commercial plants (cGMP-compliant)

BASF has a total of 11 multi-purpose production plants with a combined capacity of over 600 m<sup>3</sup>. Nine isolated reaction units (up to 8,000 liters) allow safe reactions with highly toxic substances, including phosgene, phosphoryl chloride and cyanide.

Non-GMP plants

In addition to our cGMP-compliant plants, BASF operates a variety of sophisticated multi-purpose assets in Ludwigshafen for non-GMP intermediates. Numerous processes can be performed in these plants, including enzymatic reactions and high-pressure hydrogenation up to 200 bar.

BASF – an experienced partner to handle your most complex projects.



Innovative process solutions revolutionize product development



We have the custom synthesis know-how needed to enable you to innovate and compete effectively within your market.

By working with us, you can access the global BASF research and development network where new, value-adding technologies are constantly being discovered. These technologies offer new ways to make active ingredients accessible and, in many cases, simplify production processes and reduce costs.

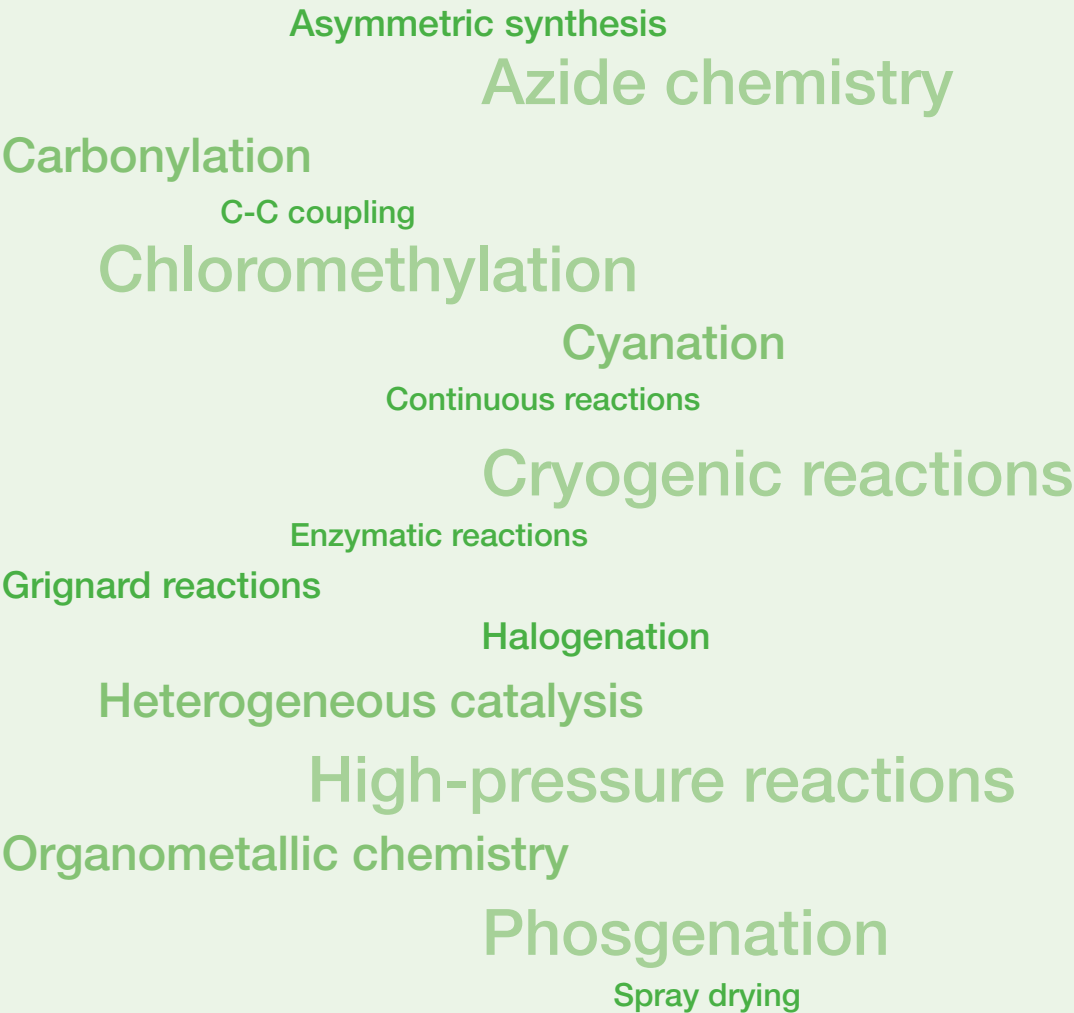
Special technologies

BASF’s differentiating technologies include phosgenation, cryogenic reactions, azide chemistry and high-pressure catalytic hydrogenation. These technologies are used in full compliance at all scales – laboratory, pilot and commercial – in our cGMP facilities.

Spray drying

Spray drying is a technology that can provide a simple solution to a number of drug delivery challenges, such as poor bio-availability of valuable compounds. We can offer spray drying of neat and formulated APIs in both aqueous and organic solutions on any scale under cGMP.

Our expert team provides support throughout the drug life cycle – from the early clinical phase, through the exclusivity period and into the later during the generic phase of a drug’s life cycle.



## **BASF – your reliable, secure partner for your supply chain**

Expert services for your peace of mind:

- A reliable partner for your APIs' supply
- A competitive partner offering unique sourcing and back-integration opportunities
- An experienced and flexible partner to handle complex projects

**Contact us to find out how Elena Schaller and her colleagues can help you develop your business. Please contact [customsynthesis@basf.com](mailto:customsynthesis@basf.com)**

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