75 years
Since 1949

Dipharma

EXPERIENCE YOU CAN TRUST

Achieving your goals more easily, safely and rapidly.

CDMO

Exclusive Synthesis

With you every step of the way, bringing innovation

What we offer

We provide a **tailor-made development of innovative and proprietary chemical processes** for new and complex molecules. Since your peace of mind is our concern, **we guarantee a true turnkey CDMO service**, with all the assistance and flexibility required through the different project stages. We believe this unique platform will expedite your journey to success.

Our talent

We push our collaboration beyond technical skills. We know how valuable it is for you to rely on a **trusted partner** for managing **complex projects**, within the **agreed timeline** and **budget**. With more than 70 years of expertise in R&D, an innovative and problem-solving mindset, **we do offer you efficient and cost-effective solutions** for the development of your molecule. **This is a talent we are proud of.**

Why you can trust us

As part of the global pharmaceutical industry, we serve human health in compliance with **the highest standards of quality and safety**. This is confirmed by a **long-lasting list of successful inspections** run by EU and US Health Authorities certifying the cGMP level of our production sites. Furthermore, every day we work to increase our **commitment to sustainability**, with a strong engagement improving human lives and protecting the environment. As a third-generation family-owned company, we have an extensive **history of stability and financial solidity**. The ability to develop **innovative synthetic processes**, combined with proven know-how in the **handling of hazardous chemicals and reactions**, makes Dipharma your optimal choice for Exclusive Synthesis services, from discovery to the commercial stage. **Experience you can trust.**

Taking CDMO services further

A history of **75 years of** proven **reliability**

All four sites governed by the strictest **cGMP Quality System**

Extensive positive track record of **inspections** by the main **Regulatory Agencies**

Full regulatory support, tailored according to the different phases of the project

Specializing in the **handling of hazardous processes**

Internal intellectual property department to fulfil customer requests

Customizing particle size to match your formulation requirements

Providing pre-formulation and solubility data to support Drug Product definition

Core Technologies

- High-pressure hydrogenation*
- Nitration*
- Nitroesterification*
- Azide chemistry
- Borane reductions
- Carbohydrate chemistry
- Cross-coupling reactions
- Curtius reaction
- Dissolving metal reduction
- Enantioselective reactions
- Enzymatic chemistry
- Epichlorohydrin chemistry
- Hoffman reaction
- Hydrogen peroxide oxidations
- Use of nitroalkanes (Henry reaction)
- Wolff-Kishner reduction

* Strategic cooperation with Biazzi SA, engineering sister company specializing in hazardous chemistry

BIAZZI

Your partner for tailor-made solutions

Since 1949 Dipharma

Our footprint

We rely on more than 550 skilled, motivated and engaged employees. Our creative R&D team counts around 80 dedicated, committed and experienced professionals and scientists in different locations (USA, Europe). The R&D team is mostly composed of MSc or PhD researchers. **Our people and their personal commitment make the difference**.

Our core capabilities

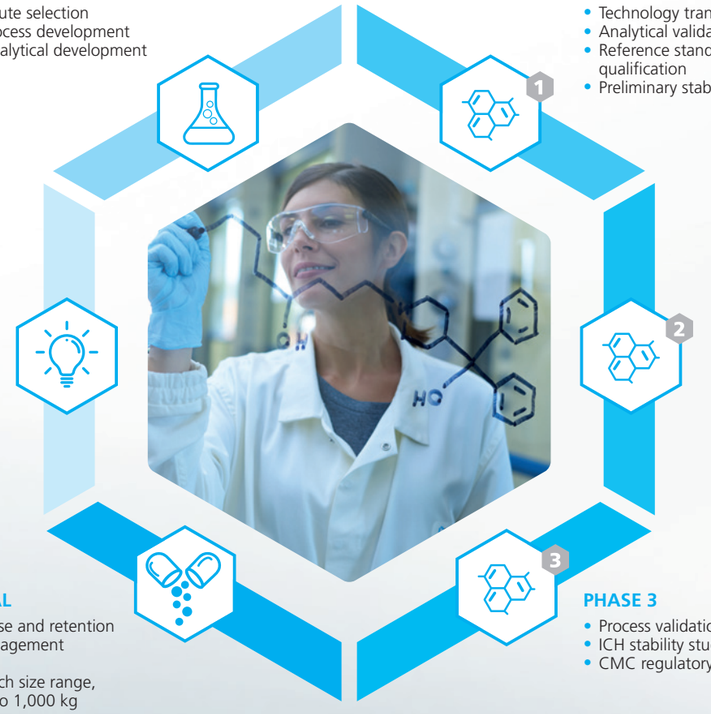
We have the right dimensions and several scale capabilities to manage processes efficiently: **sizable and experienced** enough to be solid, but **flexible and agile** enough to promptly solve any challenge in the life of the project.

Our know-how in action

Our human and technological resources work together on chemical processes for new and complex molecules. State-of-the-art **Kilolab, pilot and industrial facilities** are our assets to cover **clinical and commercial supply** with the highest standards.

PRE-CLINICAL
- Route selection
- Process development
- Analytical development

PHASE 1
- Technology transfer
- Analytical validation
- Reference standard and impurity qualification
- Preliminary stability studies



DISCOVERY
- Medicinal chemistry
- Custom synthesis
- Stable label synthesis

PHASE 2
- Solid state characterization
- Quality by Design (QbD) approach
- Determination of critical process parameters (CPP)
- Identification of critical quality attributes (CQA)

COMMERCIAL
- Product release and retention
- Lifecycle management
- IP protection
- Extensive batch size range, from 0.1 kg to 1,000 kg

PHASE 3
- Process validation
- ICH stability studies
- CMC regulatory support

Project Management

A project should run like clockwork.
A dedicated team, managed by a project leader, will assist you throughout the different stages of the project.

Our approach to Exclusive Synthesis pays special attention to:

- The requirement for absolute confidentiality
- Frequent, open and honest communication between the parties
- The flexibility required to accommodate the project's needs within the Dipharma organization
- The pro-activity of our skilled professionals, who aim to quickly find the best solution for your project
- The objective and realistic planning necessary to control the project development with continuous progress tracking
- Careful risk assessment to minimize the impact of issues and changes and manage them actively

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Dipharma

Where we are

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