



Custom Synthesis

Reliable, Flexible and Competitive

About ISO CHEM

ISO CHEM is a fine chemical company offering custom manufacturing and catalogue products and its primary market is the manufacture of cGMP Intermediates and Active Pharmaceutical Ingredients (APIs) for Pharmaceutical companies worldwide.



A FINE CHEMICAL COMPANY

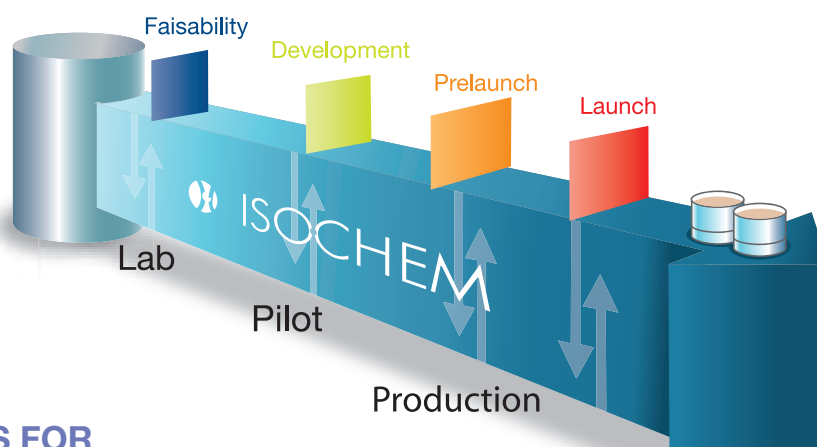
ISO CHEM serves a broad range of customers in many application fields, from leading global companies to virtual and emerging organizations. ISO CHEM implements almost all the chemical reactions classically used in multi-step synthesis and offers you renowned differentiating know-how:

- Safe implementation of hazardous reaction such as phosgenation, nitration, cryogenic reaction and high pressure hydrogenation.
- Attractive building blocks such as activated aminoacids (N-CarboxyAnhydride) in peptide chemistry.

ISO CHEM products play an important role in the production of novel healthcare, functional and specialty products.

Custom Synthesis

ISOICHEM offers GMP and non GMP industrial exclusive custom synthesis and provides tailor made services that range from development to production, including route selection, process and analytical development as well as process optimization.



BENEFITS FOR YOUR PROJECT

Flexible Solutions: ISOICHEM's highly skilled teams interact closely with the pilot units and multipurpose facilities. The proven project management system combined with a broad technology platform allow to design custom tailored programs adapted to your timeline.

Appropriate Quality: ISOICHEM's quality policy based on a long experience working with the guidelines of various markets ensures the exact quality level required by your product.

Reduced Time to Market: ISOICHEM's knowledge and management tools ensure the optimized timing for your project.

Continuous Cost Savings: ISOICHEM delivers substantial improvements in manufacturing and creates additional value by reducing capital and operating costs.

Security of Supply Chain: ISOICHEM optimizes and secures sourcing of raw materials, based on total transparency with customers.

Project management

PROJECT EVALUATION

- identification:
 - of critical points
 - of key technologies and required skills
- regulation diagnostic
- economic evaluation

COMPREHENSIVE SERVICE OFFER

- prerequisites - hypotheses
- technical program
- regulation support (DMF, REACH)
- project management
- transparency - communication
- detailed planning

KICK OFF MEETING

- validation of input data and objective

RELIABILITY AND TRANSPARENCY

- project team leader
- regular reporting
- project reviews
- creative process
- analytic support
- tailor-made documentation
- timely supplies (product and reports)
- confidentiality
- controlled lead times and costs

RELIABLE PRODUCTION

- FDA and customer audit satisfaction
- best EHS standards

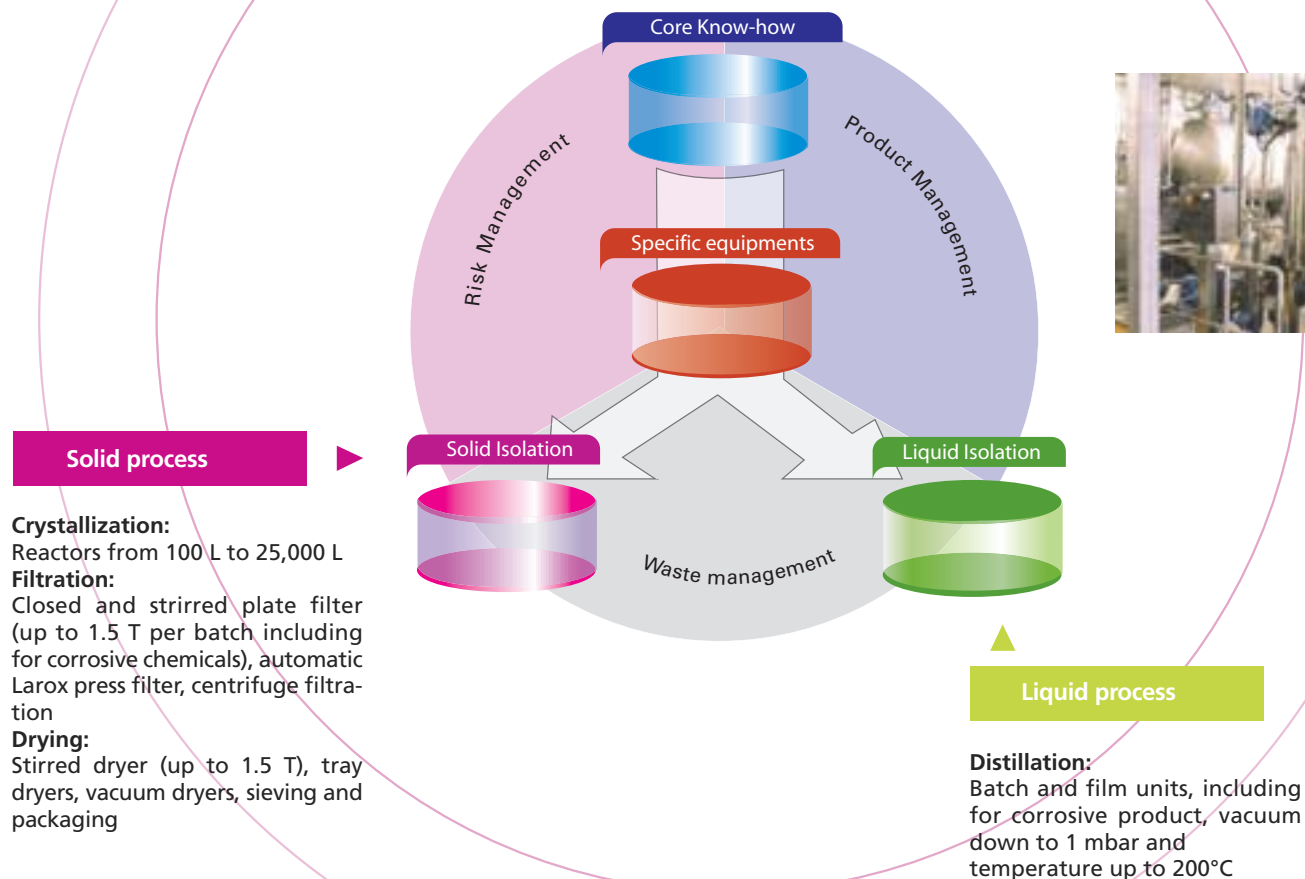


Our technologies

- Hydrazines and downstream heterocyclic chemistry
- Phosgene chemistry
- Organometallic chemistry including organo-lithium reagents (BuLi, LDA, LiHMDS,...)
- Chlorination (POCl₃, PCl₃, SOCl₂, SO₂Cl₂, ...)
- Reductions with boron and aluminium hydrides and in situ generated B₂H₆
- Halogenation (bromination and iodination)
- Catalytic hydrogenation up to 40 bar
- Carbon disulfide chemistry
- Lewis catalyst (BCl₃, TiCl₄, BF₃, AlCl₃ ...)
- Amino acid N-Carboxyanhydride synthesis and polymerization (NCA, UNCA)
- Liquid phase peptide synthesis
- Chiral chemistry
- Phosphites (PCl₃ derivatives)

Reaction process

Reaction volume: 350 m³
Reactor size: from 100 L to 25,000 L (glass lined and stainless steel)
Reaction temperature: from -70°C to 250°C
Pressure reaction: up to 40 bar



Solid process

Crystallization:

Reactors from 100 L to 25,000 L

Filtration:

Closed and stirred plate filter (up to 1.5 T per batch including for corrosive chemicals), automatic Larox press filter, centrifuge filtration

Drying:

Stirred dryer (up to 1.5 T), tray dryers, vacuum dryers, sieving and packaging

Liquid process

Distillation:

Batch and film units, including for corrosive product, vacuum down to 1 mbar and temperature up to 200°C

Innovation

Considering innovation as an opportunity, ISOICHEM 's teams are day to day seeking for new valuable solution from any field of our activity.

Innovation is powered by skilled teams who combine, open-mind, creativity, enthusiasm, and pragmatism. Customer Satisfaction is ISOICHEM's favorite metric of its innovation performance.

Track record in some figures

- 40 years of experience in fine chemistry
- 19 FDA audits (3 audits in 2014 - 2 with no 483 forms)
- 25 customer audits/year
- More than 50 DMF submitted
- 15 ANSM Audits
- Exportation > 80% of Turnover

SUSTAINABLE DEVELOPMENT

Sustainable development is a corner stone of ISOICHEM's policy. ISOICHEM long term success relies on respect of core values like the protection of social environment and the safety and health of employees and neighbours in a strict compliance with local and international regulations.

ISOICHEM is a member of the Responsible Care program. ISOICHEM management defines objectives for continuous improvement and progress.

ISOICHEM's best practices for Safety, Health and Environment are stated in a Policy Act on Safety Health and Environment.

ISOICHEM has been awarded at the 2014's Challenge for "Responsible Chemistry" of Union the French Chemical Industry (UIC), or an innovative and eco-responsible process.



ISOICHEM OPERATES 5 PRODUCTION SITES.

This offers a total reaction capacity of 350 m³ including 3 cGMP production sites with 255 m³ of reaction capacity.

ISOICHEM runs a large range of glass lined and stainless steel vessels, from 100L to 25,000L, coupled with equipments for liquid and solid purification and separation. This offers the most attractive multipurpose industrial capacity for your products.

Manufacturing facilities

- Gennevilliers
- Pithiviers
- Vert-Le-Petit
- Pont-de-Claix
- Wychem



QUALITY

Appropriate Quality:

ISOICHEM's quality system based on a long experience working with the guidelines of various markets is designed to meet the exact quality standard required by your market.

Global Quality System:

ISOICHEM established a global Quality System which complies with internal policies as well as with national and international standards (ISO9001/2008) and regulations (cGMP).

cGMP standards

With a long tradition of manufacturing active pharmaceutical ingredients and regulatory intermediates, ISOICHEM is able to manage your project according to the best practices.

In addition, ISOICHEM brings all necessary regulatory support such as registration of new substances through IND or DMF filing in CTD format. More than 50 DMF were filed by ISOICHEM in different countries.

Our certifications:

	GENNEVILLIERS	PITHIVIERS	VERT-LE-PETIT	PONT DE CLAIX
ISO 9001: 2008	✓	✓	✓	✓
cGMP (Q7)	✓	✓	✓	
Inspected by the FDA	✓	✓	✓	
FDA listed	✓	✓	✓	





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