

Pharma Chemicals


# Bright Science. Brighter Living.™

APIs, Registered Intermediates,  
and Registered Starting Materials



**For DSM, quality is a way of life. This is the core of Quality for Life™.** Quality for Life™ is the mark of quality, reliability and traceability. It means that DSM customers are getting superior products and services, knowing the source on which they depend. Quality for Life™ means sustainability. It symbolizes our commitment to our environment, consumers, our business partners, our people and the regulatory framework that governs our operations.

*With the Quality for Life™ seal, we guarantee peace of mind for you and for your customers.*



Our purpose is to create brighter lives for people today and generations to come. We connect our unique competencies in life sciences and materials sciences to create solutions that nourish, protect, and improve performance.

DSM is fully aligned with the needs of pharma and biotech, offering committed partnerships that apply our broad technologies, exceptional facilities, and regulatory excellence to the manufacture of customers' products.

Broad diversification and financial strength provide a robust platform for all business units, geared towards sustainability. DSM is focused on growth-oriented positioning in its strategic markets, which ensures it is not only a partner for today, but an intelligent choice for tomorrow.

#### Pharma Chemicals

DSM provides a broad spectrum of clinical to commercial services that are aligned with the long-term needs for pharma and biotech with small molecule projects.

- :: Technology Transfer and Commercial Launch
- :: Late Stage Clinical (CT<sub>2</sub> and CT<sub>3</sub>)
- :: R&D/Early Stage
- :: Multi-customer product portfolio

#### Supply Chain Coverage

Pharma Chemicals is positioned alongside our Finished Dosage Forms and Biologics businesses to give customers the opportunity for integrated sourcing from a single, reliable partner. We offer dosage form manufacturing for pharmaceuticals and biopharmaceuticals, as well as expertise in biologics cell line platforms for the production of antibodies and proteins.





# Sustainability

Pharma companies are continually faced with the question of how to best manage their supply network. We provide the capability to turn fixed costs into variable costs while maintaining long-term security of supply, superior quality and exceptional regulatory compliance. Most of our suppliers sign our code of conduct with respect to sustainable manufacturing, which contributes to our leadership position in the Dow Jones Sustainability Index.

There is a corporate framework at DSM for sustainability. We are part of a financially-strong, independent, life science and material science-focused corporation, and there is ongoing long-term board commitment to pharmaceutical markets. In 2010, DSM ranked #1 in the global chemical sector of the Dow Jones Sustainability World Index.

The merging of this positioning with our insight into future market trends means DSM is not only an exceptional partner today, but a logical choice among a likely streamlined number of contract manufacturers in the long term.

\* The Dow Jones Sustainability World Index includes over 300 companies from 34 countries that rank among the top 10% for corporate sustainability in their industry.



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# Quality

## Quality for Life™

While our technology and regulatory track record offer reassurances on quality and robust supply, we also provide cost efficient approaches that are an equal driver of sustainability for competitive outsourcing of chemical manufacturing across the pharmaceutical life cycle.

## Regulatory Confidence

DSM's track record and reputation among regulatory bodies is exemplary. We share responsibility with our customers through our comprehensive regulatory service. For many products, we hold a Certificate of Sustainability of EDQM or a U.S. Drug Master File. Our approach and regular customer audits offer assurance and result in an easier path to market.

This level of performance and reputation is not only appealing to companies with new business to place, but also to those with existing products at outdated or unsuitable facilities. We have an extremely high degree of experience throughout our personnel, and the resources and expertise to smooth the process of tech transfer for later-phase projects.

# Innovation

## Green Chemistry Toolbox

One of the key developments in serving customers and sustainability as a long-term supplier is DSM's implementation of a green chemistry toolbox. This reflects a number of approaches aimed at optimizing processes, reducing costs and mitigating raw material usage and environmental impact. Process intensification offers shorter and more efficient scale up, speeds up development, and drives down material costs.

## Route Scouting Services

As a long-time supplier with continuous commitment to pharmaceutical and biotech markets, DSM has been researching and testing more cost effective solutions for a considerable time. InnoSyn™ route scouting services employ an interdisciplinary approach across pharmaceutical chemistry and biotechnology, which identifies optimal synthesis routes and commercial scale up for production of active pharmaceutical ingredients. This encompasses biocatalysis, homogenous catalysis and micro reactor technology.

## Micro Reactor Technology

Micro reactors contain thousands of continuous small-diameter tubes that have an overall volume of around three liters, compared to 10,000 liters for a traditional large vessel. DSM has had success leading the advances in micro reactor technology as an alternative production method for pharmaceuticals at its Linz facility.

The manufacturing footprint for micro reactors is smaller and more efficient, yet they can handle 1,000-2,000 kilograms of product per hour with yields up to 20% higher than traditional large vessels. With each small tube surrounded by coolant, the reactors use less energy and produce less CO<sub>2</sub> and other undesirable by-products.

Due to their smaller scale, the reaction rate is quicker and easier to control, which facilitates the higher yields and lower costs. Optimization of the reaction parameters can be much faster than for a typical batch reaction. The process is also scalable and enables process conditions that are not otherwise possible.

This technology offers superior processing performance and a more cost-effective and environmentally friendly way to produce intermediates and APIs. Micro reactors can also handle hazardous processes in a safe, controlled way—while still achieving higher yields and cost advantages.



By developing process intensification technologies, we have been able to offer shorter and more efficient scale up of chemicals—speeding development and reducing costs. Added benefits include mitigated environmental impacts, reduced raw materials usage, and safer handling procedures.



# Secure Supply

Our manufacturing resources offer scalable manufacturing—from kilos to tons—providing the flexibility required in today's market.

We also sit apart from many manufacturers in terms of being able to provide an integrated source for scale-up, commercial manufacture, and finished dosage forms.

## Large Scale: Technology Transfer and Commercial Launch

Our Linz facility in Austria and Venlo site in The Netherlands are highly reputable manufacturing plants that provide flexible commercial manufacturing under full cGMP conditions.

## Late Stage Clinical Business B30/B70; CT2 and CT3;

These facilities offer comprehensive quality systems and regulatory expertise that inspire confidence, speed, and cost efficiency.

## R&D / Early Stage

Our DSM site in The Netherlands houses our research department, where new catalytic technologies and manufacturing concepts are developed to further improve API synthesis. DSM offers rapid scale-up from the lab phase with manufacturing up to pilot scale, and seamless integrated project transfer to one of DSM's commercial-scale cGMP facilities.

# Route Scouting Services

DSM offers focused and flexible stand alone route scouting services to meet the individual needs of customers with our broad and unique technology toolbox. DSM's world-class route scouting capabilities lead to significant cost savings by the reduction of synthesis steps or redesign of synthesis routes.

The InnoSyn™ route scouting team, located at our facilities in Geleen, The Netherlands, offers unique route scouting services to support you with research and development, and the implementation of economical and scalable routes. Unique value-creating solutions are provided by integrating the full range of enabling DSM competencies such as biocatalysis, homogeneous catalysis, and organic synthesis as well as continuous chemistry such as micro reactors. Our proven capabilities to rapidly screen a wide variety of catalysts, speed up feasibility studies for chemocatalytic and biocatalytic steps.

Recent success stories have introduced new efficient enzymes, such as pharmaPLE®, lyases, transaminases, dehydrogenases and new, easily accessible homogeneous catalysts for asymmetric hydrogenations, aromatic substitutions, and oxidations. Furthermore, a safe and clean nitration reaction was implemented under cGMP for manufacturing of an API based on DSM's micro reactor technology.

InnoSyn™ is a trademark of DSM  
pharmaPLE® is a registered trademark of DSM





**The Quality for Life™ commitment.**

*...gives you "Peace of Mind"*

∴ It is the mark of product—*quality, reliability & traceability*

∴ It means you are getting the very *best ingredients*

∴ You know *where the ingredients come from* and you know you can *rely on this source*

*...means Sustainability*

∴ It symbolizes our *commitment* to our environment, our business partners, our people and the regulatory framework that governs our operation

## DSM

For further information, please see:

[www.dsmpharmaceuticals.com](http://www.dsmpharmaceuticals.com)

or contact:

### Europe / Rest of World

DSM Pharma Chemicals

Operngasse 17-21

P.O. Box 119, 1040 Vienna

Austria

Tel: +43 1 585 05 15 49

Email: [info.dsmpharmaceuticalseu@dsm.com](mailto:info.dsmpharmaceuticalseu@dsm.com)

### North America

DSM Pharma Chemicals

45 Waterview Boulevard

Parsippany, NJ 07054-1298

USA

Tel: +1 973 257 8011

Email: [info.dsmpharmaceuticalsna@dsm.com](mailto:info.dsmpharmaceuticalsna@dsm.com)

### DSM Pharmaceutical Products

45 Waterview Boulevard

Parsippany, NJ 07054-1298

USA

[www.dsmpharmaceuticalproducts.com](http://www.dsmpharmaceuticalproducts.com)