

## DSM

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BioSolutions

Bright Science.  
Brighter Living.™

Microbial Fermentation  
Technologies & Services

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HEALTH • NUTRITION • MATERIALS





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.

#### BioSolutions

DSM has over 100 years of experience in fermentation-based technologies. These have been developed for a large variety of microorganisms and a multitude of products, ranging from simple and complex metabolites (e.g. anti-infectives) to highly-complex proteins (enzymes, pharmaceutical proteins).

BioSolutions offers custom manufacturing services relating to microbial fermentation. It offers access to:  
:: State-of-the-art infrastructure

DSM's infrastructure for fermentation and associated product recovery and purification centers on a multipurpose production facility in Capua, Italy, which currently produces pharmaceutical APIs (exclusively non beta-lactams) and food/nutrition-related products. In the pharma area, production lines are available for cGMP manufacturing of small molecules and pharmaceutical proteins. The facilities comply with all relevant regulations and are regularly inspected by the respective authorities (e.g. FDA).  
:: DSM know-how in fermentation process development



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.

### The Right Platform

For protein products, DSM will help evaluate the project's molecule to choose the right strain for manufacturing. More than two decades ago, DSM established its PluGBug® platform to address this critical element. Customers can tap into this expertise and benefit from ready-to-use platforms, including:

- :: Escherichia coli
- :: Pichia. pastoris
- :: Kluyveromyces lactis
- :: Aspergillus niger
- :: Bacillus subtilis

DSM's in-depth knowledge of these host microorganisms guarantees short and predictable fermentation development timelines. For all organisms, detailed studies with respect to their needs for optimal fermentation conditions have resulted in standardized basic protocols. Product-specific aspects can be addressed by further optimization of fermentation conditions and through development of a tailor-made downstream process.

Customers seeking to bring the productivity and robustness of their own strains up to state-of-the-art levels can rely on DSM's capabilities, which are based on a century of experience in process development for single cell and filamentous microorganisms (fungi & bacteria).

### Complete Service

With expertise at DSM ranging from microbial strain construction and improvement to product purification, customers also benefit from the considerable R&D knowledge base within the DSM Biotechnology Center in Delft, The Netherlands.

This location not only offers high-tech microbial fermentation process development capabilities, but also an intimate knowledge of the Capua production infrastructure—ensuring seamless transfer of processes from R&D to production.

- :: Professional project management

In all project phases, DSM's project management team is continually available and responsive to customer needs or questions.

Scale-up for commercial manufacturing is available in Capua, Italy—up to a scale of 35 m<sup>3</sup> for cGMP. Non-cGMP projects can be accommodated at an even larger scale to meet economical needs.



## Process Development & Analytical Support

Customers can benefit by accessing DSM's infrastructure and know-how, supporting the following unit operations:

- :: WCB cGMP production
- :: MCB and WCB cGMP storage
- :: Lab-scale and pilot-scale fermenters
- :: Membrane filtration (MF, UF, NF)
- :: Centrifugation
- :: Extraction
- :: Chromatography
- :: Crystallization
- :: Drying and formulation
- :: Chemical and enzymatic modification

In parallel, DSM's team of experts will develop the analytical assays needed for in-process control and product characterization. All modern technologies—like NMR, LC-MS, chromatography etc.—are available.

## Microbial Capabilities

- :: Production strain construction and/or improvement
- :: Production process development and optimization
- :: Analytical development
- :: Chemical modification of fermentation products
- :: Enzymatic modification of chemicals & fermentation products
- :: In-process and final product analytics
- :: non-cGMP manufacturing from 10 L to 100 m<sup>3</sup>
- :: cGMP manufacturing from 3 m<sup>3</sup> to 35 m<sup>3</sup>
- :: FDA / EMEA-approved facilities with up to Class 10,000 clean rooms
- :: Purification chromatography
- :: -20<sup>o</sup> C cGMP storage for APIs
- :: Stability studies
- :: Regulatory affairs support (IND/ IMPD and NDA / BLA filing)



### 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