

DSM

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Finished Dosage Forms

Bright Science.
Brighter Living.™

Sterile Dosage Form Fill & Finish,
Solid Dosage Form Manufacturing
& Finished Product Packaging

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HEALTH • NUTRITION • MATERIALS



Quality

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.

Finished Dosage Forms

DSM is a global provider of finished dosage form manufacturing and related services to pharmaceutical and biopharmaceutical markets—providing broad capabilities in aseptic filling of liquid & lyophilized compounds and manufacture of tablets & capsules. Specialized capabilities include filling of sterile cytotoxic compounds, production of Clinical Trial Materials and Controlled Substances for both sterile and solid dosage forms, and a full range of Pharmaceutical Development Services.

Long-term stability and unparalleled expertise, combined with the advanced way our Greenville facility is engineered and operated, mean one visit is enough to convince most people that DSM is the ideal partner.

Supply Chain Coverage

Finish Dosage Forms is positioned alongside our Pharma Chemicals and Biologics businesses to give customers the opportunity for integrated sourcing from a single, reliable partner. We offer a broad spectrum of clinical to commercial services, as well as expertise in biologics cell line platforms for the production of antibodies and proteins.



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.

Sustainable Partner

DSM has established a corporate framework for sustainability, encompassing economic, environmental, social and quality-related performance. The merging of this philosophy, corporate strength, and insight into future market trends means DSM is not only an exceptional service provider right now, but a logical choice among what will likely be a streamlined number of contract manufacturers in the long term.

DSM's position reflects a distinct approach to partnership with customers. While its technology and regulatory expertise are as exceptional as any provider, DSM is focused as a supplier and innovator of services that bring real value to customers.

DSM has the track record to claim superior customer service and technical expertise—characteristics that make it a leading CMO today. Other factors differentiate DSM as a partner in business innovation—bringing long-term total value to customers. These factors are sustainability, premium quality, regulatory excellence, a compelling facility and unparalleled experience.

Such factors are critical as pharma and biotech increasingly seek to outsource while ensuring long-term security of supply. For mid-size and small pharma and biotech with limited or no manufacturing capabilities, the value is in being able to focus on the product development pipeline.

DSM can be a company's sole service and product provider, supporting all market segments as they evolve with extensive development services, fast and cost-efficient tech transfers, and dependable commercial product supply.



In 2010, DSM ranked the #1 in the global chemical sector of the Dow Jones Sustainability World Index.*

* 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.



Compelling Facility

DSM's pharmaceutical finished dosage form manufacturing is centered in Greenville, North Carolina. Its 1.5M square foot facility is located in 29 buildings on 640 acres. The way this site is engineered and operated makes it one of the world's leading facilities for the manufacture of aseptic liquid fill and lyophilized products and oral solid dosage forms, along with related services.

DSM has invested over \$170 million since 2001 to ensure that Greenville continues to offer state-of-the-art technology, from production and quality processes to project management systems and regulatory support. One visit to Greenville is enough to convince most companies that DSM is the partner of choice.

Unparalleled Experience

DSM has operated the Greenville facility since late 2000, yet there is nearly four decades of experience at this location. The average staff tenure is greater than 14 years.

This knowledge base not only sustains extremely high operational and regulatory performance but also supports some extraordinary statistics. DSM has repeatedly launched 10 or more products annually. Product launches have included high-end processes such as lyophilization and complex solid dose formulations. DSM fills and/or freeze dries several of the top five biotech products on the market.

- General capabilities include:
- :: Aseptic Liquid Filling & Lyophilization
 - :: Tablet & Capsule Manufacture
 - :: Sterile Cytotoxic Formulation & Filling
 - :: Pharmaceutical Development Services
 - :: Sterile Clinical Trial Material Formulation & Filling
 - :: Scheduled Drugs
 - :: Packaging

Premium Quality

DSM's regulatory track record results in numerous pre-approval inspections being waived.

DSM's quality systems are driven by a suite of validated computerized systems. SAP manages material control, release, preventative maintenance, and calibration. Documentum is used for document and work order control, while LIMS manages lab data. Trackwise manages deviation, change control, audit findings, and corrective actions.

DSM uses a proprietary software system called iMost for planning, scheduling, and as a data hub. This is also used to provide online, real-time batch data to clients. These systems are fully integrated, and provide consistent and timely reporting to ensure up-to-date availability of all relevant supply chain data, including batch release status.

The Greenville facility is approved by the FDA, EMEA and many other international regulatory agencies, enabling DSM to ship to countries throughout the world. The infrastructure and unstinting approach to quality, which includes predictive modeling and risk analysis, represents invaluable service to customers.

Regulatory Excellence

DSM's track record and reputation among regulatory bodies is exemplary. We implement a regulatory strategy based on in-depth knowledge of FDA procedures and guidelines.

More than 90% of pre-approval inspections (PAIs) have been waived since 2007, which reflects a major benefit to customers in terms of optimizing time to market. Greenville is also a DEA-licensed facility, and mandated DEA processes are supported by state-of-the-art security, planning and scheduling.

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. Tech transfer to the Greenville site can be achieved quickly and cost-effectively, with long-term cost benefits for commercial product supply.



Solid Dosage Forms

DSM is a leader in dosage form manufacturing of tablets and capsules. With almost four decades of experience at the Greenville site, DSM offers high quality services in the production of instant and sustained-release, and scheduled and non-scheduled drugs. More than 200,000 square feet of manufacturing capacity allows for extensive blending, granulation, compression, encapsulation, coating, drying, and formulation capabilities.

Scheduled Drugs

DSM performs custom manufacturing services for solid dose and sterile scheduled drugs in post-discovery or commercial manufacturing phases. We have the infrastructure—from management and administrative personnel to facilities and operations experts—to provide the knowledge, control and scientific capabilities necessary to optimize a project from start to finish. Scheduled injectable drug production is a unique niche capability of DSM.



Sterile Dosage Forms

Aseptic liquid filling

DSM offers aseptic liquid filling using a proprietary, flexible, state-of-the-art distributed control system. The system is used on all filling lines operating under aseptic production methods, and controls all SCADA, D3, and electronic cycle run report functions in a single unified solution.

Utilizing a product-specific, recipe-driven single communication interface, all production operations from supply and filling to packaging and warehousing occur with minimal interaction from production staff.

This system offers two major benefits:

- :: Minimal operator contact during filling operations increases sterility assurance
- :: Automated production controls enhance product quality from the outset

Lyophilization

DSM offers pharmaceutical and biopharmaceutical customers a lyophilization system with unique benefits. It has the precision to serve increasingly demanding lyophilization cycles, a critical requirement for successful product launches and high commercial yields.

The lyophilizers range in size from 8 to 640 square feet, and are equipped with proprietary software called LyoAdvantage™ for cycle control, which provides the accuracy necessary for high value products. A key benefit is the ability to efficiently scale up from an 8 square foot, non-cGMP unit to any commercial unit (up to 640 square feet).

LyoAdvantage™ is a trademark of DSM N.V.



Cytotoxic Formulation & Filling

Logical extension

As a global leader in the manufacture of commercial-scale sterile pharmaceuticals, a logical step for DSM was to expand this expertise by offering filling and lyophilization of cytotoxic products. Originally requested by customers and now implemented since early 2008, this represents another valuable integrated service.

Flexibility and safety

DSM's cytotoxic services are flexible, with complete aseptic liquid filling and lyophilization capabilities, variable batch sizes, options for expanded development and analytical services, and adaptable scheduling.

The Greenville facility has received Potent Compound Safety Certification from SafeBridge Consultants, Inc. This certification recognizes DSM's competency and proficiency in the safe handling of potent APIs and potent drug products, and applies to the site's potent sterile production area and the associated quality control laboratories.

Pharmaceutical Development Services

Packaging services

DSM has a Packaging Services Group with capabilities integrated into the entire portfolio of pharmaceutical manufacturing services provided at Greenville. A team of experienced professionals offers expertise in package engineering, graphic design, and testing. Knowledge of domestic and international pharmacopoeia regulations and specific packaging requirements ensure that packaging is managed and delivered effectively, and integrated with the product needs and timeline.

Significant value is provided in terms of vendor recommendations, process optimization, pallet pattern creation, CAD-designed packaging, and component coordination. DSM provides primary and secondary packaging, and material selection and testing.

The Greenville operation has a group of scientists and project managers dedicated exclusively to providing these services. Customers can therefore minimize the expense of tech transfers leading to launch and commercial supply.

Services include:

- :: Drug substance characterization
- :: Preformulation studies
- :: Formulation development
- :: Solid dosage clinical trial material manufacturing
- :: ICH / custom stability studies
- :: Evaluation of new delivery technologies
- :: Analytical method development / validation
- :: Lyophilization cycle optimization

DSM offers pharmaceutical development services, analytical development services, and clinical trial material manufacturing for solid dosage forms. With numerous annual product launches and nearly four decades of experience on site, DSM's services bring added value to customers in terms of cost reduction and accelerated time to market.



Sterile Clinical Trial Material Formulation & Filling

DSM offers sterile clinical trial formulation and filling that meets the unique needs of global pharmaceutical and biotech customers. Whether a project is in post discovery, cGMP Phases I–II, or ready for commercial manufacturing, DSM can provide all the resources necessary to provide assured delivery. Global account managers and R&D experts offer extensive experience in CTM services and worldwide distribution.



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