# Your ideal partner in benefiting patient health worldwide

## Pharmaceutical Solutions North America 2019

NUTRITION · HEALTH · SUSTAINABLE LIVING

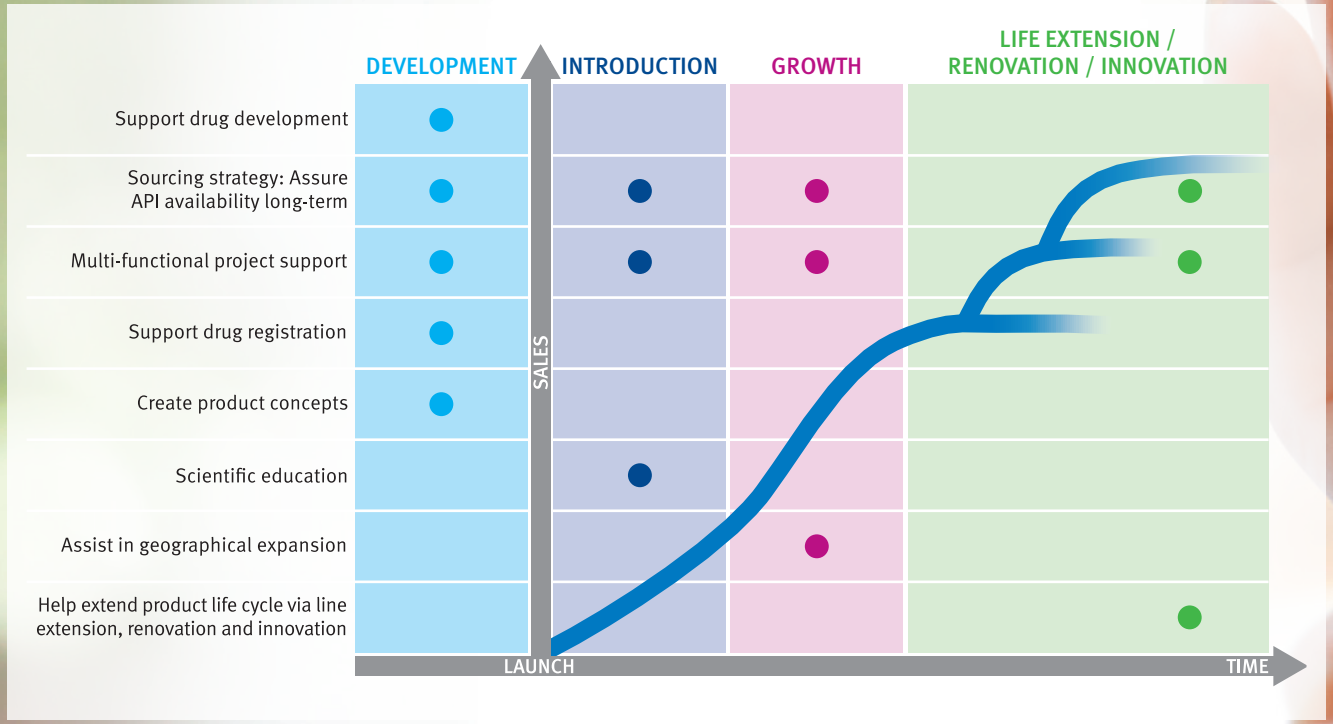
DSM
BRIGHT SCIENCE. BRIGHTER LIVING.

# Your long-term partner

With an annual growth rate of 5%,[1] the pharmaceutical market offers an opportunity for drug manufacturers to develop and launch products for a rapidly-expanding customer base. In such a fast-moving and competitive marketplace, it is critical to have the right partner in place for the development of new over-the-counter products and prescription medicines and to support the growth and evolution of these products across their life cycle. With more than 70 years of experience in pharmaceutical applications, DSM helps you do just that by helping to:

1. Assure agile drug development
2. Ensure seamless introduction
3. Enable fast growth
4. Optimize maturity and extend the life cycle

Our unique set of capabilities and commitment to quality, innovation and sustainable supply make us an ideal partner to address emerging therapeutic areas benefiting patient health worldwide and will help you meet your long-term growth aspirations.




1 Pharmaceutical Commerce [website] http://pharmaceuticalcommerce.com/business-and-finance/global-pharma-market-will-reach-1-12-trillion-2022/ (accessed 2 June 2017)

# We are global

DSM is the first and only company in the world that can provide access to both US Drug Master Files (DMFs) and Certificates of Suitability (CEPs) for all 13 vitamins, giving our pharmaceutical customers worldwide a competitive edge by accelerating the registration and market entry process. We also can produce EPA and DHA derived from either sustainable marine sources or microbial fermentation, offering unparalleled flexibility to provide what you need.

Our APIs are available through a global network, ensuring consistent and secure supply for our customers across multiple regions around the globe, long-term.

Our APIs, including the related services for the use in registered over-the-counter products and prescription medicines, help you to choose the right product form for the development of targeted products that benefit patient health worldwide.

# Our APIs

| Product Family | Product Description | Product Code | Regulatory Certification† | |
|---|---|---|---|---|
| | | | US DMF | CEP‡ |
| Vitamin A | Retinyl Palmitate 1.7 MIUg Ph | 5016262 | ● | ● |
| Vitamin B1 | Thiamine Hydrochloride Ph | 5016257 | ● | ● |
| Vitamin B1 | Thiamine Mononitrate | 0418943 | | ● |
| Vitamin B2 | Riboflavin 5-Phosphate Ph | 5016261 | ● | ● |
| Vitamin B2 | Riboflavin Universal | 0470406 | | ● |
| Vitamin B3** | Niacinamide | 0487848 | | ● |
| Vitamin B3** | Niacinamide Ph | 5016291 | ● | |
| Vitamin B5 | Calcium D-Pantothenate | 0412678 | | ● |
| Pro-Vitamin B5 | D-Panthenol Ph | 5016258 | ● | ● |
| Vitamin B6 | Pyridoxine Hydrochloride Ph | 5016265 | ●* | ● |
| Vitamin B7 | D-Biotin Ph | 5016264 | ● | ● |
| Vitamin B9 | Folic Acid Ph | 5016259 | ● | ● |
| Vitamin B12** | Vitamin B12 Crystalline | 0429155 | | ● |
| Vitamin B12** | Vitamin B12 Crystalline Ph | 5016300 | ● | |
| Vitamin C | Ascorbic Acid Fine Granular | 0408093 | | ● |
| Vitamin C | Ascorbic Acid Fine Powder | 0422460 | | ● |
| Vitamin C | Ascorbic Acid Ph | 5016255 | ● | ● |
| Vitamin C | Calcium Ascorbate | 0419443 | | ● |
| Vitamin C | Sodium Ascorbate Ph | 5016256 | ● | ● |
| Vitamin C | Ascorbic Acid Ultra Fine Powder | 5009766 | | ● |

| Product Family | Product Description | Product Code | Regulatory Certification† | |
|---|---|---|---|---|
| | | | US DMF | CEP‡ |
| Vitamin D3 | Dry Vitamin D3 100 SD/S Ph | 5016212 | | ● |
| Vitamin D3 | Vitamin D3 Crystalline Ph | 5016263 | ● | ● |
| Vitamin E | dl-a-Tocopheryl Acetate Ph | 5016260 | ● | ● |
| Vitamin K1 | Vitamin K 1 | 0435015 | | ● |
| Vitamin K1 | Vitamin K1 API | 5013224 | ● | |
| β-Carotene | β-Carotene Crystalline Ph | 5014344 | | ● |
| EPA/DHA | MEG-3™ 4717EE (460mg EPA/160mg DHA) | 5015474 | ● | |
| EPA/DHA | MEG-3™ 5010EE (550mg EPA/100mg DHA) | 5015255 | ● | |

† *Additional regulatory certifications are available. Please contact us in case of guidance for applicability of our API portfolio outside of US and Canada.*

‡ *CEP: The role of the Certificate of suitability of European Pharmacopeia monograph (CEP) is to certify that the quality of a given substance produced by a specific manufacturer is suitably controlled and in compliance with the relevant monograph(s) of the European Pharmacopeia. It is granted by the European Directorate for the Quality of Medicines & HealthCare (EDQM).*

* *Expected to be filed in 2019.*

** *Accessible through a third party supplier.*

# You can count on us

DSM has a proud heritage as Roche Vitamins, which was acquired in 2003. Through the Roche Vitamins acquisition, we have over 70 years of experience producing vitamins for the food and pharmaceutical industry, and this experience has been the basis for our evolving capabilities in vitamin manufacturing for pharmaceutical applications. We pride ourselves on our record of zero product recalls on our vitamins and lipids.

As the largest vitamin and lipid manufacturer in the world, we are pioneers in B-vitamin production, and were the first company to synthesize vitamins A, D, E and K. We are also the largest supplier of marine oil concentrates and algal oil in the world, and are the premier supplier for lipid APIs, including the omega-3 polyunsaturated fatty acids (PUFAs), EPA and DHA.

# Setting standards

DSM's global network of regulatory specialists and strong track record with regulatory authorities means we are well equipped to provide support and cater to our customers' local regulations. Our production is supported by multiple plants worldwide, and by operations in each of our regions – all of which meet the highest local and international standards.

Our API quality is governed by a wide range of certification systems, including:

- ICH Q7 compliant
- USP/EP/JP compliant
- US Drug Master Files
- Certificates of Suitability
- Good Manufacturing Practices (GMP) certificates by authorities

We are in contact with a number of authorities and industry associations to provide customers with the confidence that our products meet standards worldwide.

- US Food and Drug Administration (FDA)
- Health Canada (HC)
- European Directorate for the Quality of Medicines (EDQM)
- Active Pharmaceutical Ingredients Committee (APIC)
- International Pharmaceutical Excipient Councils (IPEC) Federation

# Innovation partner across the life cycle

At DSM, we are continually strengthening our capabilities to co-innovate, by connecting our scientific, technical, and regulatory expertise with your needs. This has given us a strong track record in joint innovation and allows us to deliver a science-driven approach to product development and support, through a global network of application labs, and collaborations with key opinion leaders, as well as more than 400 expert R&D partners.

DSM regularly participates in, and conducts its own, clinical trials, allowing us to stay at the forefront of innovation and product development and to further develop our strong IP portfolio. We also act as a partner in licensing therapeutic solutions and we want to work with you to discover novel treatments in fields ranging from oncology to cardiovascular disease, and others.

# Raising the bar

DSM prides itself on having proven success in quality assurance and ensuring a reliable supply of products to our customers worldwide. We draw on our unique skills in fermentation, synthesis and biotechnology to ensure all our products meet the highest standards and the strictest sustainability criteria. Our commitment to making substantial future investments in excellence and sustainability also means our global production network remains cutting edge and high quality.

For us, quality means going beyond guidelines. We have a comprehensive set of quality and safety, health and environment (SHE) policies that we apply globally to both ourselves and our manufacturing partners to ensure the products you use meet the highest standards.

Our manufacturing locations are all GMP-qualified production sites, and our supply chain for key intermediates is fully backward integrated, so customers can rest assured of the origin and traceability of our products, and the quality and sustainability with which they have been processed and manufactured.

We are also committed to being, and remaining, pioneers of the most eco-friendly technologies and production processes for APIs to reduce our carbon footprint and to stay compliant with international environmental regulations. We are proud that production efficiency


improvements now allow us to boast the lowest carbon footprint in the industry for many of our products, including Vitamins B2, B6, C and E. In addition, the raw materials for our lipid APIs are sustainably sourced from both marine fisheries around the world and produced through algal fermentation to help minimize environmental impact. These efforts help to ensure that our products meet the highest sustainability standards, and will help to provide stable and secure supply for our customers for years to come.

By combining our quality standards with our commitment to sustainability, we can provide products that are safe and effective, and manufactured in a responsible way. DSM is committed to staying in this business to help ensure security of supply for our customers.

**Dow Jones Sustainability**
Index leader

Dow Jones Sustainability Indexes

**ISO 14001**
Environmental Management Systems

DSM

For more information, please visit **www.dsm-pharmasolutions.com**
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Quality for Life®

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