

Your ideal partner in benefiting patient health worldwide

Pharmaceutical Solutions 2020

NUTRITION • HEALTH • SUSTAINABLE LIVING



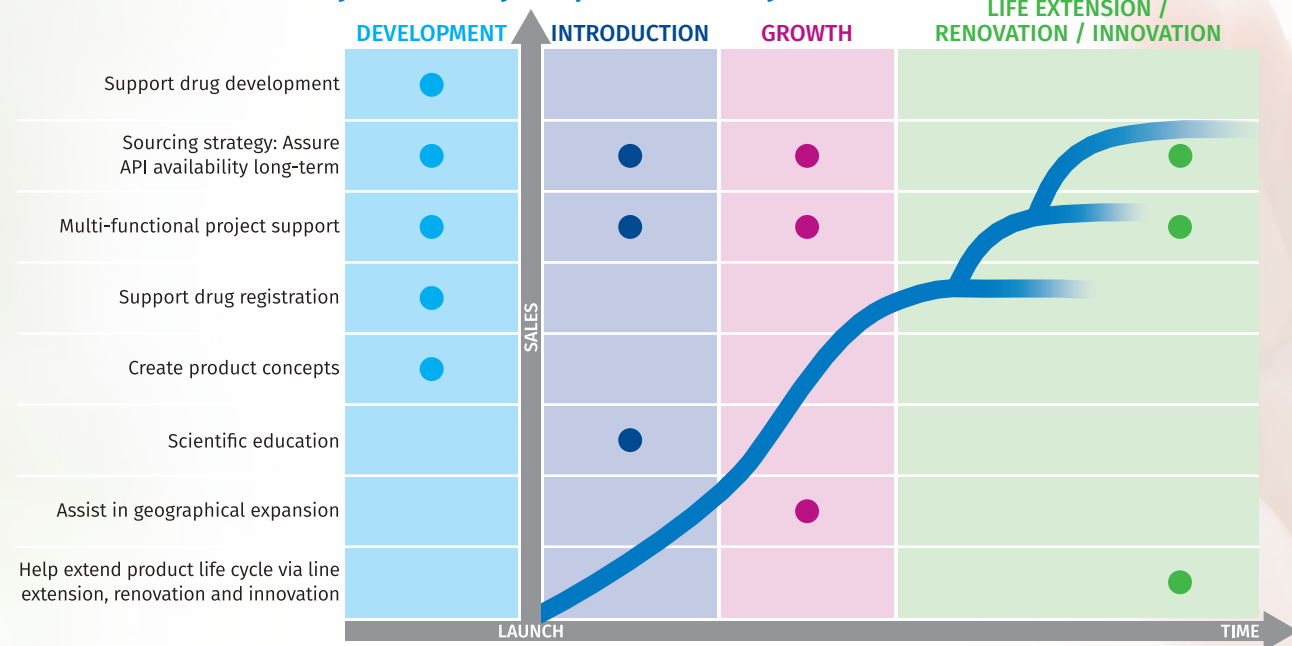
Your long-term partner

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 improving patients' lives worldwide and will help you meet your long-term growth aspirations.

DSM's commitment to you across your product life cycle



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. DSM also has the capability to produce custom quality lipid APIs and API intermediates from both marine (fish) and fermentative (algal) sources, offering unparalleled flexibility to provide what you need. DSM invests in its plants to ensure they stay state of the art and compliant to the latest standards so we can be your sustainable & reliable partner.

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, and 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 patients worldwide can benefit from.

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

Our APIs

The applicability of our portfolio for pharmaceutical application is subject to local approvals. Please check the status with local DSM Regulatory Affairs team in your region.

Product code	Product
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Vitamin A

04 2187 1	Dry Vitamin A Palmitate, Type 250 CWS/F (tocopherol)
04 2401 3	Vitamin A Palmitate 1.7 MIU/g (BHA/BHT)
04 2400 5	Vitamin A Palmitate 1.7 MIU/g ²
50 1626 2	Retinyl Palmitate 1.7 MIU/g Ph ^{1,3}
50 1227 9	Dry Vitamin A Acetate 500 B

Vitamin E

50 0112 9	Dry Vitamin E 50% CWS/S
04 2008 5	dl-alpha-Tocopheryl Acetate ²
50 1626 0	dl-a-Tocopheryl Acetate Ph ^{1,3}
04 1027 6	dl-alpha-Tocopherol

Vitamin D

50 1621 2	Dry Vitamin D3 100 SD/S Ph
50 1201 5	Dry Vitamin D3 100 CWS
50 1157 4	Vitamin D3 1.0 MIU/g
50 1626 3	Vitamin D3 Crystalline Ph

Vitamin K1

04 3492 2	Dry Vitamin K1 5% SD
04 3501 5	Vitamin K1
50 1322 4	Vitamin K1 API ⁴

Vitamin B1

04 2947 3	ROCOAT Thiamine Mononitrate 33 1/3%
04 1303 8	Thiamine Hydrochloride ²
50 1625 7	Thiamine Hydrochloride Ph ^{1,3}
04 1894 3	Thiamine Mononitrate

Product code	Product
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Vitamin B2

04 2946 5	ROCOAT Riboflavin 33 1/3%
50 1626 1	Riboflavin 5'-Phosphate Ph
04 7040 6	Riboflavin Universal

Vitamin B3

04 8784 8	Niacinamide
50 1629 1	Niacinamide Ph ^{3,4}

Vitamin B5

04 1267 8	Calcium D-Pantothenate
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Pro-Vitamin B5

04 1385 2	D-Panthenol ²
50 1625 8	D-Panthenol Ph ^{1,3}

Vitamin B6

04 2945 7	ROCOAT Pyridoxine Hydrochloride 33 1/3%
50 1626 5	Pyridoxine Hydrochloride Ph (origin: China)
04 1160 4	Pyridoxine Hydrochloride ² (origin: Germany)
50 1646 0	Pyridoxine Hydrochloride Ph ^{1,3} (origin: Germany)

Vitamin B7

50 1165 5	D-Biotin ²
50 1626 4	D-Biotin Ph ^{1,3}

Vitamin B9

50 1625 9	Folic Acid Ph
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Product code	Product
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Vitamin B12

50 1251 1	Vitamin B12 1% SD
04 2909 0	Vitamin B12 0.1% WS
50 1627 9	Vitamin B12 0.1% WS Ph ⁵
04 2915 5	Vitamin B12 Crystalline
50 1630 0	Vitamin B12 Crystalline Ph ⁴

Vitamin C

04 0809 3	Ascorbic Acid Fine Granular
04 2246 0	Ascorbic Acid Fine Powder ²
50 1645 0	Ascorbic Acid Fine Powder Ph ^{1,3}
50 1625 5	Ascorbic Acid Ph
04 1944 3	Calcium Ascorbate
50 1625 6	Sodium Ascorbate Ph
50 0976 6	Ascorbic Acid Ultra Fine Powder
04 2511 7	Coated Ascorbic Acid, Type EC
50 0774 7	Ascorbic Acid 95% Granulation

Beta-Carotene

50 1434 4	β-Carotene Crystalline Ph
50 1438 7	β-Carotene 30% FS Ph
50 1435 2	BetaTab® 20% S Ph

Lipid API Intermediates

Eicosapentaenoic Acid (EPA)	Customized concentrations and combinations to meet your needs – contact your DSM Account Manager for details.
Docosahexaenoic Acid (DHA)	
Arachadonic Acid (ARA)	

¹ API with specific service package for pharma registered applications; ² Future applicability for pharma registered products in limited markets only; ³ Launch expected during the course of 2020;

⁴ US DMF; ⁵ Pharmaceutical preparation produced according to GMP Guide Part 1 (manufacture of medicinal products).

You can count on us

- We continue to invest, ensuring we're compliant and ahead of the latest requirements
- We're here to support and serve your business, now and in the long-term future – as long as your product is on the market

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. As the largest vitamin manufacturer in the world, we are pioneers in B-vitamin production, and were the first company to synthesize vitamins A, D, E and K.

Through the acquisition of Ocean Nutrition Canada in 2012 and that of Martek Biosciences in 2011, DSM is the largest supplier of marine and algal-based lipid concentrates in the world. As the first ever USP-verified producer of marine oils, we have over 30 years of experience producing omega-3 polyunsaturated fatty acids (PUFAs) such as 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.

We are recognized by benchmarks as leading the way in integrating sustainability in operations and business

For the 3rd year DSM is on Fortune Magazine's Change the World list, 2018



Industry Group leader for the 8th time (among the leaders for past 15 years), 2018



Chemicals Industry Leader in Sustainalytics ESG ranking, 2018



A-rating for CDP Water and CPD Climate, 2017



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