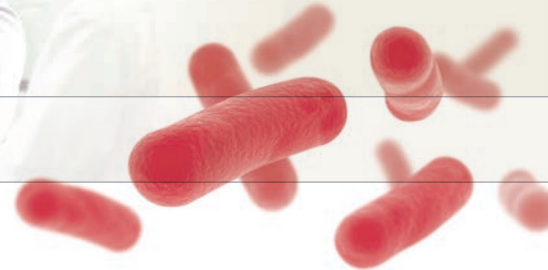


Microbial Fermentation



Full Solution Provider for Microbial Fermentation

Nordmark Biotech bundles all biotechnological activities of Nordmark. We are offering an all-in-one solution for microbial fermentation based products covering the entire value chain from process development, analytics, production of API and finished drug product up to regulatory affairs and marketing authorisation. Our worldwide customers benefit from this integrated approach, which is based on solid project management, long-standing GMP experience and recurrent EMA and FDA approvals.

Expertise in Microbial Fermentation

Nordmark Biotech and its affiliate companies offer comprehensive development services for microbial fermentation based processes. State-of-the-art cleanroom standard according to EU class D and C (FDA class 100,000 and 10,000) as well as dedicated microbial fermentation production facilities are available for these purposes.

Corporate Facts

Foundation
1927

Headquarter
Uetersen near Hamburg,
Germany

Facilities
Uetersen, Bielefeld

Number of Employees
Approx. 570 (Nordmark Group)

Contact
Nordmark Pharma GmbH
Dr. Jan Heyland
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Germany

T +49 (0)4122 712 907

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projects@nordmark-biotech.de

USP



Strain and process development

- > Strain development and genetic engineering
- > Cultivation setup of aerobic and anaerobic microbial hosts up to BSL 2
- > DoE based process development
- > Development of batch and fed-batch cultivation processes

DSP



Purification / downstream

- > Individual purification process development for enzymes
- > DoE based process development
- > State-of-the-art analytics (e.g. activity-assays, aggregates, identity and purity, HCPs and DNA, isoforms)

PRODUCTION



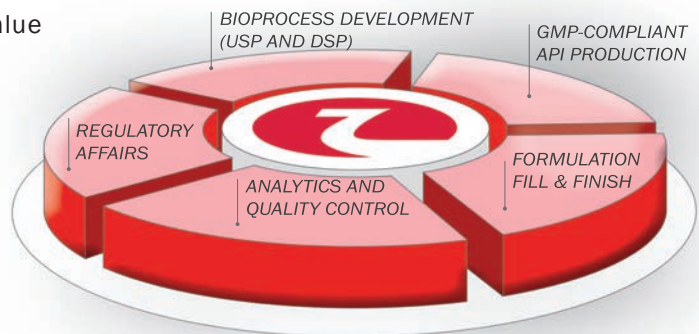
Highest GMP standards on all levels

- > Lab scale (0.1 to 40 L) – for development
- > Pilot scale (up to 500 L) – for clinical trials
- > Production scale (up to 1,500 L) – for continuous market supply

Biotech from one Expert Source

One-Stop Shop

Nordmark Biotech is able to cover the entire value chain from process development to marketed drug products. We manufacture APIs and finished drug products for recognized pharma companies as well as for our own brands according to cGMP. Our value added services include pharmaceutical and analytical method development, stability testing and regulatory support during approval processes (worldwide).

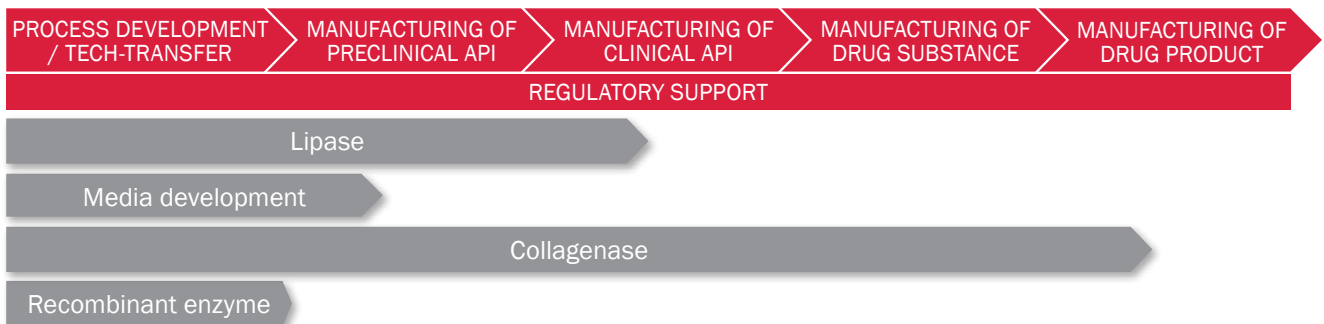


Project Management - Nordmark Biotech as Partner

At Nordmark Biotech we account for each client's individual need for customized project support – from the first idea to supplying the finished drug product. As a family owned business we are used to work with maximum care and attention and lean decision making processes. We are committed to your success – regardless of project size.

In close cooperation with our customers, we define exact project goals, clear structures and responsibilities. Based on technical feasibility we develop a detailed project management concept including scheduling and cost control. Our project manager is your primary contact and is responsible for steering the entire process and driving the project to success.

Project Examples



Further Information



NW000025 08/2021