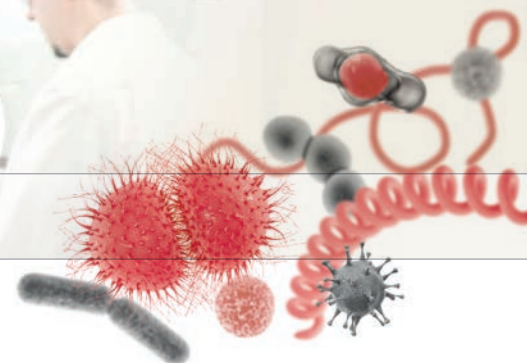


# Microbiome – Live Biotherapeutics



## Full Solution Provider for Live Biotherapeutics

Nordmark Biotech bundles all biotechnological activities of Nordmark. We are offering an all-in-one solution for microbiome based products covering the entire value chain from process development, analytics, production of drug substance (DS) and finished drug product (DP) 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 expertise and recurrent EMA and FDA approvals.

### Expertise in Microbiome Drug Substance and Drug Product

Nordmark Biotech offers all required technologies for microbiome based drug substance and drug product development, including cell bank production under GMP based on both, aerobic and anaerobic cultivation up to biosafety level 2 (BSL2). Our teams are well experienced in managing the heterogeneity of microbiota consortia as well as sterility under aerobic and anaerobic conditions (incl. viable cells).

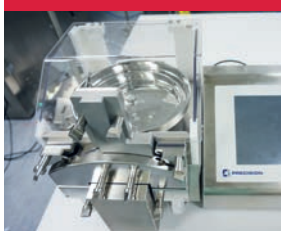
#### DRUG SUBSTANCE



#### Microbiome based drug substance:

- > Cell banking
- > GMP/BSL2
- > Aerobic and anaerobic cultivation
- > Media and process development
- > Freeze drying and milling

#### DRUG PRODUCT



#### Microbiome based drug product:

- > Broad expertise in DP formulation and process development for biological DS including BSL2 viable cells in small molecule dosage forms like capsules
- > Manufacturing train for manufacture of anaerobic BSL2 microbiota consortia based clinical supplies
- > Versatile platform technologies and formulation platforms for viable cell based DPs

#### PRODUCTION



#### GMP standards and analytics on all levels:

- > State-of-the-art GMP testing of aerobic/anaerobic BSL1/2 viable strain products like: MCBs, drug substances, drug products (single strain and consortia)
- > State-of-the-art analytics for MCBs, DS, aerobic/anaerobic strains

### 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  
Pinnauallee 4  
25436 Uetersen  
Germany

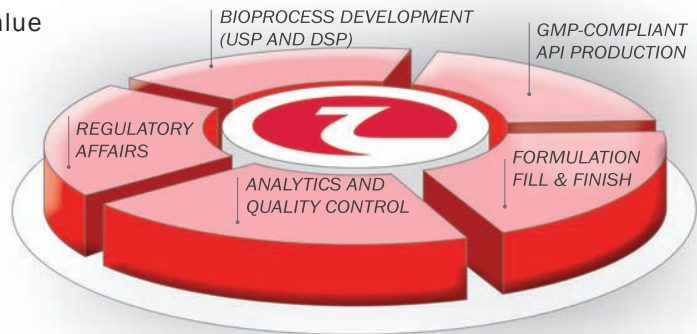
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[projects@nordmark-biotech.de](mailto:projects@nordmark-biotech.de)

# 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



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