



Nordmark Biotech

Your Partner in Biological Drug Development and Production

NORDMARK BIOTECH AT A GLANCE

- > Nordmark: a leading manufacturer of high quality biological APIs with nearly 90 years of experience
- > Nordmark Biotech is specialized on process development and GMP protein production
- > Partnering with Nordmark Biotech means benefitting from the Nordmark Group
- > Proven track record
- > Extensive regulatory experience
- > Trust based on long-lasting relationships
- > Nordmark Biotech – a flexible, reliable and committed partner at your side

Nordmark Biotech as a Partner

- > Flexible partnerships combined with a unique expertise and know-how in developing and delivering drugs to market
- > Maximum care and attention by a family owned business
- > Fast and simple decision making processes
- > Focused on success – regardless of project size

You innovate, we process, together we deliver

References

Our long-term relationships prove the quality and reliability our partners require



Nordmark Biotech Corporate Facts

Nordmark Group founded
1927

Headquarter
Uetersen near Hamburg, Germany

Production Facilities
Uetersen, Bielefeld

Management
Dr. Jörn Tonne, CEO
Detlev Baumeister
Dr. Manfred Kurfürst
Prof. Dr. Dirk Lütkemeyer

Number of Employees
About 500 (Nordmark Group)

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PARTNERING WITH NORDMARK BIOTECH IS ABOUT
ACHIEVING YOUR GOALS. TOGETHER!



Capabilities

From Drug Candidate to Drug Product

Nordmark Biotech is a leading provider for the development and manufacturing of active pharmaceutical ingredients (API) and drug products of biological and biotechnological origin, gained by extraction from animal or plant material, microbial fermentation and mammalian/CHO-based manufacturing with capabilities at every value creation stage, including sophisticated protein formulations and packaging.

The Specialist for GMP Protein Production



CELL LINE DEVELOPMENT

Mammalian cell lines and Microbial strains

- > Screening
- > Clone selection
- > Clone optimization
- > Genetic engineering
- > Cell banking under cGMP
 - Master Cell Bank (MCB)
 - Working Cell Bank (WCB)



PROCESS DEVELOPMENT

Upstream Processing

- > Batch, fed-batch, perfusion
- > Parallel cultivation systems
- > Process optimization
- > Lab to production scale
- > Scale-down studies

Downstream Processing

- > Chromatography and filtration
- > HCP and DNA removal
- > Scale-up and scale-down studies



FORMULATION DEVELOPMENT

> Screening and development of liquid, semi-solid and solid formulations

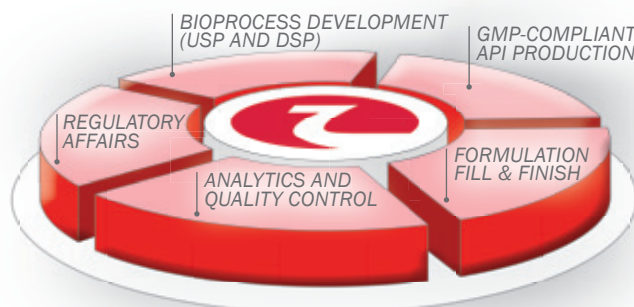
- Protein unfolding (HT- μ DSC)
- Protein structure (FT-IR, CD)
- Protein aggregation (DLS, LO)

> Manufacture of stability and preclinical batches

- > Scale-up and industrial transfer
- > Primary packaging development

Covering the entire Value Chain

Nordmark Biotech provides the complete value chain and the full range of services to meet your drug development needs all the way through to commercialization.



Track Record

With Marketed Products We Know What it Takes to Make Your Product a Success

Nordmark can refer to a significant track record in the industry with successful different process development and manufacturing projects in various stages of clinical development as well as approved and marketed products for more than 40 international partners.

Selected Biotech Projects

PARTNER	PRODUCT	ACTIVITIES
BIOCEUTICALS	EPO Biosimilar (CHO)	Process development, GMP-production of clinical material Phase III, Planning, building and operationally running the GMP production site
advanceCor	Recombinant fusion protein (CHO)	Process development, GMP production of preclinical and clinical material PH I
Ticeba	Monoclonal antibody	Purification process development, GMP production
CT Atlantic	Monoclonal antibody	Process development and GMP production
Nordmark proprietary	Ancrod, Burlulipase, Collagenase	Process development and GMP production, formulation and primary packaging development

AT THE HEART OF OUR SUCCESS ARE COMPETENCE, QUALITY, RELIABILITY AND PROVEN RELATIONSHIPS.