



Company Profile

Company introduction

Lyomark Pharma GmbH was incorporated in 1989, as a supplier of drug substances, drug products and R&D chemicals. Lyomark is specialised in niche proprietary and generic products and orphan drugs for redundant diseases, presented as sterile injectable, lyophilized formulations in pre-filled syringes, vials and ampoules.

Lyomark is active in the area of respiratory diseases, neonatology, oncology, antibiotics, antimycotics etc. Its very flexible production capacity, under GMP, GLP, ICH and EU-guidelines, enables the supply of clinical, regulatory and commercial batches on an exclusive customer oriented basis. Marketing and sales are carried out either directly through Lyomark's own sales force or through partners.

The oncological product portfolio is marketed by Lyomark's sister company Bendalis GmbH. Lyomark has consolidated international regulatory expertise and know-how in pharmaceutical formulations and manufacturing, and can offer to its partners full support and service.

Milestones

- 1989 Incorporation of Lyomark Pharma as a service provider for manufacturing of edelfosine
- 1994 In November, Dr. Helmut Wolf becomes the Chief Executive Officer
- 1995 Expansion to a service provider for toll and contract manufacturing of sterile products with Somatostatin as first product
- 2001 Development of Octreotide
- 2002 Development of Vancomycin
- 2003 Filing of international registrations for Lyomark generics
- 2005 International distribution partner for drugs and active pharmaceutical ingredients
- 2006 Acquisition of Alveofact® from Boehringer Ingelheim
Founding of sister company Bendalis GmbH
- 2007 Establishment of a dedicated sales organisation in Germany
- 2009 International registrations for Alveofact®
- 2013 Approval of Ciprofloxacin, Levofloxacin and Fluconazole
- 2016 Approval of NeoKay® in Germany
- 2017 Acquisition of majority of LYOCONTRACT

Product Portfolio

Finished Products

Product	Substance category	Strength	Form
Alveofact®	Surfactant	54mg 108mg	Lyophilized Powder
NeoKay®	Vitamin K	1mg	Softgel Capsules
Somatostatin	Peptide Hormone	3mg	Lyophilized Powder
Octreotide	Peptide Hormone	50µg 100µg 500µg 1000µg	Solution for Injection
Vancomycin	Antibiotic	500mg 1000mg	Lyophilized Powder

Worldwide Distribution

- Argentina
- Croatia
- Iran
- Oman
- Turkey
- Austria
- Denmark
- Italy
- Peru
- Turkmenistan
- Azerbaijan
- Egypt
- Kazakhstan
- Portugal
- Ukraine
- Bahrain
- Equador
- Kenya
- Qatar
- United Arab Emirates
- Belarus
- Finland
- South Korea
- Russia
- United Kingdom
- Belgium
- France
- Kosovo
- Saudi Arabia
- Uruguay
- Bulgaria
- Germany
- Kuwait
- Serbia
- USA
- Canada
- Greece
- Kyrgyzstan
- Spain
- Uzbekistan
- Chile
- Hungary
- Lithuania
- Sweden
- Venezuela
- China
- India
- Lybia
- Taiwan
- Vietnam
- Columbia
- Indonesia
- Netherlands
- Tajikistan
- Yemen
- Costa Rica
- Iraq
- Norway
- Thailand

Business Units

Lyomark Pharma GmbH

Development

- Formulation development
- Analytical development
- Out-Licensing

API

- Market analysis
- Supplier qualification
- CEP & EMDF documentation
- Logistics

Regulatory Services

- Dossiers compilation
- DCP/MRP submission
- Other services (PQR, PSUR)

Marketing

- Realisation of strategic marketing concepts in Germany for wholesalers, pharmacies and hospitals
- International distribution network with partners in over 50 countries
- Warehousing and distribution

Network

LYOCONTRACT & ProJect Pharmaceuticals



Your ideas and needs, our know-how!

We are pleased to announce that effective August 1st 2017 Lyomark Pharma GmbH shall become majority share-holder of Lyocontract GmbH. This will expand our combined capabilities and strengthen our overall position in the pharmaceutical industry.

Lyocontract is a state-of-the-art pharmaceutical manufacturing site with the capabilities of producing liquid and freeze-dried parenteral drugs in vials. The site received its manufacturing license in 2012 and has ever since earned the trust of numerous clients in Germany and abroad.



Contract Manufacturing

- Aseptic filling into vials
- Lyophilised & liquid
- Terminal sterilisation
- Secondary packaging
- Stability testing according to ICH guidelines
- Development and optimization of freeze-drying programmes
- Aseptic filling and lyophilisation of clinical trials supply
- Clinical to commercial scale up



Transforming proteins into pioneering drugs®

ProJect Pharmaceuticals offers formulation and process development for parenteral drug products to the pharmaceutical and biotech industry. We resourcefully design tailored pharmaceutical formulations that render towards more stable, safer and convenient biologics. We shape cost-effective manufacturing processes, tailor-made for the formulation and ensure that drug products run smoothly in large scale GMP manufacturing:



Development

- State-of-the-art QbD-based formulation development for all kinds of biologics including antibodies, ADCs and vaccines
- Development of robust and efficient freeze-drying cycles by high-end freeze drying technology
- Aseptic manufacturing of preclinical study material
- Process compatibility studies and technology transfer to commercial drug product manufacturing

