Factsheet Werthenstein BioPharma GmbH

About Werthenstein BioPharma GmbH

Werthenstein BioPharma GmbH is a subsidiary of MSD, a leading research-based pharmaceutical company with corporate headquarters in Kenilworth, New Jersey, USA. (The company is known as Merck & Co., Inc., Kenilworth, New Jersey, USA in the USA and Canada.)
Werthenstein BioPharma GmbH was established by Schering-Plough as Werthenstein Chemie AG in 1976. After the merger between Schering-Plough Corp. and Merck & Co., Inc., Kenilworth, New Jersey, USA the company name was changed to Werthenstein BioPharma GmbH in July 2010.

Headquarters

Werthenstein BioPharma GmbH
Industrie Nord 1
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Business Purpose

In Schachen, Lucerne, Werthenstein BioPharma GmbH develops and analyses new large molecule (i.e. biological) drug substances. Analytical laboratories at the site are equipped to test and to run stability studies on drug substances or drug products. In addition, Werthenstein BioPharma GmbH provides experimental medicines for worldwide clinical trials.
Werthenstein BioPharma GmbH provides an important contribution to MSD in the endeavor to bring new innovative medicines to patients as fast as possible, while applying highest quality standards to all activities.

Employees

Around 330 scientists, engineers, technicians, process specialists and administrative personnel from currently 15 nations are employed at the site.

Key Business Areas

- Development and clinical manufacturing of biological (large molecule) drug substances
- Development of pharmaceutical-, analytical-chemical- or biochemical testing methods for drug products and drug substances
- Packaging of Clinical Supplies
- Worldwide distribution

The manufacturing and packaging operations are supported by quality control laboratories (performing analytical-chemical, biochemical, pharmaceutical or microbiological tests).
Adherence to and conformance with regulatory and internal quality standards is ensured by the Quality Assurance Department. Internal Service Groups (as for instance IT or facility management) provide further support. A Safety Group is dedicated to environmental, health and safety aspects on site.

Therapeutic Areas

The activities at Werthenstein BioPharma GmbH are related to the main research areas of MSD. They also include therapeutic areas in which MSD already has commercial products. At the moment these are (list not exhaustive):

- Oncology
- Metabolism
- Endocrinology and Immuno-system
- Cardiovascular System
- Infectious Diseases
- Woman's Health & Hormone Therapy
- Neurosciences

Clinical Trials

Werthenstein BioPharma GmbH provides Clinical Supplies (i.e. investigational medicinal products) to Clinical Trial Sites worldwide. Each year up to 2 Million units are being labelled in more than 30 different languages and distributed into more than 50 different countries.

Relevance for the corporation

Werthenstein BioPharma GmbH was involved in the development of about 45% of MSDs products on the Swiss Market. For example, extensive work was done for Aerius, PegIntron, Remicade, Simponi, Ezetrol and Keytruda. Especially in the case of Ezetrol, it was the complex and extensive Phase III trials, supported by Werthenstein BioPharma GmbH through coordination of blinding, packaging and worldwide delivery of study and comparator medication to trials centers, which helped to quickly attain marketing authorization. In addition, the laborious blinding requirements were the start for Werthenstein BioPharma GmbH becoming a center of excellence for comparator sourcing and blinding within the entire organization.
In 2014, a biotechnological anti-cancer medicine (Keytruda), containing the active ingredient developed by Werthenstein BioPharma GmbH, was approved by the American Food & Drug Administration (FDA). The Swiss approval followed in 2015. Werthenstein BioPharma GmbH was granted the license for commercial manufacture of the drug substance for the the US-market.

Investment in R & D

Since 2012 more than 70 Million Swiss Francs were invested in Werthenstein BioPharma GmbH.

Factsheet Werthenstein BioPharma GmbH

Apprenticeship

Werthenstein BioPharma GmbH is engaged in the professional education of Laboratory Technicians (Chemistry since 1977 and Biology since 2010) and provides jobs to young apprentices.

Management Team

Peter Hofstetter, PhD
Site Head, Head Central Functions

Markus Tanner
Head Biotechnology Department

Martin Mueller, PhD
Head Bioanalytics

Holger Luebke, PhD
Head Quality Operations

Stefan Zingg
Head Global Clinical Supplies

Stephanie Moessner, PhD
Head Analytical Chemistry in Development and Supply

Sabina Compassi, PhD
Lead Improvement Engineering

Tanja Schaufelberger
HR Lead

Hansjörg Bachmann
Facility Management

Roland Bohren
Site IT Lead

History

1976
Schering-Plough opens a chemical/pharmaceutical development laboratory with 13 employees. The name of the laboratory is Werthenstein Chemie AG. Key business areas: Development of chemical drug substance synthesis, production of chemical drug substances for clinical studies. Manufacturing of dosage forms and packaging, labelling and distribution of patient kits for worldwide Clinical Trials.

1995
Venturing into the growing new area of biotechnological (biological, large molecules) manufacture of drug substances.

2000
Expansion of the capacity to manufacture biological drug substance: Increase of the volume of the cell culture fermentation unit (new 500 and 2000 L reactors) and opening of a microbiological testing lab.

2008
Further expansion of the capacity to manufacture biological drug products and phasing out/termination of the development/manufacturing activities in traditional chemistry and in the manufacture of pharmaceutical dosage forms for Clinical Trials.

2009
Merger Schering-Plough Corp. and Merck & Co., Inc., Kenilworth, New Jersey, USA.

2010
Company name was changed to Werthenstein BioPharma GmbH.

2012
Expansion into new areas:
- Opening of a Developmental laboratory to study properties of crystal forms ("Crystallisation lab")
- Installation of a semi-automated system to quality control drug dissolution from polymeric devices (such as contraceptive implants)
- Biotech-Pilot equipment to allow commercial manufacture of large molecules
- New warehouse, with modern sampling, weighing and dispensing areas
- Capacity increase of clinical packaging by implementation of an automated packaging technology
- Investments into Site Security (Security upgrade).

2013
November: Commercial production of Keytruda drug substance (large molecule/Biological drug substance).

2014
Successful Keytruda pre-approval inspection (PAI) by the Food & Drug Administration (FDA). Commercial manufacturing license granted by the FDA.

2015
End of commercial manufacturing of Keytruda. The main focus returned on clinical manufacturing of biological drug substances.

2017
Opening of the sterile filling suite in the biotech department enabling the manufacture of liquid biotechnological drug products.

2018
Opening of the forensic laboratory.

Factsheet Werthenstein BioPharma GmbH

Departments

Biotechnology *(Lead by Markus Tanner)*
Development and manufacture of biological (large molecule) drug substances and drug products for clinical studies as well as post approval commercial production. Processes and equipment are in accordance with the latest state of the art. Production starts with small to pilot-size cell cultures. Crude drug substance is produced in tanks with up to 2000L, yielding batch with different number of dose units, depending on the active ingredient concentration. After Fermentation, the drug substance is purified and finally filled in a sterile process into vials. The processes and the equipment allow attaining a purity and quality standard in conformance with requirements for both clinical studies as well as for commercial purpose.

Biologics Analytics *(Lead by Martin Mueller, PhD)*
Provides support to the Biotechnology Department by performing raw-, starting material and in-process testing for biological (large molecule) drug substances as well as maintaining an environmental monitoring program. The microbiology laboratory provides overall microbiological support for the site. Further, the department conducts stability and release testing of biological (large molecule) drug substances. It is also responsible for the global outsourcing of analytical work related to biological active ingredients. This includes identification and evaluation of CRO's, followed by study and quality monitoring to guarantee adherence to regulatory requirements and best practice.

Quality Assurance (QA*) (Lead by Holger Luebke, PhD)*
The Quality Assurance ensures Good Manufacturing Practices and adherence to regulatory or internal Quality Standards. Therefore, QA has oversight on all GMP activities, processes, systems, related infrastructure or changes on site. With the aim to drive appropriate corrections and continuous improvement, QA is involved in the investigation of irregularities and complaints. Another area of focus is equipment and facility qualifications and validations.

Global Clinical Supplies (GCS) & External Networks *(Lead by Stefan Zingg)*
GCS is responsible for the internal or outsourced blinding, packaging & labelling as well as for logistics and distribution of clinical supplies for world-wide use in clinical trials. The department is also responsible for evaluating and sourcing of comparator products to be used in a clinical trial.

Analytical Chemistry (PharmSci) *(Lead by Stephanie Moessner, PhD)*
The team provides analytical development support for small molecules. This involves release and stability testing of blinded comparators and polymeric dosage forms. The department is also acting as Quality Control unit for clinical supplies.

Commercial Analytical Support (SAS) *(Lead by Marc Grynbaum, PhD)*
This lab provides supply analytical sciences support, e.g. identification of extraneous matter in commercial supplies or support for source of supply changes worldwide.

Crystallization laboratory *(Lead by Stephanie Moessner, PhD)*
The WAG crystallization laboratory provides process development support for all new chemical active ingredients in MSD's pre-chemical development pipeline. Furthermore, the lab provides supply support for any crystallization issues at commercial sites.

Forensic Lab *(Lead by Belen Gonzalez Amoros)*
This lab investigates and provides evidence related to potential counterfeit or manipulations to MSD-products.

Process Improvement *(Lead by Sabina Compassi, PhD)*
Methodically ensures that strategic goals of the company drive progress and actions at every level within Werthenstein BioPharma GmbH and helps to align improvement projects to all pull in the same direction. Provides coaching and support to allow process improvement, standardization and simplification.

Central Services (Validation, IT, Facility Management, and Environmental Health & Safety)
(Lead by Sanna Schärli PhD, Roland Bohren, Hansjörg Bachmann and Céline Birrer)
The above mentioned central functions are responsible for the infrastructure in Werthenstein BioPharma GmbH, be it equipment, IT System, Facilities, Supplies (Water, Energy). The Environmental Health & Safety department is responsible for the implementation and adherence to internal or external national and requirements guidelines (from SUVA or BAFU) related to the protection of people and environment.

Human Resources *(Lead by Tanja Schaufelberger)*
Is the site's HR representative.

Additional information

www.msd.ch