



Pharmaceuticals Production Services – Boehringer Ingelheim

Our expertise in world-class
contract manufacturing
for your success



Successful partnership



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Being one of the world's twenty leading pharmaceutical corporations, the research-driven Boehringer Ingelheim group of companies also includes the contract manufacturing business as a key component of its strategy for Pharmaceuticals Production. The value we create for our industrial customers, through our long experience of successful partnerships, is also one of the key success factors of our supply network. We provide highly valuable contract manufacturing services to our industrial customer to create win-win partnerships.

Boehringer Ingelheim is a family-owned corporation, offers long term perspective and stability to our partners, while adapting to the competitive, fast-changing environment.

With eight world-class manufacturing facilities served by highly experienced and knowledgeable personnel, Boehringer Ingelheim offers services over three continents and can meet the most challenging expectations. The capabilities in pharmaceutical development as well as the wide range of manufacturing technologies, packaging technologies and services that our supply network can offer are many possibilities for your success.

Our long standing experience in the field of contract manufacturing services and with the support that Pharmaceuticals Production gets from interdisciplinary teams we can ensure a seamless implementation of new partnerships. The strong quality and compliance focus, the supply reliability, as well as the business process excellence mindset and the high level of commitment to meet customer needs, are a valuable basis for a competitive, best-in-class commercial supply.

As our outstanding capabilities and know-how in pharma chemicals and biopharmaceuticals can bring additional value, we also offer customized contract manufacturing solutions.

Dr Wolfram Carius



Our company



Boehringer Ingelheim is an independent corporation which operates globally and is committed to researching, developing, manufacturing and marketing drugs of high therapeutic value for human and veterinary medicine. For almost 125 years, our goal has been to secure and maintain our independence by means of continuous growth.

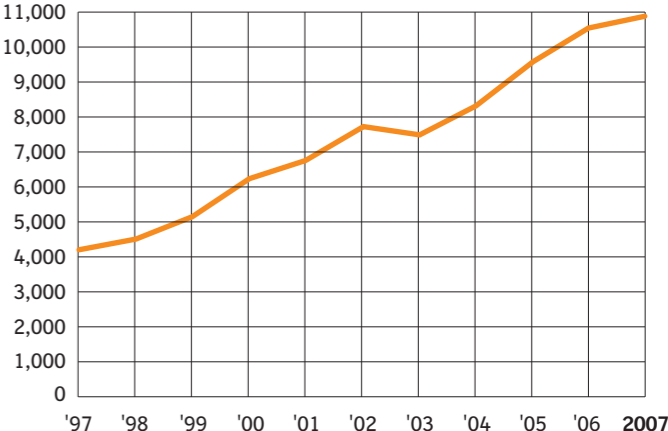
The Boehringer Ingelheim group of companies is ranked among the world's 20 leading pharmaceutical corporations. In 2007 it grew faster than the pharmaceutical market for the eighth successive year. Headquartered in Ingelheim, Germany, it operates with 135 affiliates in 47 countries and 39,800 employees.

In the business year 2007, Boehringer Ingelheim posted net sales of EUR 10.9 billion with its business units Prescription Medicines, Consumer Health Care, Industrial Customer and Animal Health. Geographically, 50 % of net sales were generated in the Americas, 33 % in Europe and 17 % in the Asia, Australasia, Africa region (AAA).

The company's R&D, manufacturing and marketing activities are spread across the entire globe, with research and development facilities in ten countries and production plants in more than 20 countries.

Boehringer Ingelheim has, for many years, been active in the contract manufacturing business, offering a wide range of services for pharmaceuticals production as well as for pharma chemicals and biopharmaceuticals. In 2007, Boehringer Ingelheim posted net sales of EUR 739 million in this business area alone.

World Net Sales 1997-2007
in millions of EUR



Contract manufacturing excellence in our supply network



As key success factors, Boehringer Ingelheim relies on a world-class pharmaceuticals production network with outstanding business process excellence. We deliver the right product at the right time. We listen carefully to our customers to meet their needs 100 percent.

The balanced scorecard methodology helps us to translate our commitments into reality.

According to your needs, our service offer can either cover the complete pharmaceutical business chain or only part of it.

To be able to launch your product on the market, we offer a comprehensive set of services: formulation and process development, clinical sample supply, scale-up, development and validation of analytical methods, stability studies in accordance with the relevant (e.g. ICH) guidelines. With the support of Boehringer Ingelheim Drug Regulatory Affairs and Legal Department we ensure that your product can hit the market on time. Our expertise in project management, regulatory support, stability studies and development of primary and secondary packaging will make a decisive contribution to the success of your contract manufacturing project.

Once your product has successfully entered the market, we will guarantee you a reliable commercial supply at the highest service level. Our expertise in production processes of pharmaceutical products, in quality management, our business process excellence mindset and strong quality and compliance focus will be the baseline for a long commercial life of your product.

Should you on the other hand, need only to change the manufacturer of a product already present on the market, you can rely on our comprehensive experience in product transfers.

Our manufacturing facilities are operating in strict compliance with current good manufacturing practices (cGMP). They are inspected and certified by the regulatory agencies across the globe (FDA, EMEA, MHRA, ANVISA, ASEAN...). In addition, our facilities are subject to regular inspections from Boehringer Ingelheim corporate auditors, ensuring a continuous improvement and a high level of cGMP awareness. Our company policy is to maintain also the highest standards for environmental protection and safety.

A wide range of technologies for contract manufacturing

	Solid forms						
	Manufacturing				Packaging		
	Granulation	Tabletting	Tablet coating	Capsule filling	Blister	Tube / Bottle	Sachet
Koropi / Greece	●	●	●	●	●		
Reggello / Italy	●	●	●		●		
Bogota / Colombia	●	●	●	●	●		●
Itapecerica / Brazil	●	●	●	●	●		●
Mexico City / Mexico	●	●	●	●	●	●	
Bogor / Indonesia	●	●	●		●	●	
Bedford / USA							
Lugano / Switzerland	●	●	●	●	●	●	

Semi-solid forms		Liquid forms	Sterile products	
Manufacturing and Packaging		Manufacturing and Packaging	Manufacturing and Packaging	
Suppositories	Ointments		Liquid filling in vials and ampoules	Lyophilization and vacuum-drying
●		●		
●	●	●		
		●		
		●		
	●	●		
			●	●
		●		

A global presence in contract manufacturing



Bedford, Ohio / USA
 Liquid and lyophilized sterile products.
 Globally approved by multiple regulatory agencies.



Koropi / Greece
 Solid forms. Supply of European, Asian, African and Australian markets.



Reggello / Italy
 Semi-solid, solid and non-sterile liquid forms.



Lugano / Switzerland
 Solid and oral liquid forms.
 Expertise in phytopharmaceuticals.



Bogota / Colombia
 Non-sterile liquid, solid, semi-solid forms and quality services for Latin American markets.



Itapecerica / Brazil
 Solid and non-sterile liquid forms. Supply of Latin American and European markets. ANVISA, ANMAT, INVIMA and EMEA approved.



Mexico City / Mexico
 Solid, non-sterile liquid and semi-solid forms. Supply of solid forms for NAFTA market. FDA approved.



Bogor / Indonesia
 Solid, oral liquid and semi-solid forms. Supply of Asian markets. ASEAN approved.



Our capabilities and service offers



Solid forms

With a worldwide presence and a large set of manufacturing and packaging technologies for solid forms, we will be able to find the optimal solution for your product. In addition to granulation and tableting technologies, we offer state-of-the-art services for film/sugar coating and capsule filling.

If you need pharmaceutical development expertise...

...your project will be in good hands in our contract manufacturing network. Formulation and process development activities will be performed by highly experienced and knowledgeable personnel.

If your product is a solid form to be market in the NAFTA region...

...our production site in Mexico will be your best qualified manufacturing partner. We offer you an integral and flexible service covering your manufacturing needs, with a competitive cost, including quality control and assurance, raw material and finished goods storage, as well as door to door delivery services. The processes and facilities are certified by the FDA (USA), the TPD (Canada) and the SSA (Health Ministry of Mexico), which have taken our production site to be the first in Mexico with the FDA certification to export prescription medicines to the NAFTA region, enabling Boehringer Ingelheim Promeco as a potential exporting company to any market in the world.

Semi-solid forms

If your product is a suppository...

...our production site in Reggello/Italy will be your site of choice for the manufacturing and packaging of suppositories. It offers both, outstanding development capabilities and commercial production capabilities.

If your product is an ointment...

...our production sites in Asia and America will provide cost effective solutions.

Sterile products

If your product has to be sterile, is liquid or lyophilized and filled into vials or ampoules...

... your development and commercial production activities will be performed at Boehringer Ingelheim Ben Venue Laboratories, Bedford/Ohio, USA, by highly experienced and knowledgeable personnel in FDA approved facilities.

Liquid forms

If your product is liquid and non sterile...

...we offer comprehensive services for the development and commercial production, over three continents, of syrups, drops, solutions, suspensions, emulsions and sprays (squeeze bottles and glass bottles with pumps).



Our expertise in pharma chemicals



Pharma chemicals

Boehringer Ingelheim's product portfolio includes high-quality active pharmaceutical ingredients, advanced intermediates and biodegradable polymers (RESOMER®). In addition we have specialized knowledge in the extraction and synthesis of phytochemicals.

All the products we manufacture comply fully with the current good manufacturing practices (cGMP) regulations; all of our production sites are inspected by the US Food and Drug Administration (FDA).

State-of-the art chemical development facilities, experienced chemists, analytical expertise, highly flexible, multi-purpose production sites, and top quality standards allow us to produce extreme complex chemicals from kilo to multiton scale.

We offer to our customers extensive services in all developmental phases – from development to launch:

- custom synthesis
- phyto expertise / extraction solutions
- analytical support
- regulatory documentation
- a worldwide sales and logistics network

We have a successful track record of bringing new chemical entities (NCEs) to market.

Our competence in biopharmaceutical development and manufacturing



Biopharmaceuticals

Boehringer Ingelheim is a pioneer in industrial biotechnology. With a workforce of more than 2,000 employees at our sites in Austria and Germany we have world leading facilities dedicated to the development and production of biopharmaceuticals using mammalian cells, microorganisms and yeast as host organisms.

In microbial fermentation, we use the most modern technologies for production, coupled with state-of-the-art extraction and purification procedures in fermentation scales up to 6,000 litres and with a total capacity of about 12,000 litres. Besides interferons, various proteins, scaffolds and antibody fragments, we also manufacture plasmid DNA for gene therapy on a commercial scale.

In mammalian cell culture we are Europe's leading manufacturer for therapeutic proteins and monoclonal antibodies with a total capacity of 180,000 litres. In addition we have state-of-the-art development facilities including a 2,000 litres pilot plant for production of clinical trial material. We offer the entire process chain from genetic engineering to the

therapeutic drug product including fill & finish and worldwide registration.

All our development and manufacturing processes are conducted according to GMP standards. To date we have registered biopharmaceuticals with the European, Canadian and US regulatory authorities.

We have generated many successful long-term partnerships in biopharmaceutical production with the world's leading pharmaceutical and biopharmaceutical companies.

We recently established a Production Alliance Network (PAN Biologics) with selected medium sized contract manufacturing companies around the globe. PAN Biologics offers most flexible solutions for process development and clinical manufacturing. Through PAN Biologics clients can get access to Boehringer Ingelheim's proprietary production technologies for early stage product development and also preferred access to our large scale manufacturing capacities for late-stage product development and commercial manufacturing."



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Contact us

If you are interested in pursuing a partnership with the Boehringer Ingelheim group of companies, please contact us to further discuss and explore the potential of your business idea.

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