Pharma&Biotech

Lonza

Lonza Guangzhou Nansha

For advanced chemical synthesis

Lonza Guangzhou Nansha Ltd

« Twenty-five years ago Lonza built one of the world's most advanced cGMP chemical manufacturing facilities for the production of active pharmaceutical ingredients (APIs) in the town of Visp, Switzerland. Today, we have taken that experience and technical know-how to establish facilities in China's southern Guangdong province for the manufacture of cutting-edge cGMP APIs and R&D services.»

A Customer-Responsive Strategy for China

This investment enables Lonza to continue addressing the needs of our expanding worldwide customer base. We have added additional manufacturing capacity at our Nansha site to expand our R&D services and increase flexibility for our customers. Lonza's continuous growth allows our customers to benefit from the high-growth potential of the domestic Chinese market.

Our inspiration is tofully serve our pharmaceutical customers with high-quality APIs and intermediates.

Lonza's further expansion into China allows us to serve the market with even greater speed, flexibility, security of supply, and uncompromised quality. Our chemical manufacturing capabilities for cGMP API production are global and comprehensive.

This is a fully integrated site with inclusive advantages:

- modern utilities
- regulatory expertise
- strong administration
- research and development
- kilo-gram laboratory capacity
- small-scale and large-scale production capabilities
- strict commitment to quality

The best of both worlds

Lonza's new API facility in Nansha, China, combines state-of-the-art facilities, industry-leading development services and advanced cGMP chemical manufacturing processes with 110 years of chemistry know-how.

1) Research and development

Lonza's Nansha facility has a full staff with state-of-the-art technologies.

- 80 scientists (25 PhDs)
- 1000 m2 lab area
- Instruments: 400 MHz NMR, LC-MS, GC-MS, HPLC, GC, IR, etc.
- Kilo-lab (10-20 L)
- Autoclave lab
- Solid-phase peptide synthesis

R&D field

- Evaluation and route screening for early phase or potential projects
- Process development and technology transfer for API small molecule in both early phase and late phase
- Process development and technology transfer for products in high performance materials and basic chemicals
- Development of nutrition ingredients
- Peptide projectdevelopment

R&D services

- Chemical customer manufacturing from milligram to kilogram scale
- Development and optimization of chemical processes, and synthetic routes, as well as pilot-scale production under ISO or cGMP standards
- Collection of process and quality parameters for customers' drug registration
- Process optimization via simulation
- Peptide synthesis and modification
- Analytical and testing services including identification of impurities as well as characterization of products and intermediates

2) Small-scale production (SSP)

Phase 1 of our SSP facility began successfully in September 2007. The fully compliant cGMP facility began Phase 2 expansion in August 2008 now observes industry ISO standards. SSP creates a bridge between the kilo-lab and commercial-scale production by providing a scale-up training tool, and accelerating regulatory file submissions.

In total, 10 reactors have been installed as part of Phase 1 and Phase 2 site development:

- 250 L production reactors
- Temperature range: -25 to 180°C
- Pressure range: 0 bar – 16 bar

3) Large-scale production (API)

Nansha's large-scale production facility with is a cGMP compliant multi-purpose plant, compromised of six production trains (three to be built) and equipped with modern centrifuges, spherical dryers and state-of-the-art clean rooms for final bulk API packaging. Off gases and waste water are carefully treated in accordance to Lonza's global safety, health and environmental standards.

Our large –scale production facility in Nansha is a multi-purpose API production line with modern centrifuges, spherical dryers, and state-of-the-art clean rooms for final bulk filling. It has reactor volumes of 10-16 m^3 with a current planned reactor capacity of 246 m^3, to be built in several phases. Successful production in the first 60 m^3 train (December 2008), followed by more success in the second train (20m^3) in 2009 indicates an excellent production potential for the large-scale facility. Our new state-of-the-art facility was designed based on the experience with our Swiss API plant and features:

- Full cGMP compliance
- Quick project change over
- Waste handling and treatment in accordance with Lonza's global safety, health and environmental standards as well as industry standards
- Powerful HVAC system
- Dedicated purified waste system
- Reliable logistics at key geographic locations
- Trouble-shooting capabilities and R&D support

Quality Compliance Inspection History

Customers expect the highest quality from Lonza. Lonza is known for high quality and manufacturing excellence and when it comes to global regulatory compliance, we strive to maintain the highest quality standards in all of our facilities. Lonza Nansha is no exception. The Nansha facility is built to Lonza's global high standards to ensure uncompromised product quality for our customers. Whether in Asia, North America or Europe, all of our custom manufacturing sites adhere to Lonza's strict global cGMP standards, which are complimentedby first-class, on-site quality control and quality assurance teams.

Lonza Nansha Inspection History

Feb 2008	sFDA re-inspection
Apr 2008	Lonza corporate quality audit
May 2008	Customer audits
Sep 2008	Lonza corporate quality audit
Oct 2008	External third party audit
Nov 2008	Customer audit
Dec 2008	Customer audit
Jan 2009	GDFDA re-inspection
Oct 2009	Customer audit
Nov 2009	Customer audit
Nov 2009	Lonza corporate quality audit
Mar 2010	Customer audit
Apr 2010	Lonza corporate quality audit
Jul 2010	Customer audit
Jul 2010	Customer audit
Nov 2010	Site assessment
Nov 2010	FDA inspection
Mar 2011	FDA inspection formally passed*
Mar 2011	Customer audit

*FDA Audit of the Nansha facility was completed on December 4, 2010 and resulted in full FDA approval March 18, 2011 (EIR received).

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