

Lonza

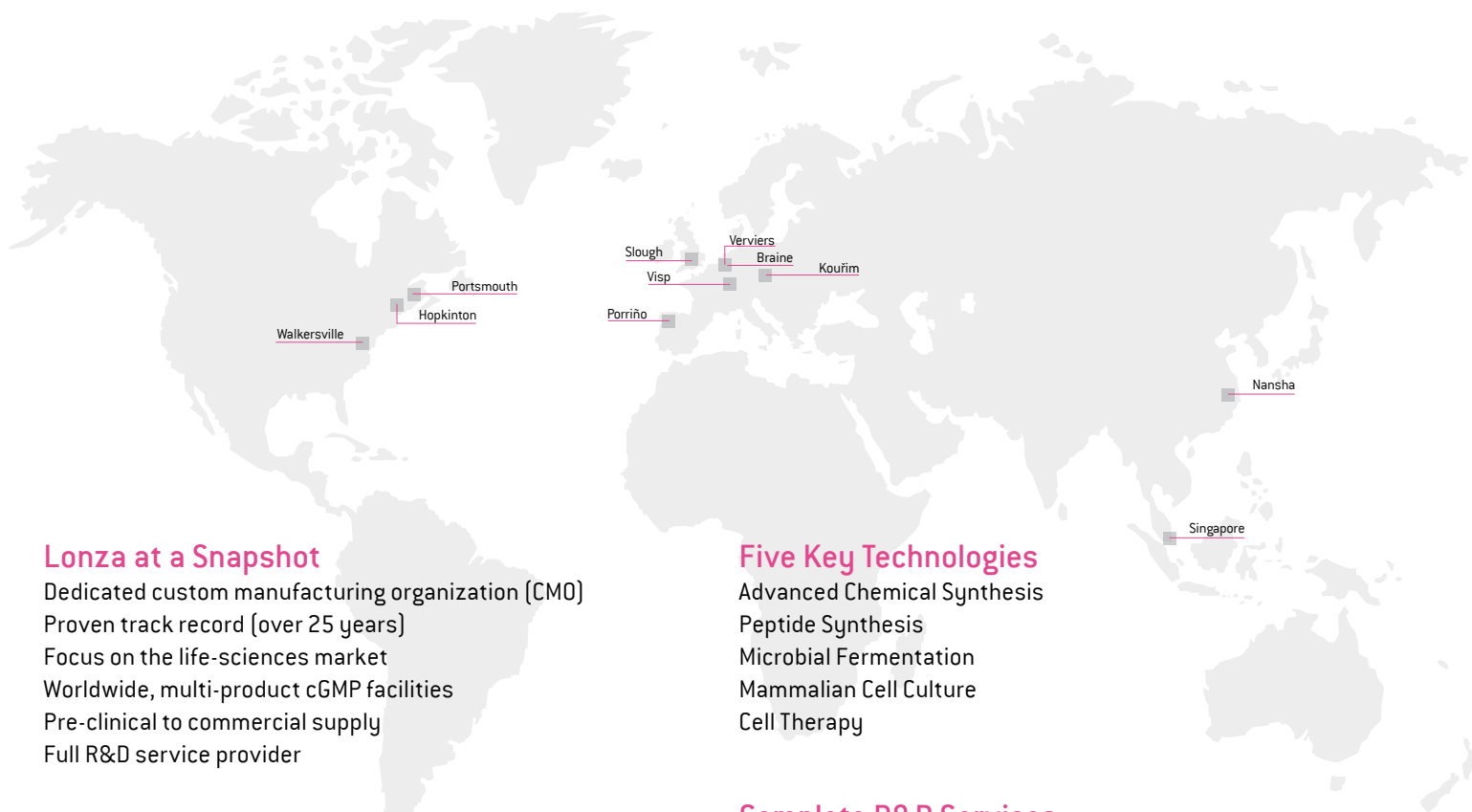
Lonza Custom Manufacturing



Overview

Lonza established the concept of custom manufacturing over 25 years ago, recognizing the trend toward outsourcing in the pharmaceutical industry. Since then, Lonza Custom Manufacturing has been helping both emerging and established pharmaceutical and biopharmaceutical companies improve and advance their products.

Whether for pre-clinical, clinical or commercial supply, Lonza's broad technology platforms, complete range of development services, and cutting-edge manufacturing processes enable your products to reach their full potential within a desirable timeframe.



Lonza at a Snapshot

- Dedicated custom manufacturing organization (CMO)
- Proven track record (over 25 years)
- Focus on the life-sciences market
- Worldwide, multi-product cGMP facilities
- Pre-clinical to commercial supply
- Full R&D service provider

Broad Product Experience

- APIs & HAPIs
- Advanced intermediates
- Monoclonal antibodies
- Antibody fragments
- Recombinant proteins
- Cell-based therapeutics
- Antibody drug conjugates
- Vaccines
- Plasmid DNA
- Peptides
- Fine chemicals
- Custom cell culture media
- Custom downstream buffers
- Water for injection

Five Key Technologies

- Advanced Chemical Synthesis
- Peptide Synthesis
- Microbial Fermentation
- Mammalian Cell Culture
- Cell Therapy

Complete R&D Services

- AggreSolve™ Protein Aggregation Predictor
- Epibase™ Immunogenicity Prediction Platform
- Tripole™ Protein Engineering Platform
- Potelligent™ CHOK1SV Cell Line
- The GS Gene Expression System™
- XS Microbial Expression Technologies™
- XSpedite Microbial Services™
- Cell Line / Strain Design
- Route selection
- Bio/Catalyst Design
- Analytical Development
- Custom Medium Optimization
- Process Development & Scale-Up
- Process Validation & Transfer
- Purification Development
- Technology Development
- Regulatory Support

Mammalian Cell Culture

Lonza is one of the world leaders in exclusive contract manufacturing of monoclonal antibodies and recombinant proteins using mammalian cell culture. Our unmatched experience, first-class cell culture capabilities, and dedicated project management teams ensure our customers – large and small – receive high-quality, secure supply on time and on budget.

At Lonza, we are committed to our customer's success, so it is our mission to ensure your product reaches its full potential. Our approach is based on providing a comprehensive yet flexible development and manufacturing package created through close interactive partnerships with our customers.

Lonza's process R&D services range from lead optimization and cell line development to full-scale manufacturing. These include a complete range of analytical services and regulatory support for clinical trials and in-market supply. Our customers regularly ask us to perform tailored work packages or the complete development program. And by using our continually upgraded, highly efficient and regulatory-accepted GS Gene Expression System™, we are able to achieve higher titers, while improving speed to market, safety and costs.

As a full service provider, Lonza offers fully customized specialty and serum-free media to allow for complete expression system optimization. Our custom bioprocess containers provide a safe and effective method for storage, harvest or waste disposal during your cell culture process. From design to final production, Lonza can provide you with effective, high-quality mammalian cell culture systems.

Europe

Slough, UK

200 L to 2 000 L

(single-use, stirred tank and airlift bioreactors)

Porriño, Spain

multiple 10 000 L

(stirred tank bioreactors)

North America

Portsmouth, New Hampshire, USA

1 500 L to 20 000 L

(stirred tank, airlift and perfusion bioreactors)

Asia

Singapore

multiple 20 000 L

(stirred tank bioreactors, on-line in 2011)

Technologies & Product Experience

- The GS Gene Expression System™
- AggreSolve™ Protein Aggregation Predictor
- Epibase™ Immunogenicity Prediction Platform
- Tripole™ Protein Engineering Platform
- Potelligent™ CHOK1SV Cell Line
- Monoclonal antibodies
- Recombinant proteins



Microbial Biopharmaceuticals

Lonza's experience in microbial fermentation began in 1983 with R&D activities in Switzerland. After building small- and large-scale capabilities, Lonza strengthened its offering by acquiring multiple small- and mid-scale trains in the United States. Today, Lonza offers a broad range of cGMP manufacturing and development services for microbial biopharmaceuticals.

We have successfully delivered clinical-grade material of many types of microbial parenteral API including launched products. From established pharmas to emerging biotechs, our customers repeatedly turn to Lonza for reliable and high-quality deliverables.

At Lonza, we know that drug development can be very dynamic, and throughout the years we have developed the sophisticated know-how to adjust our project plans as your needs evolve. Whether you're preparing your biotherapeutic for the clinic or the market, Lonza can provide an innovative manufacturing solution for you.

Injectable Grade

Europe

Visp, Switzerland *

20 L to 15 000 L

North America

Hopkinton, Massachusetts, USA *

40 L to 2 800 L

(three trains with dedicated downstream rooms)

Technologies & Product Experience

- XS Microbial Expression Technologies™
- XSpedite Microbial Services™
- Antibody fragments
- Plasmid DNA products
- Recombinant proteins
- Vaccines

Oral Grade

Europe

Kouřim, Czech Republic

15 000 L to 75 000 L

Technologies & Product Experience

- XS Microbial Expression Technologies™
- XSpedite Microbial Services™
- Therapeutic proteins (oral grade)

* Process development/technical support (US & Europe)



Peptides

Lonza has a long and established track record of exclusive peptide manufacturing for the pharmaceutical, nutraceutical and cosmeceutical markets. We have small- and large-scale cGMP manufacturing capabilities in Braine (Belgium), Kouřim (Czech Republic), Nansha (China) and Visp (Switzerland).

Lonza has proven to be a reliable custom manufacturer with all three peptide manufacturing technologies (solid-phase, liquid-phase and recombinant DNA), while covering the breadth of services for clinical trials, launch and in-market supply.

In addition, we also provide a complete range of in-house analytical and development services, as well as full regulatory management support.

Peptides

Europe

Braine, Belgium *

solid-phase and liquid-phase technology

Kouřim, Czech Republic *

recombinant DNA technology
DNA technology

Visp, Switzerland *

solid-phase, liquid-phase and
recombinant DNA technology

Asia

Nansha, China *

solid-phase and liquid-phase technology

Technologies & Product Experience

Solid Phase

FMOC chemistry
5–50 amino acid long peptides
Natural / synthetic amino acids

Liquid Phase

BOC chemistry, short peptides

Recombinant

by fermentation/concatemer approach

* preclinical to commercial supply



Lonza offers custom fermentation services to supply APIs and intermediates for the biopharmaceutical, pharmaceutical and nutrition markets. Lonza provides R&D services and multi-purpose manufacturing facilities in Kouřim, near beautiful Prague, in the European Union. Here your biopharma product is taken from process development and validation to large-scale manufacture (up to 75 000 liters), including chromatography, lyophilization, etc.

In Kouřim, we also offer lyophilization of BSL-2 strain biomass up to 15 000 liter scale and 10m³ crystallizers that yield 1-2 metric tons. The validated high-throughput design of our plant allows for efficient and flexible delivery of your material requirements as a concentrated, vacuum-dried, spray-dried or lyophilized bulk material.

In cooperation with our chemical services in Visp, Switzerland, we can execute complex semi-synthetic production orders, and our process development and technical teams can provide additional support.

Europe

Kouřim, Czech Republic

15m³ to 75m³

{total reactor volume over 500m³}

FDA approved, cGMP, HACCP, FAMI-QS and other standards

Process development services

Visp, Switzerland

Process R&D services and technical support

Technologies & Product Experience

- XS Microbial Expression Technologies™
- XSpedite Microbial Services™
- Therapeutic proteins (for oral & topical applications)
- Secondary metabolites
- Modified peptides
- Carbohydrates
- Enzymes
- Biotransformation products
- Lyophilized or frozen biomass

Microbiological Experience

E. coli, *Pichia*, *Hansenula*, *Pseudomonas*, *Saccharomyces*, *Aspergillus*, *Bacillus*, *Streptomyces*, *Trichoderma*, and a dozen other microbial species, including GMO and BSL-2 organisms.



Advanced Chemical Synthesis

Chemical synthesis for small molecule manufacturing is one of our key competencies. While many manufacturers focus their attention exclusively on biologics, Lonza recognizes that chemistry still represents 70-80% of the drugs on the market and in late-phase development. A well-rounded custom manufacturer will embrace the current market excitement of biologics while leveraging and innovating advanced chemical synthesis to adopt a broad, balanced portfolio of technologies. Using the latest chemical processes, we offer our customers exclusive synthesis of fine chemical intermediates, APIs, HAPIs and antibody drug conjugates under full cGMP requirements for use in pharmaceutical products.

Since 1897, Lonza has been investing in advanced chemical technologies and state-of-the-art facilities. Our modern chemical technology toolbox is based on a broad range of expertise at each of our manufacturing sites in Europe, North America and Asia. We have additional non-GMP facilities capable of manufacturing intermediates and building blocks for many different industries.

By optimizing synergies that exist between biotechnology and classical chemistry, Lonza provides alternative and innovative manufacturing pathways. Our production capacity ranges from gram to multi-ton quantities.

cGMP Facilities

Europe

Visp, Switzerland *

Kilo Lab: 10 to 30 L vessels

Small-Scale Plant: 16 reactors (up to 250 L)

Launch Plant: 27 trains, 57 multi-purpose reactors (250 to 3000 L)

Commercial Scale: 6 multi-purpose plants with 10m³ reactors

Phosgene plant (630 to 10 000 L)

HPAPI plant (10 to 10 000 L)

MicroReactor technologies (lab to commercial scale)

Antibody Drug Conjugate plant (10 to 600 L)

Asia

Nansha, China

Small Scale Plant: 6 reactors (up to 250 L)

Commercial Scale: 6 multi-purpose trains (10m³–16m³ reactors)

* Low temperature capabilities at all scales



Cell Therapy

One of the largest contract manufacturers of biologics in the world, Lonza is the global leader in cell therapy manufacturing. Lonza delivers the technical expertise and state-of-the-art manufacturing capabilities you need, with an unrivaled commitment to large-scale production.

With more than 40 years experience with normal human cells (Clonetics® and Poietics®), Lonza Cell Therapy helps clients in all phases of cell therapy commercialization maximize the return on their research investments. From tissue acquisition support and process development to full-scale cGMP commercial manufacturing, our staff can design, develop, and implement a manufacturing process that meets your needs for tissue engineering and autologous or allogeneic cell therapy. Our experience includes manufacture and testing of master and working cell banks, patient dose manufacturing from small to very large scale, regulatory support, medium optimization, and a host of other services.

North America

Walkersville, MD – USA
ISO Class 7 (Class 10,000)

Europe

Vervier, Belgium
EU ISO Class 5 (Class B)

Asia

Singapore
ISO Class 7 (Class 10,000)
(on-line in 2011)

Products & Services

- Tissue acquisition
- Cell isolation
- Custom medium optimization
- Process development
- Cell therapy manufacturing
- Custom bioassays
- Regulatory support



Contact Sales & Marketing

We welcome the opportunity to be challenged by your manufacturing requirements. Whether you have immediate or long-term needs, Lonza is ready to help find a custom manufacturing solution for you.



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