

# your next BLA submission...

Let's cut the timelines together.

## **ibex**<sup>TM</sup> / **develop**

The efficacy and safety of biopharmaceutical products, combined with their ability to address previously untreatable conditions is driving strong demand. Concurrently, to accelerate access to life-changing medicines, the number of breakthrough therapies and fast track designations are increasing, shortening drug development timelines considerably.

### **Compact timelines with no quality compromise**

To help you accelerate your market readiness without compromising on quality or flexibility, we have created Ibex™ Develop, an innovative CDMO service offering which aims to take you from process characterization to BLA submission in just 22 months<sup>1</sup>.

As clinical and commercial production are located under the same roof, it simplifies comparability requirements and eliminates the need for tech transfers between sites. Additionally, you can commercialize from the same bioreactor that was used for production of your clinical material.

### **Flexible capacity to meet your clinical and commercial needs:**

- Single-use process technology raises efficiency and enables quick adaptation to new processes, formats, and titers.
- Fully-modular operating suites addresses product demand unpredictability to flexibly reach your expansion requirements on site.
- Access to our global supply network with production scales up to 20,000 L.
- Drug product batch sizes from 5 to 500 L for clinical and launch supplies of liquid or lyophilized product.

Regardless if you had started with an Ibex™ Design program, reached IND and are moving towards BLA, or if you are joining with your own cell-line, Ibex™ Develop offers capacity tailored to your needs.

**22**  
months

**BLA**

- Capacity tailored to your needs
- Drug substance and drug product, under one roof
- No need for tech transfers between sites

**Seamless transition from clinical to commercial manufacturing**

Ibex™ Develop combines drug substance and drug product capabilities in one location enabling you to manage your product's lifecycle at a single site, under one quality system. In addition, it offers a holistic and tightly integrated product development concept, a key prerequisite to secure your journey to clinical production and beyond.

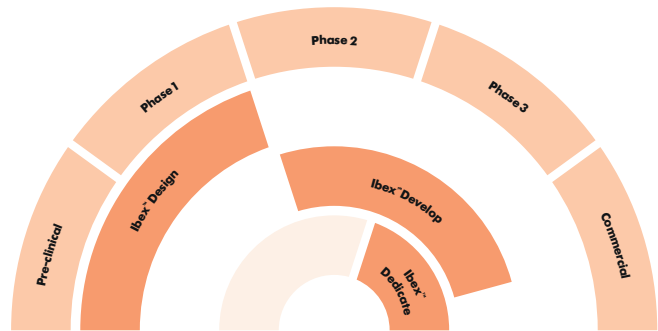
**Increased product control**

To help you de-risk your BLA submission, Ibex™ Develop relies on advanced technology and process design. This includes single-use process technology to lower contamination risk. It also applies serialization technology to protect your product against drug counterfeiting and adulteration.

The use of machine-learning algorithms in the drug product manufacturing concept decreases drug substance waste. Additionally, to detect silicone leakage in the lyophilization chambers, it utilizes drug product isolator technologies, modern separation techniques, PAT, novel drying technologies, and in-line mass spectrometry.

**Your next clinical stage... let's go there together**

As your project progresses to later clinical stages and commercial, you can conveniently leverage **Ibex™ Dedicate**, a technology-agnostic supply solution that helps you save up to 30 months-time to market and control investment risks with tailored business and ownership models.



**Ibex™ Solutions** consist of three CDMO offerings: Ibex™ Design, Ibex™ Develop and Ibex™ Dedicate that span the complete biopharmaceutical lifecycle – from preclinical to commercial stages, from drug substance to drug product, all in one location. The variety of solutions offerings provide the flexibility of a complete program – from gene to drug product, or the option to drop in at a later stage depending where you are in your journey.

Explore how Ibex™ Solutions can help you take your next drug to the market more quickly with game changing business and operating models [www.ibex.lonza.com](http://www.ibex.lonza.com)

**Contact us**

USA +1 201 316 9200  
Japan +81 (0)3 6264 0600  
Rest of world +41 61 316 81 11  
Email [ibex@lonza.com](mailto:ibex@lonza.com)

[ibex.lonza.com](http://ibex.lonza.com)



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