Lonza

Pharma & Biotech

Product lifecycle management in one site

ibex™

design
develop
dedicate

Today's world provides multiple opportunities for a biopharma company.

An aging global population and the prevalence of chronic and communicable diseases are creating increased medical needs. This dynamic will continue to fuel the growth of the life sciences sector in the future[1].

Innovation is key to meet evolving patient needs and companies are ramping up their research and development (R&D) expenditures.

In the second quarter of 2017, the R&D spend of publicly traded emerging biopharmaceutical companies reached almost $3.9 billion, 45% greater compared with the second quarter of 2015[1].

[1]Deloitte 2017 Global Life Sciences Outlook

At the same time, the biopharma environment is complex and uncertain, with evolving regulations, requirements to decrease cost, and growing competition.

This puts pressure on both large and small life sciences organizations. All aspects in the lifecycle of a biopharmaceutical product are now under scrutiny and companies are increasingly looking at transformational business and operating models as a solution.

To streamline offerings and/or operations, one attractive alternative is to outsource non-core functions in research, development and manufacturing. For a large company, this can provide increased efficiency across an entire organization. For a small company that lacks in-house capacity and capabilities, outsourcing is often the only viable path forward.

The problem that remains is to find the right outsourcing partner.

The diligence required before engaging with a new partner is time consuming. Moreover, the time and effort needed to manage a relationship with a CDMO successfully should not be underestimated. Especially when problems arise (because they do ...). If more than one CDMO is used, the complexity increases – and in the end you may question whether your outsourcing strategy actually simplifies things or if the result is rather the opposite.

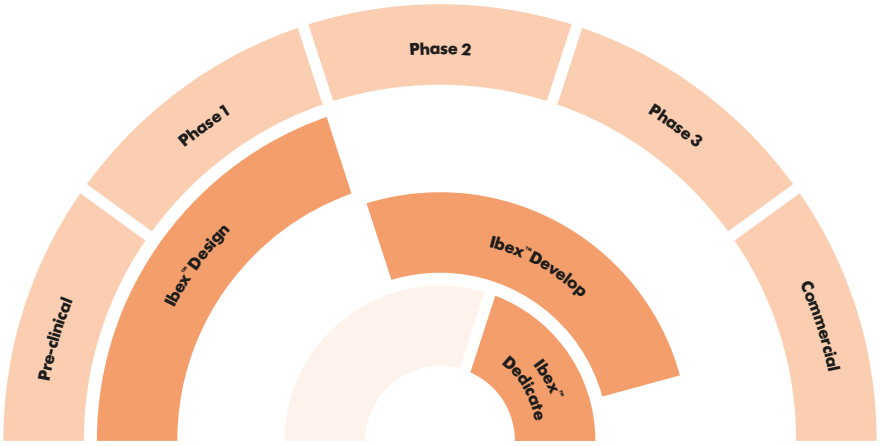
At the same time, speed is critical and you often need to make key decisions about outsourcing and capacity build at a time point when you don't have all the information to hand. How can you then know what the best way forward is for your company?

Welcome to Ibex™ Solutions.

Ibex™ Solutions consist of three innovative CDMO offerings that span the complete product lifecycle of a biopharmaceutical – from preclinical to commercial stages, from drug substance to drug product, all in one location.

The three offerings Ibex™ Design, Ibex™ Develop, and Ibex™ Dedicate have been developed as a response to a dynamic market and evolving needs. To help you take your drug candidate to market quickly. To give you flexibility to manage the unknown. To streamline your supply. To increase predictability.

The home for Ibex™ Solutions is the Lonza biopark in Visp (CH), which leverages Lonza's existing infrastructure, support networks and a stable and highly skilled workforce.



ibex™ | design develop dedicate

The combined offering provides the following key benefits:

- / Speed to clinic and market
- / Flexibility to manage uncertainty
- / Supply chain simplification
- / Risk management across the entire product lifecycle

Ibex™ Solutions let you benefit from a complete solution from the very start or conveniently drop in at a later stage. It all depends on where you are in your journey and where you want to go.

design

Move quickly to clinical trials, with the funding you have available

Simplicity / Fixed price gene-to-vial package

/ Drug product within **12** months

Speed

Ibex™ Design is a complete service offering for your preclinical needs through to IND and clinical phase 1. It includes a pioneering fixed price gene-to-vial package, with delivery of drug product within 12 months and at least 1 kg drug substance.

To further increase predictability for you, we will keep a manufacturing slot reserved for your clinical resupply.

Risk management / Reserved slot for resupply batch

As your project progresses to later clinical stages, you can conveniently leverage the capabilities in Ibex™ Develop in the same building – no need for tech transfer to a different site. Benefit from our proven GS Gene Expression System® bioprocess platform and from a holistic development strategy with the endpoint in mind.

develop

Seamless transition from clinical phase 2 to commercial manufacturing

22
MONTHS

/ No tech transfer between sites

/ Drug substance and drug product under one roof

When the goal is commercialization, there is no time to lose. With the services in Ibex™ Develop, we can help you to achieve your BLA submission in just 22 months[2].

Here, clinical and commercial production are located under the same roof, which simplifies comparability requirements and eliminates the need for tech transfers between sites. If applicable, you can commercialize from the same vessel that was used for production of clinical material.

BLA

Our regulatory experience further contributes to de-risk your filing. We helped prepare seven fast track BLA submissions in 2012 to 2017 so we know both how to do it fast, and how to do it right.

[2]From the start of process characterization

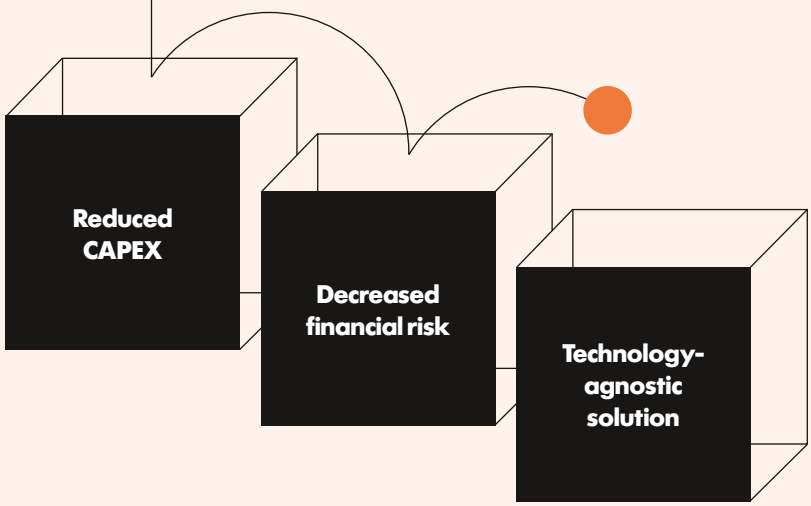
dedicate

A fully customized supply solution, exclusive for your product or portfolio

Our high-responsive supply solution Ibex™ Dedicate offers an innovative alternative to building capacity and capabilities on your own.

Together with Lonza, you can invest in a pre-built facility wing that can be tailored to suit virtually any biologics including mammalian and microbial production, vaccines, bioconjugates, and cell and gene therapy. The fact that construction of your building has already begun, in combination with a faster ramp-up, can save you up to 30 months total time to market.

This allows you to delay your build decision and better manage investment risk. Flexible ownership and operating models give you freedom of choice.



“We’re taking the provision of CDMO services to a new level”

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