MERCK

BioReliance® End-to-End Solutions

Plug & Play Upstream Development Service

A service exactly tailored to small-sized biotechs and start-ups, needing to balance cost and speed to clinic while getting it right the first time.

BioReliance®

Pharma & Biopharma Manufacturing & Testing Services

Our Experience

31+
Years in process development

250+
Biologics
(antibodies, hormones, fc-fusion and recombinant proteins)

100%
Success rate in IND filing

BioReliance® End-to-End Solutions

We are an adaptable CDMO partner for start-ups and small biotechs needing to develop and commercialize biologics. We do this by balancing speed, risk and cost through custom solutions, by leveraging our bioprocessing technologies and process development expertise, and by allowing our clients to transfer their process and knowledge to their end point at any step of their drug development. So rest assured that with more than 31 years' experience, more than 250 biomolecules and numerous GMP clinical Drug Substance batches, we can build strong working relationships around you.

Realize Your Drug Development Vision

Upstream development can be a major stepping stone towards your goal. Our experience in process development and regulatory expertise help you make the right decisions to get it right the first time and set your path to long-term success.

An Adaptive Approach to Deliver Against Your Timeline

In-silico codon optimization

Establish stable pools

Choose the right clone

High-producing stable cell line

Establish a master cell bank

Get good quality material quickly for pre-clinical studies

Documentation of monoclonality and stability

Documentation ready for IND filing

Process Development

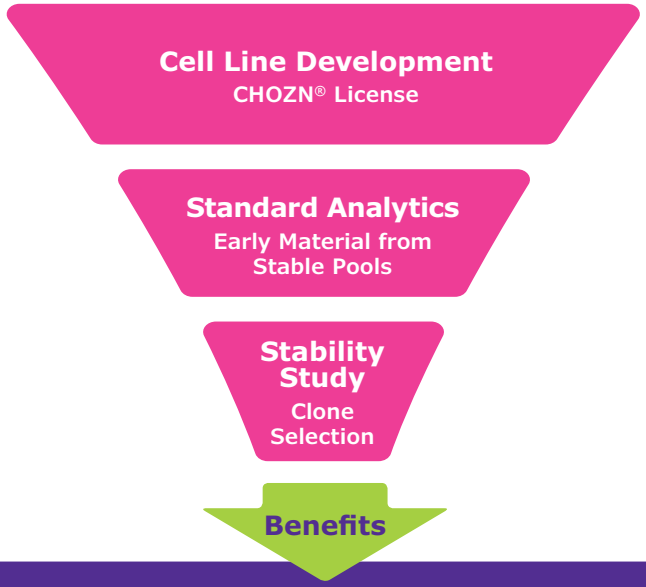
Get GMP supply for clinical trials

Functional and structural assays for your regulatory confidence

Plug & Play Upstream Development Service

We offer you exactly the service and expertise needed to get you to your next milestone, balancing cost and speed to clinic without sacrificing quality at times when funding is often limited.

Get Easy Access to a Tailored Suite of Services



Add-on services give you options to choose the path that's right for you:

- Off-the-shelf Media & Feed Screening
- Analytical Method Development
- Complete Analytics
- GMP Master Cell Bank & Cell Bank Characterization
- MCB Storage

We accommodate your needs at every step

- Leverage our experience with a variety of CHO cell lines or choose our proprietary CHOZN® license
- Risk Assessment and Regulatory support
- Analytical development in parallel to your cell line development to get you progressing faster
- Clone selection in parallel to process development to save you 10 weeks to first PD experiment
- No royalty fees assessed
- Dedicated project managers keep you deeply involved in the process
- Freedom to tech transfer at any stage, to any partner

Our Expertise

Monoclonality and Stability Validation Approach

Get the confidence you need with our fully documented validation approach based on regulatory expectations and statistical approach. We provide you a report demonstrating monoclonality for each cell line in compliance with the validation dossier.

Analytical Method Development and Product Characterization

Our analytical method development and cell line development teams work side by side to enable a seamless process. Our BioReliance® Product Characterization team works in parallel to determine and monitor all key physiochemical, binding and functional Critical Quality Attributes of the molecule, in order to meet the expectations, set by the developer and to select the lead clone for the generation of the desired product.

Automated Mini-Pool Approach as Fast-Track Process

Our robust and automated mini-pool approach allows us to confidently generate early material for process development, reducing your timeline by 10 weeks. With the right balance of speed and risk, we run process development and clone selection in parallel, without ever sacrificing quality.

Process Development

When you are ready to proceed to process development, we can either support your tech transfer to any partner or we develop your process for you.





Get Access to a Wealth of In-House Expertise

Glasgow, UK

Boston, USA

Rockville

Bordeaux, France *GMP*

Shanghai, China

Singapore

Product characterization, Biosafety testing

Cell line development

Biodevelopment and production

To learn more about BioReliance® End-to-End Solutions, please visit **MerckMillipore.com/adaptive-CDMO**

For additional information, please visit **MerckMillipore.com**
To place an order or receive technical assistance, please visit **MerckMillipore.com/contactPS**

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