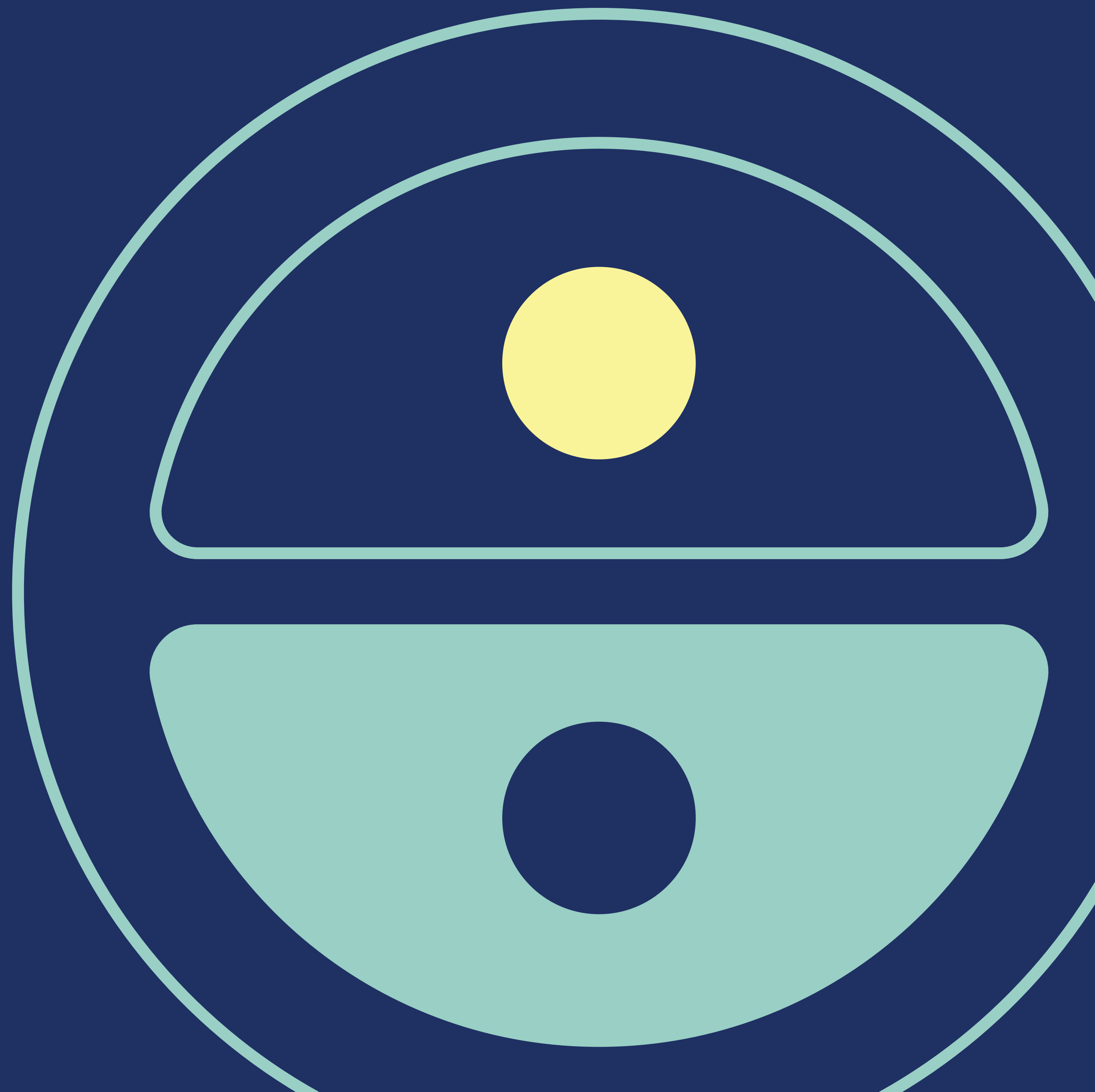


# HyClone™ Cell Culture Services

Transforming the future of process development



# Transforming the future of process development

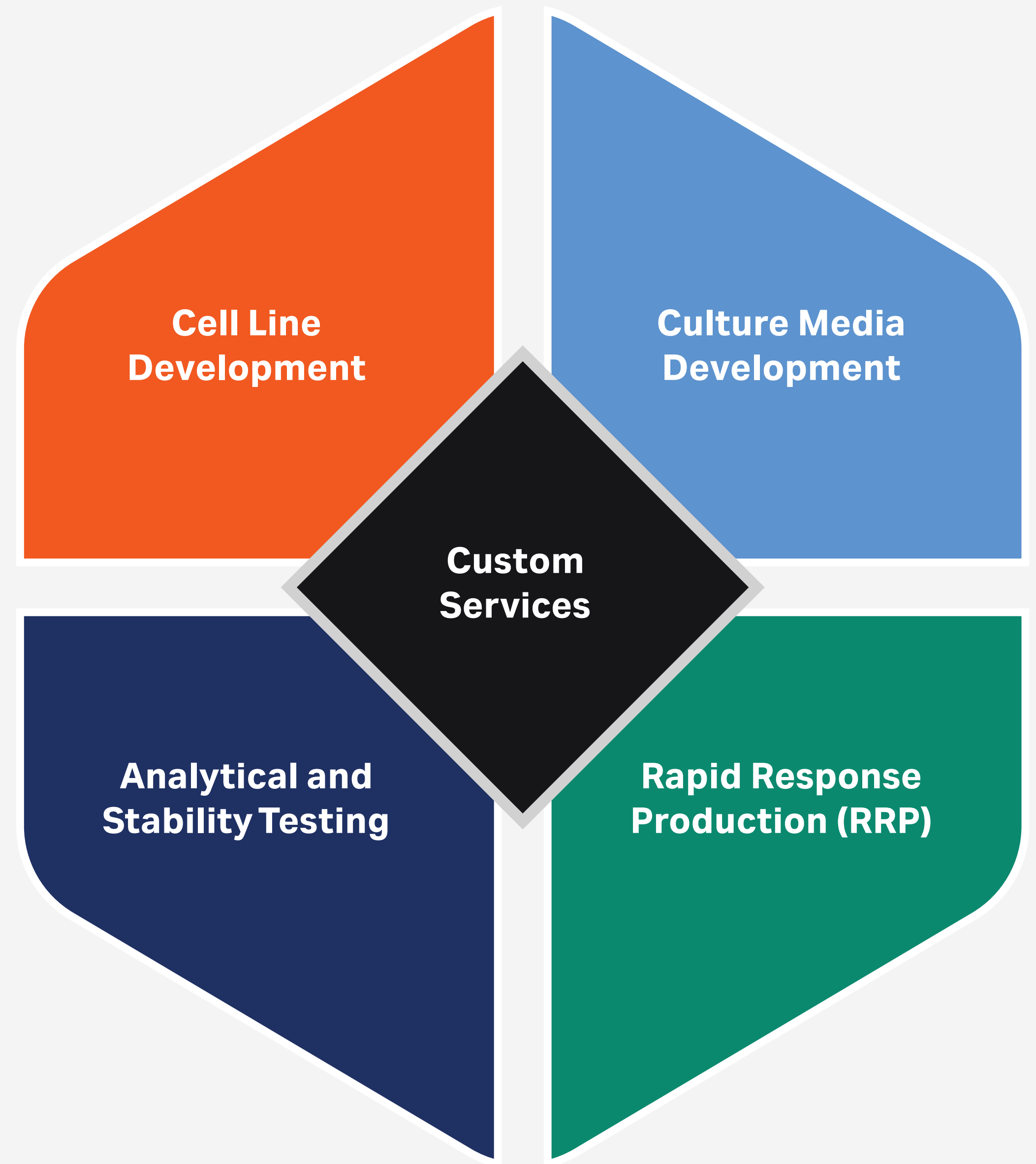
with HyClone™ Cell Culture Services

Are you looking to develop your new process quickly, while steering clear of major roadblocks?

We can help you develop cell lines, perform analytical tests, design custom cell culture media, or optimize your process — from bench to bioreactor.

With our approach, technology, and decades of industry experience, we will help you address the challenges of diverse and emerging molecules to:

- Reduce manufacturing and regulatory risks
- Improve cell culture performance to meet your goals — with tailored solutions (e.g. cell viability, productivity, product quality, platform development)
- Gain speed to market — or your next milestone





# Cell Line Development

## Integrated CHO cell line and media platform

To make your molecule, you need a clone with stable expression. Save time and effort by getting the right start. Develop a cell line with our GOCHO™ expression platform, integrated with chemically defined (CD) and animal-derived component free (ADCF) media. Obtain a stable mAb clone that meets current industry standard for titer and productivity — with the speed you need.

- Integrated CHO cell line and cell culture media platform
- Fully documented host cell line lineage
- Flexible commercial licensing terms and no royalty fees
- High mAb productivity levels — up to 6 g/L with minimal process optimization

# Cell Culture Media Development

Maximize cell culture performance by optimizing media and feeds

Just like people, each cell line is unique. And no project goals are identical. We take the time to understand your objectives and design a custom solution that allows you to reach your desired project outcomes.

Whether you need fast prototype media, a consult, or complete outsourcing — we partner with our customers to understand their objectives and challenges and design custom solutions to improve their process.

- **Customized prototype:** Based on your screening results with Cytiva's off-the-shelf media or prototypes, obtain proprietary media variants customized for your cell line.
- **Consultation:** Partnering to provide the study design, cell culture media and analysis while you maintain your cell lines in-house.
- **Full service:** Provides tailored media development solutions to meet your cell culture objectives at our state-of-the-art facility



# Analytical and stability testing

Gain better insight into your cell culture performance

## Analytical testing

How we test your samples: Using industry accepted high-resolution methods for quantitative analyses, combined with decades of experience in HyClone™ cell culture media and bioproduction. The result? Improved performance for consistent, high-quality results.

All analytical methods are harmonized with current ICH standards. Choose from:

- **Spent media analysis:** Identify key growth and production component levels such as trace elements, amino acids, and vitamins to optimize feed strategy.
- **Microbial testing:** Ensure product and container integrity with endotoxin, bioburden, and sterility testing.
- **Protein quality:** Select critical quality attribute analyses for your mAb — including charge variant, aggregation, and glycosylation.
- **Quality control analysis:** Determine the ranges required for your formulation and evaluate components for cell culture media and buffers.

## Stability testing

We conduct stability testing in a cGMP laboratory and storage facility. And we use industry-accepted International Conference on Harmonization (ICH) guidelines for quantitative analyses of your custom formulation.





# Rapid Response Production (RRP)

## Fast non-GMP cell culture prototypes

When you need small volumes of customized cell culture products quickly, consider our Rapid Response Production (RRP) service. We replicate standard manufacturing practices for customized cell culture media, feeds, reagents, buffers, and process liquids, within five business days of your order.

Looking to smoothly transition to cGMP? Documentation of RRP lots provides component-specific tracking, so you can easily do so. Our team is trained in accordance with established manufacturing practices. If needed, we can use single-contact, animal-derived component-free manufacturing equipment or facilities.

- Flexibility in formulations
- Short time to delivery
- Efficient future transfer to cGMP production
- Uniformity in global processes for consistency

### Standard packaging

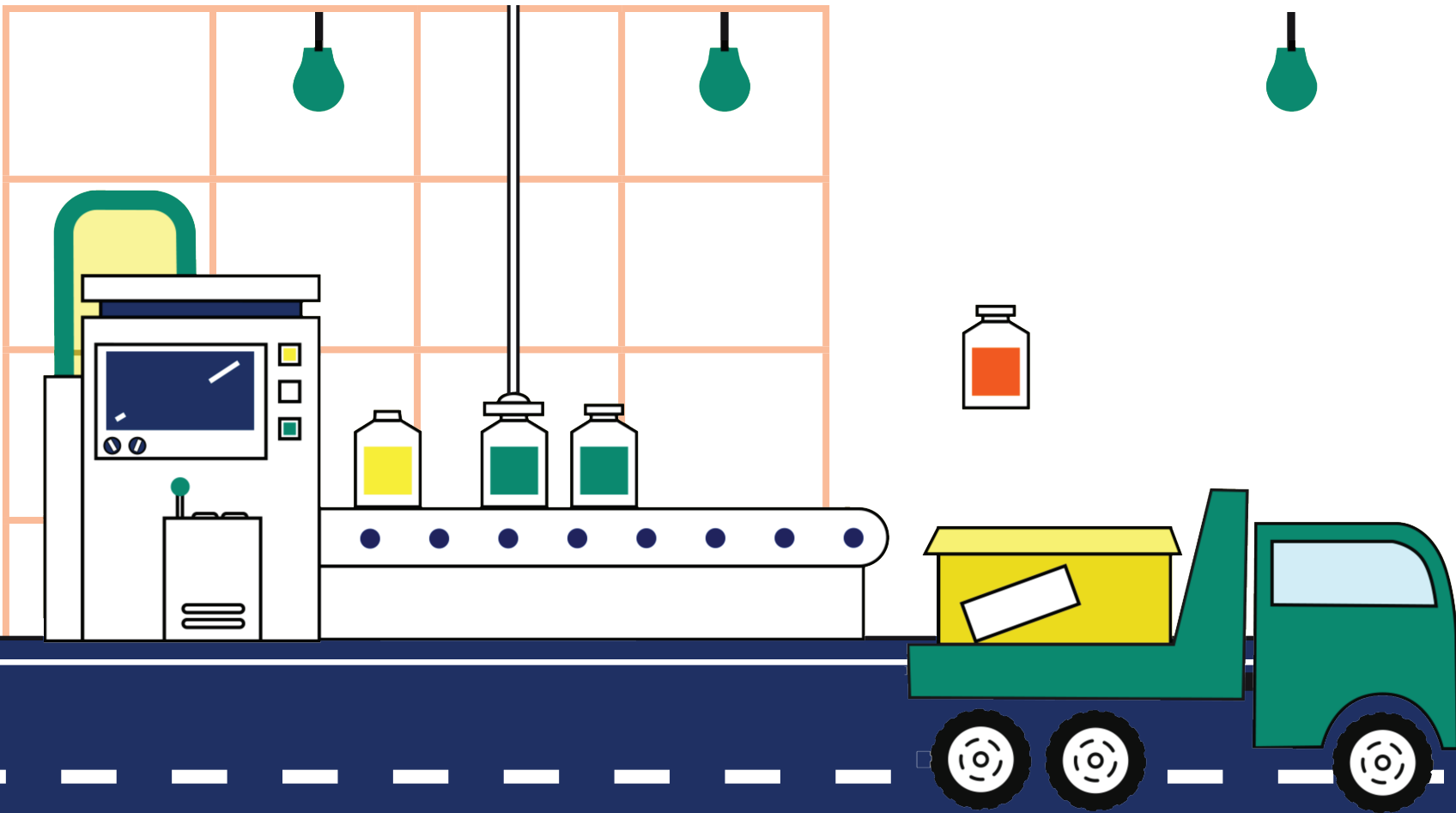
Select from standard packaging — or request a custom option — to meet your product requirements.

Format	Delivery system	Lot sizes
Liquid	100 mL bottles	10 to 20 L
Liquid	500 mL bottles	10 to 100 L
Liquid	1000 mL bottles	10 to 200 L
Liquid	5 to 200 L*	10 to 200 L
Powder	Volume-specific (L)*	500 g to 20 kg
Powder	Bulk powder	500 g to 20 kg

\* Single-use containers

### Quality control

Various quality control parameters can be measured to establish or confirm specifications (for information only, not as release criteria). Additional testing can be performed by request.



# We're global because our customers are

Our global team includes scientific support, technical expertise, and more. We've invested — and we're committed to continue investing — to expand manufacturing, add new sites, and provide the products and services you need.

Ready to start your custom project? Contact your local account manager or sales manager, who will work with you to find the solutions that match your specific needs.

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