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WHY CHOOSING A CLIENT-CENTRIC CTDMO IS CRITICAL WHEN OUTSOURCING BIOMANUFACTURING PROJECTS

28%
OF FDA APPROVALS IN 2021 WERE FOR BIOLOGIC DRUGS[1]

30%
OF BIOMANUFACTURING IS OUTSOURCED[2]

The development of biologic drugs, including monoclonal antibodies and other large molecules produced in mammalian cells, is on the rise. For some biologic drugs, manufacturing is a well-established process. But in other scenarios biomanufacturers continue to be confronted with a number of challenges and bottlenecks at the level of bioprocess optimization, capacity constraints, supply chain hurdles, and regulatory requirements.

A promising solution for companies that do not have the technical expertise and comprehensive in-house capacity to address these issues is outsourcing different drug development phases to an end-to-end specialized Contract Testing, Development, and Manufacturing Organization (CTDMO). A CTDMO can be a mere service provider or a thought partner, and thus selecting the right CTDMO partner becomes vital for the success of the biomanufacturing project.

A RECENT SURVEY ASKED 40+ BIOPHARMA RESPONDERS: "WHY DO YOU OUTSOURCE TO A CDMO?"

Survey participants profile: Global audience, knowledgeable on CDMO outsourcing

THE REPLIES:

Pre-Clinical Phase	Clinical Phase	Commercial Phase
1 Risk mitigation 20%	1 Risk mitigation 24%	1 Adapting to scale 20%
2 Speed 16%	2 Speed 16%	2 Production slot availability 15%
3 End-to-end capabilities 15%	3 End-to-end capabilities 16%	3 Speed 14%

60% of respondents think that **project management, robust and transparent planning, and timely progress against critical milestones** are essential for a CDMO partner.

WHAT TO LOOK FOR IN A CTDMO PARTNER

- Balances risk and speed
- Advances projects in a cost-effective, streamlined fashion
- Provides access to a multidisciplinary team
- Manages unpredictable, evolving priorities
- Manages supply chain complexity

According to the survey's results, a trusted CTDMO understands the client's situation, strategy, and goals and can provide the right solutions. To do this and appropriately balance risk and speed through the constantly changing dynamics of biomanufacturing, CTDMOs need to have extensive regulatory experience and in-house analytical capabilities.

HOW CAN MILLIPORE® CTDMO SERVICES SUPPORT YOUR PROJECTS?

Our Millipore® CTDMO services for biologics offers a single-source CTDMO with tailored solutions to clients' needs, priorities, drug type, therapeutic area, and market conditions. We understand the uniqueness of each project by taking into account the project history and building on it, and offer open communication, flexibility in process templates, and tailored risk mitigation strategies that will ensure efficiency and success.

> *We add value by becoming an extension of our client's team in every project we undertake.*
>
> Céline Raymond, Upstream Process Development Manager, Life Science Services, Merck

WHAT MAKES US A TRUSTED CTDMO PARTNER?

Transparent communication

1 Clear point of contact per project

Speed/Risk balance

280+ Developed biologics
25+ Years GMP biopharma manufacturing

MERCK'S CLIENT-CENTRIC CTDMO APPROACH AND MULTIDISCIPLINARY PROJECT TEAM

3 key roles assigned to each project to ensure transparent and efficient communication…

A **Project Manager** is assigned to each project to deliver proactive, transparent communication as well as stakeholder engagement and connection.

A **Technical Lead** is assigned to each project to oversee all technical aspects and ensure flexible and timely problem solving.

A **Sales Development Manager** extends customer support by transforming it into a true partnership.

…with CTDMO solutions at every step…

Pre-clinical | Phase I | Phase II | Phase III | Pre-launch | Commercial

IND filing — BLA filing

- Cell line development and cell banking
- Analytical methods and process development/optimization
- GMP clinical manufacturing
- Scale up
- GMP commercial manufacturing
- Characterization testing
- Process validation
- Lot release testing
- Regulatory filings and support services

…and access to Merck's ecosystem…

- In-house analytical and testing services
- Leading single-use technology
- Proprietary raw materials used in our processes
- Quality and regulatory professionals
- Robust quality systems

…have resulted in 95% customer satisfaction with communication and project management services.

Is your new drug a biologic? Ensure the success of your project by choosing a trustworthy experienced partner to help you along the rocky path. **Contact** the Merck team to learn more about their **CTDMO services** for biologic development and manufacturing.

Text: Maya Chergova, PhD
Design: Kateryna Zharko

Sources:
- *Value Chain Insights*
- *Pharmaceutical Outsourcing*
- *European Pharmaceutical Review*
- *Perspectives on: Trends in Outsourcing the Development and Manufacturing of Biologics*
- *Bioprocess Online*
- Labiotech.eu
- Merck's mAbs CTDMO Services

Created with love at labiotech.eu

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