

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

OF FDA APPROVALS IN 2021 WERE FOR BIOLOGIC DRUGS¹

OF BIOMANUFACTURING IS OUTSOURCED²

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

The development of biologic drugs,

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?"

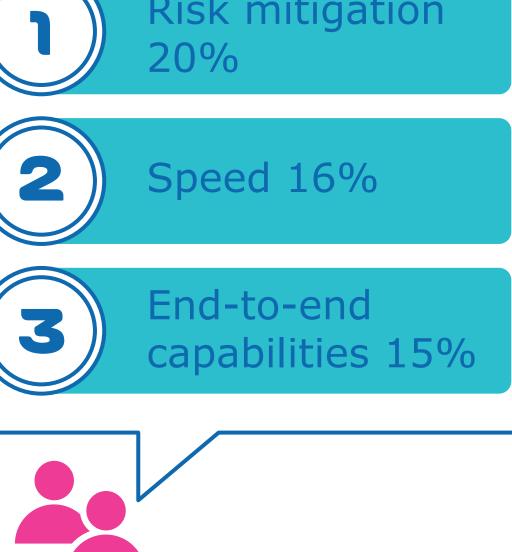
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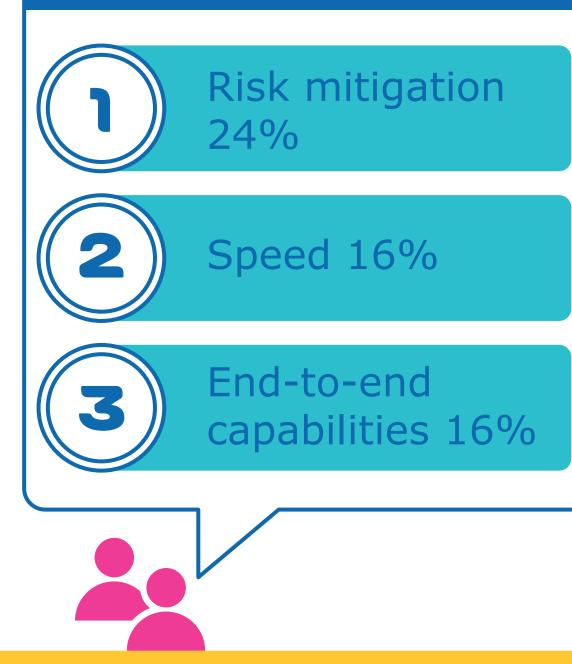


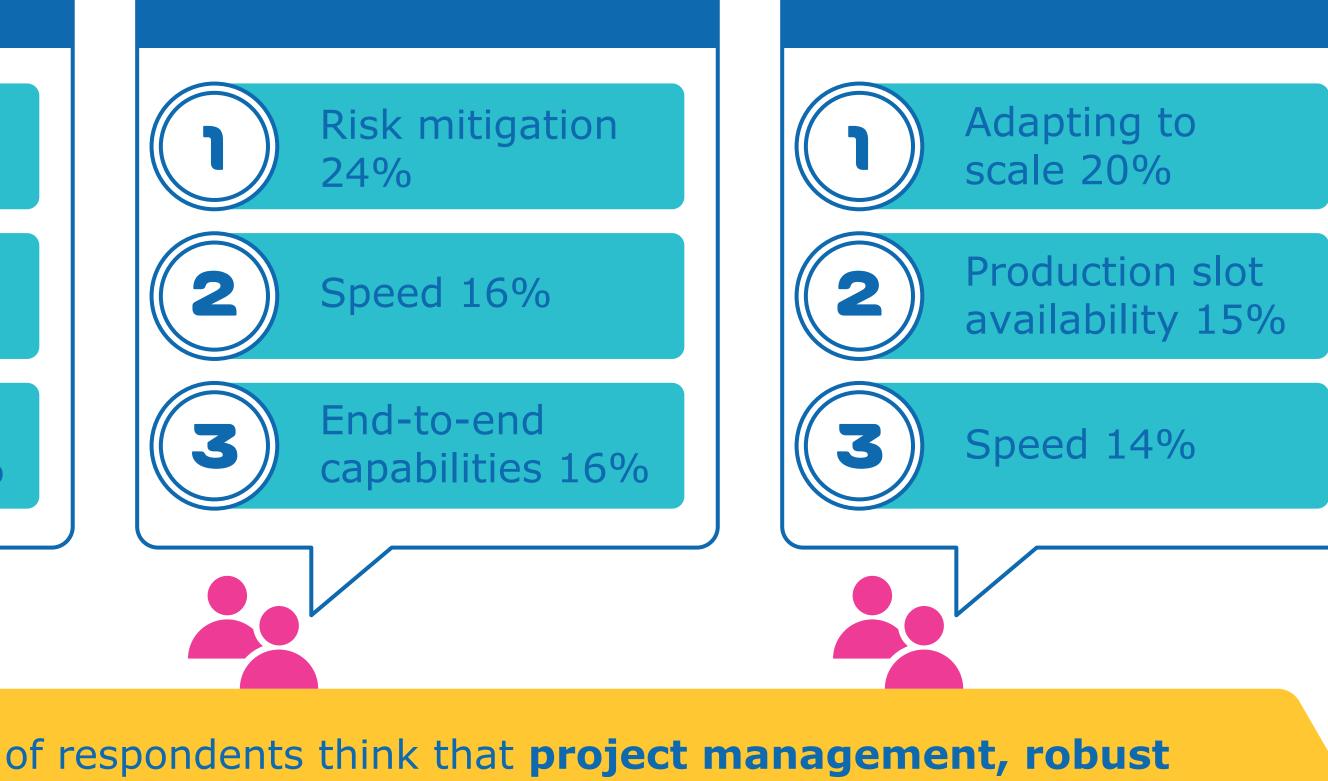


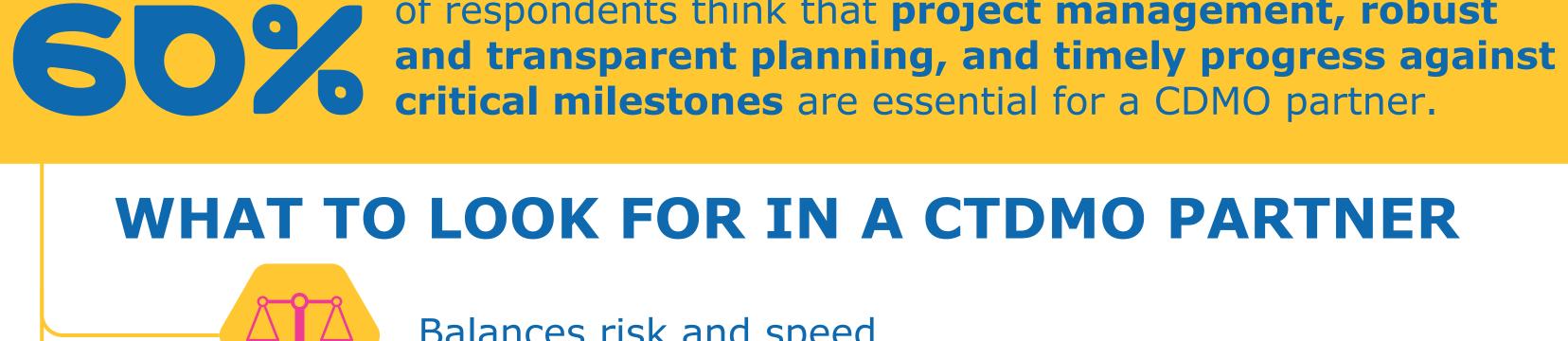
on CDMO outsourcing











WHAT TO LOOK FOR IN A CTDMO PARTNER

Advances projects in a cost-effective, streamlined fashion

Balances risk and speed





Manages unpredictable, evolving priorities

Provides access to a multidisciplinary team



Manages supply chain complexity

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

solutions. To do this and appropriately balance risk and speed through

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.

CTDMO with tailored solutions to clients' needs, priorities, drug type,

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



WHAT MAKES US A TRUSTED CTDMO PARTNER?



1 Clear point of

Transparent

communication

contact per project

Life Science Services, MilliporeSigma



Speed/Risk

balance

280+ Developed biologics

25+ Years GMP biopharma

manufacturing

MILLIPORESIGMA'S CLIENT-CENTRIC CTDMO

APPROACH AND MULTIDISCIPLINARY PROJECT TEAM 3 key roles assigned to each project to ensure transparent and efficient communication...

transparent communication as well as stakeholder engagement and connection. TECHNICAL **PROJECT MANAGER** LEAD A Technical Lead is assigned to each project to oversee all technical



SUBJECT MATTER

CLIENT

transforming it into a true partnership.

Pre-launch

BLA filing

Commercial

A **Project Manager** is assigned to

each project to deliver proactive,

aspects and ensure flexible and

A Sales Development Manager

extends customer support by

timely problem solving.

Phase III

GMP commercial Scale up manufacturing

technology



\$ \$ \$ -

Characterization

testing

and testing

services

Regulatory filings and support services

Process validation

Lot release testing

...and access to MilliporeSigma's ecosystem... In-house Leading analytical single-use

GMP clinical

manufacturing

O

Quality and Robust regulatory quality professionals systems

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 MilliporeSigma team to learn more about

...have resulted in 95% customer satisfaction with

Design: Kateryna Zharko manufacturing.

Review

Manufacturing

Sources:

- Value Chain Insights • Pharmaceutical Outsouricng
- European Pharmaceutical

Text: Maya Chergova, PhD

- Perspectives on: Trends in Outsourcing the Development and
- Manufacturing of Biologics • Bioprocess Online
- Labiotech.eu MilliporeSigma's mABs
- Life Science business of Merck KGaA, Darmstadt, Germany.
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their CTDMO services for biologic development and

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raw materials

used in our

processes