Looking both ways for your small biopharma clients

Which path are your biopharma clients headed down?

Standard CDMO

Delays by limited regulatory experience

Smaller CDMOs often do not have a regulatory staff expert due to budget constraints, so they may be uninformed of the data requirements for testing and/or Investigational New Drug (IND) filings.

Without a regulatory expert on staff, changes in FDA's requirements may go unnoticed until an IND filing is rejected by the agency due to missing information.

Setbacks due to changes in clinical product demand

Forecasting clinical demand can be tricky. When biopharma clients end up with a supply shortfall, such an underestimation can lead to significant risks to the commercialization process, increased costs, and stalled timelines.

Securing another batch to fill the gaps is challenging due to limited manufacturing capacity. Clients may be lucky in locating instant capacity, but often capacity will be reserved for up to a year in advance.

Poor upfront tech transfer planning

As a molecule matures, there comes a need to transfer to a larger CDMO with late-stage development expertise. Clients may experience a laborious tech transfer, especially if either CDMOs lacks clear communication, a roadmap of procedures, or adequate data reporting.

Poor planning upfront can cause the loss of historical data or process development reports during the tech transfer, extending deadlines, duplicating efforts, and increasing development costs.

Limited CMC resources available

Many small biopharma clients often don't have CMC experience or a CMC budget, leaving knowledge gaps. Clients may not realize how early in the development process the data collection for IND filing begins.

Without the proper data for IND filing, clients are sent back late in the process to generate the missing CMC information, straining resources and delaying timelines by years.

Thermo Fisher Scientific as CDMO

Molecule advancement with established regulatory experience and expertise

Select a CDMO partner that offers more than machinery and availability. A global network of experts can provide deep technical and regulatory expertise that is critical for molecule success as they progress towards commercialization.

We have supported **37 INDs/IMPDs** for biologic molecules (2017-2021).

Flexibility to program changes, adapting to clinical demand

At Thermo Fisher Scientific, we offer custom and flexible manufacturing solutions able to facilitate multiple production options and support variable clinical demand. Utilizing our services such as multiplexing bioreactors can keep clients' plans on track for regulatory and market success.

We have manufactured **332 biologics clinical batches** (2017-2021).

Robust tech transfer plan; setting up for success as you scale

Our solutions involve a single project manager and integrated quality systems eliminating hand-off challenges, and resulting in enhanced communication, stronger CMC (chemistry manufacturing controls) filing and time savings of 14–20 weeks.

In 2021, we managed **232 active tech transfer projects**.

Large network of CMC resources and SMEs (subject matter experts)

As a solutions provider, we assign each project several SMEs who can progress the product through its lifecycle while collecting CMC data. At Thermo Fisher Scientific, we operate with an approach focused on delivery and success for the customer.

We serve **over 1,200 customers** across pharmaceutical, biotech, research and clinical lab, medical device, consumer, academic and government segments.

With Thermo Fisher Scientific as your CDMO:

Avoid delays or suspended efforts

Gain financial return vs. risk

Develop and advance molecules

Interested in connecting with us? Contact a Thermo Fisher Scientific sales representative today.

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