ThermoFisher SCIENTIFIC

A TALE OF TWO CDMOs

WHICH CHOICE WILL YOUR BIOPHARMA MAKE?

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The road to a successful biologic is up to you

Today's growing biologics challenges make the choice of a CDMO critical. You need a trusted and experienced partner from DNA sequence to commercial launch and at each checkpoint along the way.

1 Upstream development: Building molecule momentum

One CDMO leverages technical expertise, manufacturing platforms and the latest technologies to:

- Quickly move from DNA sequence to final clone
- Produce proteins with desired product quality
- Complete process development and harvest strategy within expected timelines

The other CDMO struggles with the technical process of developing a complex biologic and:

- Fails to properly screen for quality and bioreactor conditions when selecting a clone
- Does not consider large-scale execution during development
- Repeats process steps and delays program due to poor experimental design

2 Downstream development: Avoiding roadblocks on the way to IND

One CDMO taps into deep scientific experience and invests in technology to:

- Develop advanced chromatography purification techniques via high-throughput screening
- Design processes with predictable and robust viral clearance
- Produce stable and safe drug substance ready for clinical trial requirements

The other CDMO's inexperienced approach and misinterpretation of regulatory requirements leads to:

- Unacceptable impurity levels within drug substance
- Inadequate purity, stability and viral clearance for program's clinical phase
- Inaccurate data, multiple batch failures and a clinical hold

3 Analytical development: Ensuring product quality

One CDMO uses proven expertise and established analytical procedures to:

- Produce appropriate and robust methods of testing critical product quality
- Confirm method status is phase appropriate and supports process-related activities
- Design and perform product characterization studies to support FDA filings

The other CDMO's shortfall of experience and regulatory understanding leads to:

- Analytical methods with poor performance and failed qualification/validation
- A scarcity of key product characterization data for filings
- An inability to help its client troubleshoot the production process

4 Phase I and II clinical trials: Supplying confidence and meeting demand

One CDMO leverages early-phase regulatory knowledge and process and analytical platforms to:

- Guide client through stability, toxicology and other FDA-required studies
- Produce GMP-quality material for first-in-human clinical trials within 15 months
- Execute lean, phase-appropriate strategies for targeted, cost-efficient development

The other CDMO lacks adequate analytical capabilities and process experience, resulting in:

- Insufficient data captured during development stages
- Poor quality performance and failed stability studies
- Major rework and missed milestones, causing client to lose funding

5 Phase III clinical trials: Navigating the last clinical turn

One CDMO leans on in-house regulatory expertise, risk analysis and production capabilities to:

- Direct client through process characterization and validation for Biologics License Application (BLA)
- Increase batch size to 5,000 L to meet market demand while optimizing cost of goods
- Navigate complex regulatory requirements quickly and efficiently

The other CDMO fails to plan for flexibility of scale during development stages, which causes:

- An inability to produce enough material within facility to meet demand
- A sudden need for significantly more money to boost production
- Client to take product to another CDMO, delaying program by years

6 Commercialization: Driving your drug to market

One CDMO focuses on product quality and commercial validation from day one, setting the stage for:

- A nimble development approach that tracks key data
- Achievement of BLA filing approval ahead of schedule
- Production and shipment of ample drug product – and a successful market launch

The other CDMO's limited commercialization experience and regulatory know-how precipitates:

- Inadequate prep time within production facilities for commercial validation
- Failed BLA filing due to insufficient process validation studies
- A multi-year program delay – and the client not reaching its first-to-market goal

Ready to make your choice?

Be sure the CDMO you are working with – or considering – has the expertise, experience, capabilities and proven track record to reach your in-market goal on time.

See how Patheon pharma services can help meet every biologics challenge on your road to approval.

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