ASK THE EXPERT

Accelerating Antibody Development

A Proven Path from Gene to GMP

with Laura Daley

Catalent's Rapid Antibody platform offers a robust approach to monoclonal antibody (mAb) development. It provides a comprehensive drug-substance pathway — from gene of interest (GoI) to good manufacturing practice (GMP) stages — that can be completed in just eight months. That accelerated timeline helps teams meet critical industry deadlines. Missing an investigational new drug (IND) window can jeopardize funding, erode competitive position, and delay patient access to life-saving treatments. "Sponsors need a path that is fast but also predictable and defensible with regulators and investors," noted Laura Daley (senior director of cell biology and process development at Catalent) during a March 2026 Ask the Expert webinar.

Daley's Presentation

The platform designs multiple activities to run in parallel from the start, eliminating traditional waiting periods between steps, inefficiency, and miscommunication that can extend development timelines. At the core of that integrated approach is Catalent's GPEX Lightning cell line, which helps to deliver high expression titers with predictable performance and predictable performance. The cell line can generate stable pools within 25 days from receipt of gene construct, facilitating early productivity assessment and fast progression to clone selection and scale-up. Within the first three months, top clones can be identified and supported with early process data from an Ambr 250 bioreactor system (Sartorius), cultures from which serve as scale-down models for the platform process.

The program is structured around scale progression and decision-making milestones. Beginning with GPEX Lightning cell-line development alongside process formulation and analytical development, the platform creates cell pools and runs 10-L scale operations to generate material for parallel downstream development, method development, and formulation. Following clonal selection using the Beacon high-throughput screening instrument (Bruker), the process moves into Ambr 250 clone confirmation, in which key upstream processes are run while downstream and analytical work continues simultaneously.

Success of the eight-month timeline depends on specific program assumptions, including use of traditional mAbs with low aggregation propensity, ≤10 g/L titers, 14-day production duration, and immediate materials procurement after contract signature. The platform incorporates early decision points at cell-pool production to ensure that molecules are suitable for the accelerated timeline, emphasizing right-first-time execution rather than forcing unsuitable candidates through the process. The manufacturing solution provides added value through regulatory confidence and supply-chain transparency.

Questions and Answers

What early signals show that a molecule might be a platform outlier? One of the first things that I would consider a platform outlier is the format of the antibody itself. Complex formats such as bispecifics and heavily engineered constructs often require tailored purification. I also suggest looking for high aggregation and low-pH instability because those factors also could require cutom processes.

What should sponsors prepare up front to maximize the odds of an eight-month success? Clients need clarity, alignment, and commitment up front, specifically around molecule readiness, decision-making speed, and risk tolerance. Rapid programs succeed when critical inputs are locked early, decisions are made quickly, and both clients and Catalent are aligned on what it takes to meet IND-enabling milestones. Success is not driven by doing everything faster, but by doing the right things early.

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