

# Strategies for Accelerated CMC Development

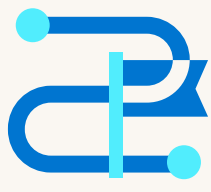
"Need for speed" is now business as usual, driving demand for faster CMC development.



## Partnerships with CDMOs

Robust and early vetting includes defining program goals, timelines, budgets, and expectations. Selection must address performance, capabilities, flexibility, transparency, and talent retention; a history of successful projects and global regulatory approvals.

### Partnerships must encompass:



01

#### Abbreviated Timeline for Material Generation for Clinical Studies

New technology reduces timelines for clinical studies, IND filings, and approvals.



02

#### Early Interactions with Regulatory Authorities

Joint review strategies and new FDA guidelines on Emergency Use Authorization can expedite development.



03

#### Quality and Safety Standards in Rapid Development

Strict adherence to cross-disciplinary quality, safety, data, automation, and digital solutions is imperative.

## Late-Stage Considerations

Small organizations can assist in the early stages, but late-stage considerations include an understanding of CDMOs full range of services and capabilities as you drive towards commercial material.



## Globalization and Regulatory Adherence

CDMOs must navigate regulatory requirements and supply chain challenges in international markets.



### Transformative Partnership with Syner-G

Faster timelines must not compromise product quality. Risks must be identified, addressed and mitigation strategies put in place to ensure product safety and efficacy. Syner-G stands at the forefront of CMC expertise, guiding innovators through the intricate CMC process amidst changing industry practices and expectations.