Syner·G

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.