The Business Case for Investing in CMC:

Protecting Your Asset and Ensuring Success

CMC: A Critical Factor in Drug Development Success

Up to 20% of drug development costs are driven by CMC activities.

CMC issues contribute to 20% of clinical holds in biologics, risking costly delays.

For a drug with $1 billion peak sales, a one-year delay can cut the drug's value by 10% or more, impacting revenue and market launch.

What Causes Most CRLs?

45-50%

CMC Deficiencies such as inadequate stability data, manufacturing issues, or control gaps

~20%

Labeling discrepancies, inaccuracies, or misalignments with clinical data

~15%

Inspectional findings, including observation notices like Form 483s

10-15%

Incomplete data submissions, missing modules, or insufficient datasets

~5-20%

Misalignment with regulatory expectations or guidance

Key Strategies for Reducing Risk

Data Integrity & Traceability
- Maintain high-quality, compliant data throughout development

Pre-NDA/BLA Meeting Alignment
- Ensure regulatory expectations are met upfront

Labeling & Guidance Compliance
- Align labeling with FDA standards early

Pre-Approval Inspection (PAI) Readiness
- Prepare for successful site inspections

Lifecycle-Centric CMC Package
- Implement robust, adaptable CMC controls to support seamless approval and post-approval changes

Investing in a proactive CMC approach reduces delays, mitigates risks, and accelerates your path to approval and commercialization.

Learn more at synergbiopharma.com and email info@synergbiopharma.com to schedule a free consultation today.

References:

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