

## 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.

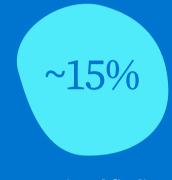
### What Causes Most CRLs?



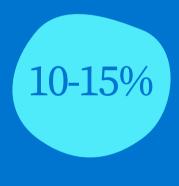
CMC Deficiencies such as inadequate stability data, manufacturing issues, or control gaps



Labeling discrepancies. inaccuracies, or misalignments with clinical data



**Inspectional findings** including observation notices like Form 483s



**Incomplete data** submissions. missing modules, or insufficient datasets



**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

## Align labeling with FDA standards early

**Labeling & Guidance Compliance** 

**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:**
- 1. MAbs 2020 May 23;12(1):1754999. doi: 10.1080/19420862.2020.1754999 2. Molecular Therapy: Methods & Clinical Development Vol. 31 December 2023
- 3. (https://www.bioprocessonline.com/doc/the-expanding-role-of-cmc-in-biotech-investor-decision-making-0001) 4. FDA. (2020). Office of Pharmaceutical Quality Annual Report. U.S. Food & Drug Administration.
- https://www.fda.gov/media/147798/download 5. GAO. (2023). Drug Application Oversight: FDA Review of Applications. GAO-23-106339. U.S. Government Accountability Office.
- https://www.gao.gov/assets/gao-23-106339.pdf 6. FDA. (Ongoing). Redacted NDA/BLA Letters Database. https://www.accessdata.fda.gov/scripts/cder/ndaletter/index.cfm