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REGULATORY WRITING & CONSULTING

CASE STUDY

Rushing vs. Readiness — The High Cost of a Clinical Hold on a Biologics IND

Therapeutic Area: Oncology

Product Type: Autologous T-cell Therapy

Document: Phase 1 IND

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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GLOBAL'S REGULATORY CMC CAPABILITIES

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ABOUT THE CLIENTS

Company A and Company B are early-stage biotechs developing autologous T-cell therapies for a rare hematologic malignancy. Both companies have completed GLP toxicology studies and are preparing their first-in-human IND submissions.

ABOUT THE PROJECTS

In the race to be first-in-human, some biotech startups feel intense pressure to submit their biologics IND as soon as possible. But when submission comes before readiness, the result is often a clinical hold—a regulatory pause that not only delays trials but erodes credibility with the FDA.

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ABOUT THE PROJECTS CONTINUED

Cell therapy products represent some of the most complex and promising advancements in modern medicine—but they also pose significant regulatory challenges. Unlike traditional small molecules, cell therapies require detailed documentation around manufacturing processes, raw materials, cell sources, and potency assays—even at the earliest stages of development.

This case study compares two biotech startups, both developing autologous cell therapies for oncology. Their divergent approaches to Phase 1 IND submission highlight the importance of taking time upfront to ensure regulatory readiness.

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COMPANY COMPARISONS

Attribute	Company A	Company B
IND Submisiion Timeline	Month 14 (after tox study)	Month 10 (after tox study)
Pre-IND Meeting	Yes, held at month 8	Skipped
CMC Documentation	Complete: cell source, process control, comparability, potency	Partial: preliminary assay, incomplete raw material control
Assay Validation	Qualified potency assay reflecting biological activity or MoA	Exploratory assay with minimal validation
FDA Outcome	IND cleared without clinical hold	Clinical hold issued within 30 days

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WHAT WENT RIGHT - COMPANY A

Company A took a deliberate and strategic approach, building in time to address the inherent complexities of a cell therapy IND. Their preparation included:

- Pre-IND meeting with the FDA to confirm expectations and align on CMC and clinical protocol elements
- A well-defined manufacturing process with clear lot release criteria, in-process controls, and full documentation of cell sourcing and manipulation
- Qualified potency assay linked to mechanism of action, with supportive analytical data
- Thorough characterization of raw materials, including viral vectors and cell banks

Result: FDA cleared the IND in 29 days with only minor comments on protocol amendments. Company A dosed their first patient in Month 15, just one month after submission clearance.

WHAT WENT WRONG - COMPANY B

In contrast, Company B operated under aggressive internal timelines and investor pressure to be "first to clinic." Their approach included:

- Skipping the pre-IND meeting, assuming CMC could be finalized post-submission
- Submitting an incomplete manufacturing section, with gaps in raw material traceability and unclear control strategy
- Including only exploratory potency data, without MoA linkage or qualification
- Relying on "just-in-time" documentation to patch sections during FDA review

Result: The IND was placed on clinical hold due to:

- Inadequate product characterization
- Insufficient validation of the potency assay
- Unclear donor eligibility criteria and cell handling protocols

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OUTCOME

Metric	Impact for Company B
Clinical Delay	+6 months to address hold
Financial Cost	Additional funding burn (lab work, consultants, regulatory meetings)
Reputation with FDA	FDA flagged the team as less prepared, increasing scrutiny for future submissions
Investor Confidence	Decreased; required an extension bridge around

CONCLUSIONS

1. The Time You Save Now May Cost You Later
Rushing to submit an IND—especially for complex biologics—can backfire. A clinical hold often takes more time and resources to resolve than waiting a few extra months to submit a stronger, cleaner application.

2. CMC is Often the Bottleneck
For biologics, the CMC section is rarely "plug and play." It demands high-quality documentation, method validation, and product understanding. Regulators expect a mature, reproducible manufacturing process—even at Phase 1.

3. Potency Assays Are Not Optional
Even for exploratory therapies, the potency assay must demonstrate biological relevance and consistency. "Placeholder" assays are a common reason for clinical hold.

CONCLUSIONS

4. FDA Trust Matters
The first IND sets the tone. Company A earned trust with a complete and thoughtful submission. Company B now faces increased scrutiny in all future interactions.

5. Use the Pre-IND Meeting
Company A's use of a pre-IND meeting helped them proactively address FDA concerns. Company B skipped this step—and paid the price.

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CONCLUSIONS

The pressure to move fast is real—but speed without readiness is a costly illusion in biologics development. A clinical hold not only delays your program but risks investor confidence, burns resources, and damages regulatory relationships.

Submitting a robust, well-documented IND not only clears the regulatory path more smoothly, it sets up your program (and your FDA relationship) for long-term success.

Taking the time to get your IND right the first time is not a delay, it's a strategic investment.

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