



# Early CMC Decisions That Shape IND Readiness

Translating discovery science into IND-ready execution

## The Inflection Point

### Candidate nomination changes everything

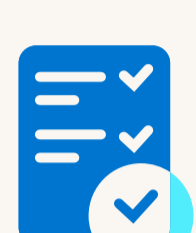
- Marks the shift from discovery to early CMC
- Scientific promise must translate into clinical readiness
- Early decisions shape IND success

## The Reality



### Milligrams are just the start

- Discovery begins with milligrams
- Demand escalates quickly to IND-enabling quantities
- Timelines compress fast



### What Early CMC Must Deliver

- Toxicology material
- Formulation development
- Controlled manufacture
- Clinical drug supply

## The Critical Question

### Is the discovery route scalable?

Discovery routes favor speed, not scale.

#### Common challenges include:

- Costly or limited reagents
- Inconsistent reaction conditions
- Inefficient or unreliable purification

Early choices determine long-term feasibility.



## A Development-Focused Approach

### Build robustness early

#### Key considerations:

- Vendor selection
- Impurity control
- Yield consistency
- Process safety and scalability



Aligned with ICH Q11 expectations for process understanding and control.

## Beyond Chemistry

### Early CMC includes supply chain strategy

#### A fit-for-purpose supply chain balances:

- Speed
- Quality
- Cost
- Regulatory foresight

Includes raw material sourcing, supplier qualification, and clear non-GMP to GMP transition points.



## Vendor Strategy Matters

### Partners influence IND readiness

#### Evaluate for:

- Technical capability
- Capacity and timelines
- Quality systems
- Regulatory experience



## The Goal

### De-risk the path to IND



Anticipate future needs



Integrate CMC with development strategy



Maintain flexibility as data evolves

**Result:** smoother IND submissions and stronger regulatory confidence

## How Syner-G Helps

- Establish a structured CMC manifold
- Design scalable, phase-appropriate processes
- Manage quality control and process oversight

**Outcome:** Quality material delivered on time, minimized technical and regulatory risk, and IND strategies aligned to long-term clinical goals.



### Bottom Line

Early CMC decisions determine IND readiness long before submission.

Syner-G helps translate discovery science into IND-ready execution with confidence.