



SIGNATURE COURSE | LEVEL ONE

SUGGESTED PREREQUISITE: DRUG DEVELOPMENT IMMERSION

## ■ Commercialization Readiness from Preclinical to First Launch: The First Time Biotech CEOs Playbook

### OVERVIEW

**Commercialization Readiness from Preclinical to First Launch** will equip early-stage biotechnology leaders with the commercialization knowledge they need to strategically position their organizations for financing success and meeting critical Commercial and Medical Affairs milestones.

The drug development process is complex and multifaceted, and understanding the commercialization considerations at each phase is vital. From preclinical to first product launch, this one-day course will help biotech executives make informed strategic choices for long-term success.

Beginning with Phase I, this interactive course will cover the phase-specific commercialization activities and preparation emerging companies need to make for a successful first launch, including Market analysis with competitive landscape assessment, the Commercialization Roadmap development including launch critical success factors, FTEs and dollar spend required for launch, market access pricing and reimbursement, value proposition development, and go-to-market preparation and regulatory considerations. *Note these early commercial flows inform the corporate and partnering strategy at emerging biotech companies.*

Russ Belden, founder and CEO of Bridge, will guide you through this course by sharing real-world examples and valuable insights. Russ is a biotech commercialization leader with over 36 years of senior operational experience in the preclinical to 1st launch space.



### Five Takeaways:

1. Discover how defensible revenue forecasts and meaningful clinical differentiation are the underpinnings of value creation at Preclinical to Phase 1 companies.
2. Access and review McKinsey, IQVIA, and Syneos data illustrating why most commercial launches fail (and how to prevent that).
3. Recognize the value of the Commercialization Roadmap and how it impacts both commercial and corporate strategy.
4. Identify key commercialization success factors and their value as a core, differentiating competency that impacts strategy and spending.
5. Gain a comprehensive understanding of the product launch process and understand the scope of work your CCO is responsible for heading to a successful launch.

## AGENDA

---

### Why Most Commercial Launches Fail

30 minutes

---

### Commercial Imperatives That Impact Value:

**Preclinical – Phase I** 60 minutes

Target product profiles and differentiation  
“Defensible” revenue forecasting  
Impacts of the IRA on development portfolios  
Portfolio prioritization  
ISAN naming  
Early commercialization visioning

---

**Break** 15 minutes

### Commercial and Medical Affairs

**Imperatives: Phase II–Phase III (pre-data)**  
**60 minutes**

Commercialization roadmap: the commercial vision and costs (to inform corporate strategy)  
MD, payer, and HEOR market research: key inputs for pivotal trial design  
KOL development  
Scientific narrative  
MSL  
Key hires  
Commercialization alternatives

---

**Lunch** 60 minutes

**Commercial and Medical Affairs**

**Imperatives: Positive Data Readout to Launch** 50 minutes

Updated commercial assessment (revenue forecast)  
Product strategy and marketing  
Market access, pricing, and reimbursement (MAPR)  
Health economics and outcomes research (HEOR)  
Sales force  
Distribution  
Commercial ops and analytics  
Training

**Medical Affairs Imperatives** 55 minutes

Scientific narrative, KOLs, and publication planning

Medical education

Medical affairs (Phase IV's & ISTs, pharmacovigilance)

- Launch critical success factors
- Brand name
- Branding
- Value proposition
- Information technology
- Hiring plan

---

**Life Cycle Management** 30 minutes

---

**Course Wrap-Up and Evaluation** 15 minutes