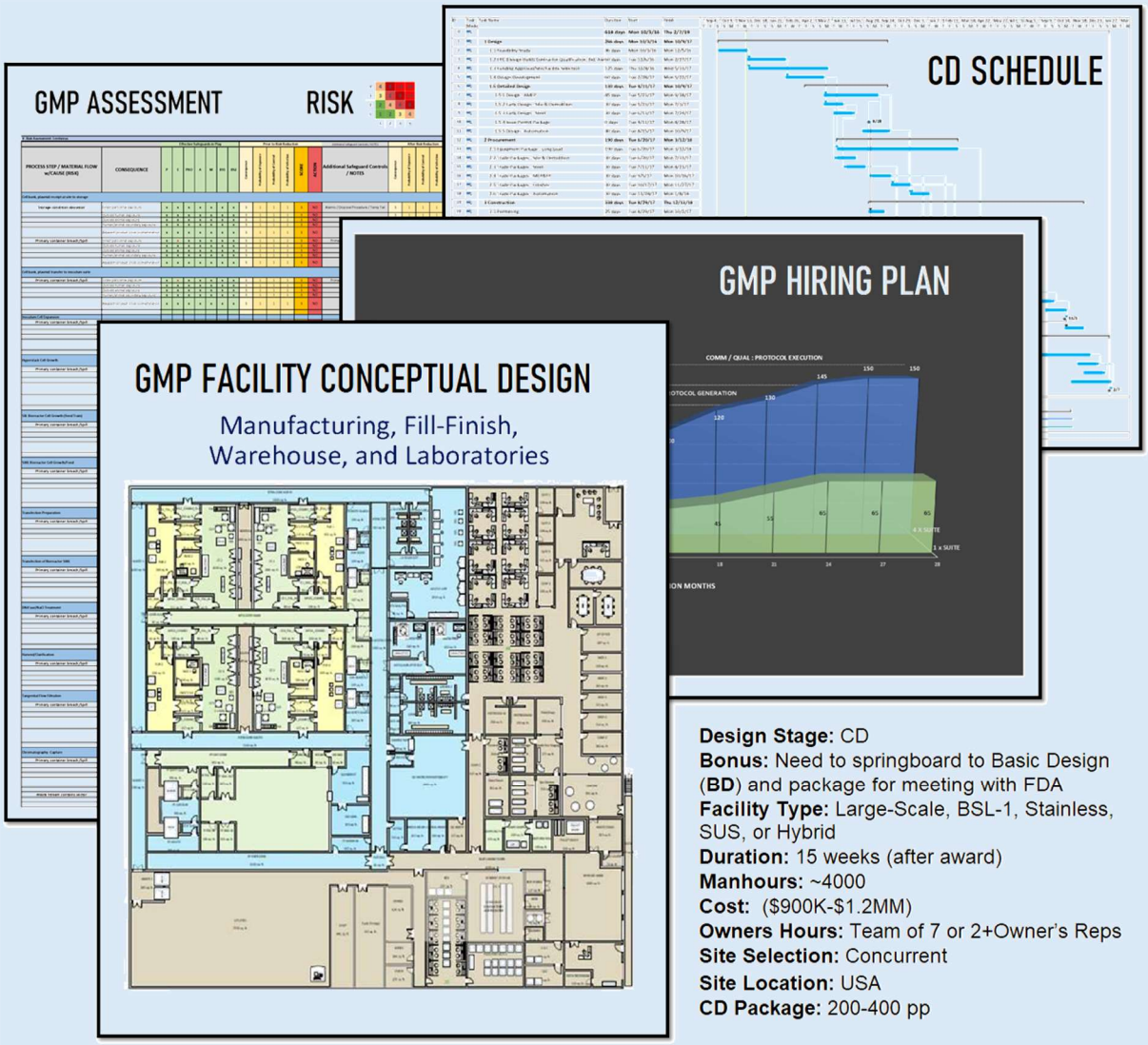
GMP Conceptual Design

12 x 7,000-Liter Biologics CDMO Facility Design Framework



Design Stage: CD
Bonus: Need to springboard to Basic Design (**BD**) and package for meeting with FDA
Facility Type: Large-Scale, BSL-1, Stainless, SUS, or Hybrid
Duration: 15 weeks (after award)
Manhours: ~4000
Cost: ($900K-$1.2MM)
Owners Hours: Team of 7 or 2+Owner's Reps
Site Selection: Concurrent
Site Location: USA
CD Package: 200-400 pp

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GMP Conceptual Design for a 12 x 7,000-Liter Biologics CDMO Facility

Introduction

The conceptual design (CD) phase is a critical initial step in developing a GMP-compliant biologics manufacturing facility. Proper conceptual design minimizes errors, supports regulatory compliance, facilitates operational efficiency, and ensures a flexible, scalable manufacturing environment suitable for complex biologic products. For a 12 x 7,000-liter biologics CDMO facility in Boston, MA, the conceptual design (**CD**) must integrate current GMP regulations with best industry practices to meet capacity and quality objectives while considering future expansion and technological evolution.

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For Future Reading (References are 2022 - 2025)

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