





Operational Excellence and Strategy Consulting for Advanced Therapy CDMOs

We are a science-driven consulting boutique that provides comprehensive services including start-up strategy, facility oversight, CMC support, regulatory guidance, and operational improvements for CGT and biologics CDMOs.

WHO WE HELP

-  New CDMOs that are intending to set up a new GMP facility
-  Existing CDMOs that require additional expertise to manage plant or human resource expansions
-  Existing CDMOs in need of external remediation to improve processes, workflows, and regulatory compliance
-  CDMOs that are moving from traditional modalities into advanced therapies or complex biologics

14

Consultants

200+

Years of combined experience

Millions

Of dollars saved by our clients

The CGT CDMO landscape is highly competitive, consisting of a rapid influx of new players and the expansion of established ones, all vying to capture a share of the therapeutic pipeline. In an environment where manufacturing complexity is immense and timelines are critical, a CDMO can no longer compete on capacity alone. It is through deep-rooted operational excellence that a partner truly stands out.



OUR CIRCLE OF CDMO EXCELLENCE

Right-First-Time Facility

Providing general facility requirements; writing RFPs; A&E firm oversight

Operational Excellence

Standardizing workflows to ensure safety, efficiency, productivity, and quality

Embedded Quality by Design

An embrace of QbD principles to create robust manufacturing processes, with risk-based approaches to enhance product consistency.

Supply Chain Guidance

Providing recommendations for critical equipment, raw materials and consumables vendors; vendor selection and negotiation

Workforce Development

Process/analytical development, CMC, QbD, and regulatory training

Remediation Services

Process improvements and regulatory compliance

