



CAPACITY CHALLENGES

BRG supports GMP clients as they select, engage, and work externally with a large EPCM partner

1

Support GMP clients with internal audit(s) that uncovers internal capacity without an expansion or new GMP facility.

2

Support GMP clients as they search, score, audit, award, and manage a DS/DP CDMO.

3

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Biotech Resources Group (BRG) helps GMP biologics companies make better manufacturing decisions at the moments that matter most: when building new capacity, unlocking more from an existing facility, or selecting and managing a CDMO partner. Each service is designed to reduce risk, improve execution, and turn complex GMP choices into practical next steps.

3 SERVICE TYPES

DOING NOTHING IS NOT AN OPTION



DESIRED OUTCOMES

NEW FACILITY / EXPANSION (EPCM Partner)

- Steer and Challenge the EPCM Partner
- Layouts, Segregation aligned with FDA/Annex-1
- Fewer design changes and surprises
- Strong Governance and Design Control

EXTERNAL CDMO CAPACITY

- Shortlisted CDMO's screened for technical fit, maturity, and real capacity
- Strong Governance and Expectation Management

INTERNAL CAPACITY AUDIT

- GMP Capacity Remediation Roadmap
- Review Equipment, Processes, and Operations
- Defer Capex & CDMO expenses



SERVICES

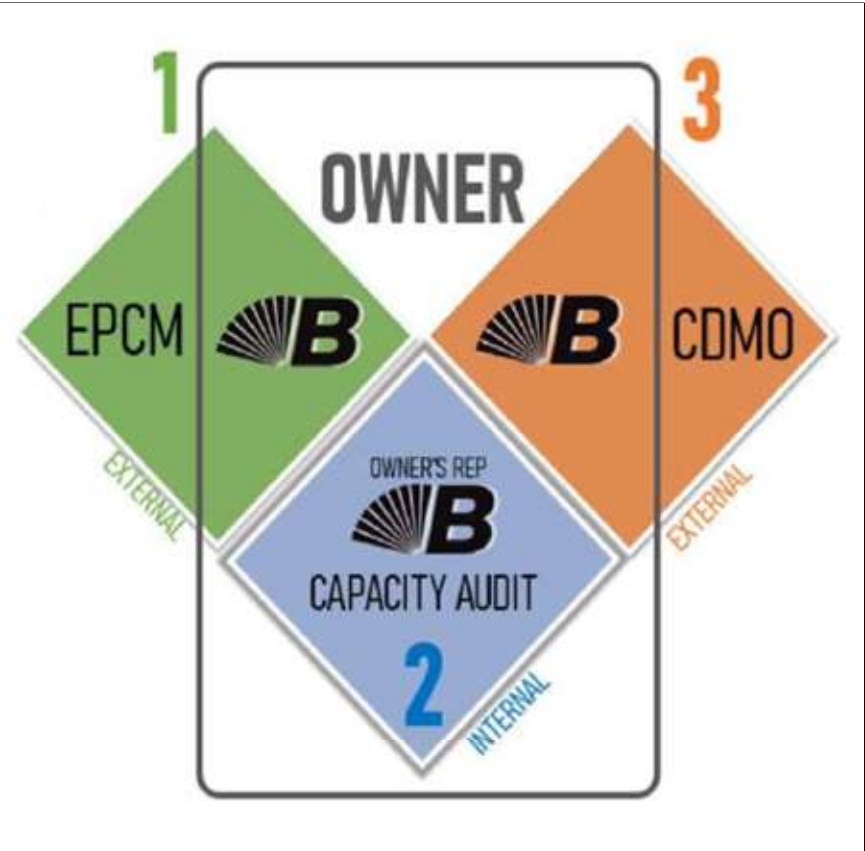
TYPE-1 NEW FACILITY / EXPANSION; OWNERS-REP EPCM SUPPORT
TYPE-2 UNCOVER HIDDEN CAPACITY / OPERATIONAL SWEET SPOT AUDIT
TYPE-3 CDMO SELECTION, AWARD, SPONSOR-SIDE MANAGEMENT

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Resolve **GMP** Capacity Constraints : 3 Ways

SERVICE TYPE	BRG SKILLSET	CLIENT SIZE/TYPES
1 Support GMP clients* as they select, engage, and work externally with a large (EPCM), high-horsepower engineering and design team. OUTCOME: New Facility, Capacity Increase	Site Selection / Incentives Conceptual/Basic Design Support BFD, PFD, Time & Motion Procure, FAT, Install, SAT Steering Committee	MEDIUM-SIZED MATURE INNOVATOR
2 Support GMP clients with internal audit(s) that uncovers internal capacity without an expansion or new facility. OUTCOME: Increased Capacity, Agility	Facility Audits (All Departments) Facility Design Review Equipment Qualification Time-Motion/Process Staffing, Expertise, Experience	MEDIUM/LARGE VERY MATURE INNOVATOR & CDMO
3 Support GMP clients as they search, score, audit, award, and manage a DS/DP CDMO. OUTCOME: Increased Capacity, Expertise	Facility Audits CDMO Qualification, Award, PM Start-Up, Comm, Qual TYPE-C / NMPA Meetings	SMALL/MEDIUM MATURE, INNOVATOR



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HIGH-VALUE PROJECT OUTCOMES / SUMMARIES

BRG PROOF POINTS: BUILD, OPTIMIZE, BUY

CASE-1 BUILD

Locked an EPCM Partner for a Sub-\$1B Greenfield Campus — On Time, On Budget

- CLIENT Large CDMO, fewer than 2,000 employees, planning a multi-modal greenfield GMP campus to expand DS/DP capacity.
- CHALLENGE The team needed an EPCM partner plus internal alignment on budget, headcount master planning, qualification criteria, and governance before award decisions could move confidently.
- BRG MOVE Served as independent Owner's Rep through selection, award, conceptual design, and basic design; screened global EPCM candidates and narrowed to a final shortlist.

HIGH-VALUE OUTCOMES

- 3-MONTH EPCM LOCK WITH BOARD-READY RFP SCORING
- ON-TIME, ON-BUDGET CONCEPTUAL DESIGN KICKOFF
- <0.25% OF TOTAL INSTALLED COST IN BRG FEES
- DOCUMENTATION HEAVY ENOUGH FOR A FRICTIONLESS BASIC-DESIGN HANDOFF



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SERVICE TYPE-1

NEW FACILITY DESIGN/BUILD, EXPANSION;
OWNERS-REP EPCM SUPPORT

BRG PROOF POINTS: BUILD, OPTIMIZE, BUY

CASE-2 OPTIMIZE

Found 30% More Capacity Without Adding a Single Square Foot

- CLIENT Mature biologics CDMO with more than 500 employees and a commercial monoclonal antibody or biosimilar manufacturing site.
- CHALLENGE Leadership had equipment and people but could not hit target output because persistent deviations, contamination, and scheduling losses obscured the true bottleneck.
- BRG MOVE Ran a multi-point HAZOP-style bottleneck review and delivered a scored, sequenced remediation plan instead of a broad advisory memo.

HIGH-VALUE OUTCOMES

- 30% CAPACITY INCREASE WITH NO NEW FOOTPRINT
- RESOLVED PERSISTENT CONTAMINATION LINKED TO BIOFILM
- BOOSTED TEAM MORALE AND PERSONNEL RETENTION
- SHIFTED THE SITE FROM CRISIS RESPONSE TO CONTINUOUS IMPROVEMENT



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SERVICE TYPE-2

UNCOVER HIDDEN CAPACITY; REMEDY
DYSFUNCTIONAL PLANT; FACILITY AUDIT

BRG PROOF POINTS: BUILD, OPTIMIZE, BUY

CASE-3 BUY

Turned a First-Time CDMO Search Into a Board-Defensible Decision

- CLIENT Series C biotech innovator with fewer than 100 employees, advancing a monoclonal antibody program from Phase 1 to Phase 2.
- CHALLENGE The company had never run a formal biologics DS/DP CDMO search, audit, or award sequence and needed speed without making an expensive partner mistake.
- BRG MOVE Applied a CDMO fit matrix across 100+ global candidates, narrowed to a scored finalist set, and supported RFP review, pricing, quality agreement structure, and capability-gap analysis.

HIGH-VALUE OUTCOMES

- 30%+ FASTER SEARCH TIMELINE, FROM 21 WEEKS TO 14
- SELECTED CDMO, HIT TECH TRANSFER AND DS/DP BATCH TARGETS
- <\$10MM PROGRAM DELIVERY WITH A DEFENSIBLE BOARD RATIONALE
- <\$100K BRG FEE, ABOUT 1% OF PROGRAM BUDGET

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SERVICE TYPE-3

CDMO SEACH, RFI, AUDIT, SCORE, AWARD;
SPONSOR-SIDE MANAGEMENT

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