

Resolve **GMP** capacity constraints: Build, Optimize, Buy.

Biotech Resources Group helps GMP biologics companies make better manufacturing decisions at the moments that matter most. Tariffs, BIOSECURE, and leaner teams are forcing those decisions sooner.

WHY CAPACITY DECISIONS CAN'T WAIT

\$400B+

in new US pharma manufacturing investment commitments¹

79%

of biopharma companies have a China-linked CDMO relationship²

4 in 5

biologics facilities outsource at least part of production³

22,000+

roles cut at the largest drugmakers in one year⁴

SERVICE TYPE-1

BUILD

**New facility or expansion:
Owner's Rep EPCM support**

Onshoring is driving new US capacity. We make sure your EPCM partner builds the right plant.

- Site selection and incentives
- EPCM selection, award, steering
- Layouts aligned with FDA/Annex 1
- Procurement, FAT, install, SAT

Best for: medium-sized, mature innovators

PROOF POINT

3-month EPCM lock

Large CDMO, sub-\$1B greenfield campus. On time, on budget; fees under 0.25% of installed cost.

SERVICE TYPE-2

OPTIMIZE

**Uncover hidden capacity:
Operational Sweet Spot Audit**

With lean teams and tight capital, the fastest capacity is often already in your plant.

- Audits across all departments
- Equipment, process, time-motion
- GMP capacity remediation roadmap
- Defer capex and CDMO spend

Best for: medium/large innovators and CDMOs

PROOF POINT

30% more capacity

Mature biologics CDMO. No new footprint, and persistent biofilm contamination resolved.

SERVICE TYPE-3

BUY

**CDMO search, audit, award:
sponsor-side management**

BIOSECURE and tariffs are reshaping CDMO choices. We find real capacity and manage it.

- Fit screening, RFI, audit, scoring
- Award, pricing, quality agreements
- Start-up, C&Q, tech transfer
- Type C and NMPA meetings

Best for: small/medium, mature innovators

PROOF POINT

21 weeks to 14

Series C mAb innovator, first DS/DP CDMO search. BRG fee about 1% of program budget.

IS THIS YOU?

- ☐ Tariffs are forcing a US build-or-buy decision
- ☐ A program depends on one CDMO or a China-linked supplier
- ☐ Your plant has equipment and people but misses output
- ☐ You are choosing an EPCM partner or a first DS/DP CDMO
- ☐ Your team is too lean to run the search or oversight

DOING NOTHING IS NOT AN OPTION.

Talk with us about your next capacity decision: build, optimize, or buy.

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Sources: 1. The CrossCheck, thecrosscheck.org/factcheck/2026-10-04-trump-bayer-ohio-pharma-tariffs-factcheck/ 2. BIO survey, via KBI Biopharma, kbibiopharma.com/our-resources/biosecure-tariffs-and-the-new-cdmO-reality-for-biopharma-innovators 3. BioPlan Associates, via Bourne Partners, bourne-partners.com/wp-content/uploads/2026/09/Bourne-Brief-Contract-Pharma-Conf-Takeaways-Sept-2026.pdf 4. IQVIA/FiercePharma analysis, via Chosun Biz, biz.chosun.com/en/en-science/2026/05/19/Z376O4DSG5G6ZPJDBI73XVWHQA/



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

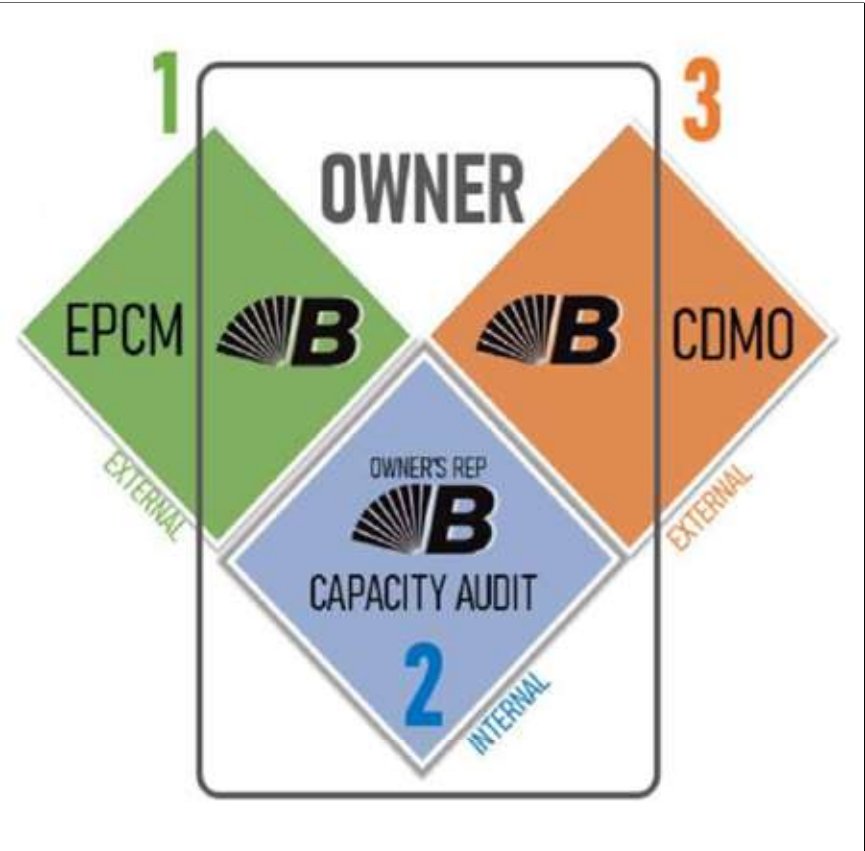
TYPE-1 NEW FACILITY / EXPANSION; OWNERS-REP EPCM SUPPORT
TYPE-2 UNCOVER HIDDEN CAPACITY / OPERATIONAL SWEET SPOT AUDIT
TYPE-3 CDMO SELECTION, AWARD, SPONSOR-SIDE MANAGEMENT

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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



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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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