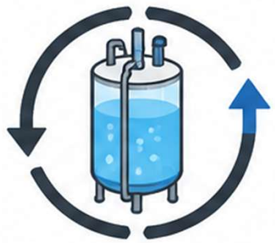
IS YOUR GMP CAPACITY THE NEW CRITICAL PATH?

Biotech Resources Group (BRG) helps GMP biologics companies make better manufacturing capacity decisions when it matters most—whether you need to **Optimize, Build, and/or Buy.**

OPTIMIZE



UNLOCK CAPACITY

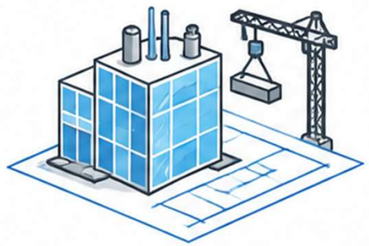


REMOVE BOTTLENECKS

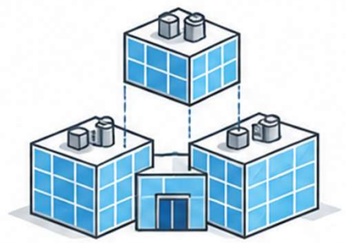


ELEVATE PERFORMANCE

BUILD



BUILD WITH PURPOSE



SHAPE YOUR CAPACITY



DESIGN TO DELIVER

BUY



FIND THE RIGHT FIT



PARTNER WITH CONFIDENCE



CHOOSE WITH CLARITY

BRIDGEONE BUILD - OPTIMIZE - BUY

3 GMP CAPACITY LEVERS: OPTIMIZE, BUILD, BUY

BRG BIOTECH RESOURCES GROUP

GMP CAPACITY ADVISORS

TECHNICAL

- Site Selection / Incentives
- Vendor Qualification, Award, PM
- Conceptual Design Support
- Basic Design Support
- Detail Design Support
- BFD, PFD, Time & Motion
- Equipment URS/Datasheets
- Constructability Review
- Procure: Design/Fab/FAT/SAT/
- Stainless / CFD / Superskid
- Single-Use Systems
- MOD / POD's

OPS, QMS

- Facility Audits
- CDMO Qualification, Award,
- PM Start-Up, Comm, Qual
- TYPE-C / NMPA Meetings

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Robert Valdes (Bob) GMP Advisor, Founder

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 commitments[1]

79%
of biopharma companies have a China-linked CDMO relationship[2]

4 in 5
biologics facilities outsource at least part of production[3]

22,000+
roles cut at the largest drugmakers in one year[4]

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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BridgeOne GMP Services Ecosystem · © 2026 Biotech Resources Group, LLC

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

Biotech Resources Group (BRG) helps biotech companies make better manufacturing decisions at the moments that matter most: **unlock more from existing assets, build new capacity, and select and manage a CDMO partner.**

BRIDGEONE

OPTIMIZE ✦ BUILD ✦ BUY

BridgeOne GMP Services Ecosystem by Biotech Resources Group

DESIRED OUTCOMES

Tariffs, BIOSECURE and leaner teams are forcing these decisions sooner. Each service reduces risk, improves execution, and turns complex GMP choices into practical next steps.

OPTIMIZE | Get more capacity from existing assets

Best for: medium/large innovators and CDMOs

	CHALLENGE → OUTCOME	
Losses are visible, but root causes are unclear	1	**A clear map of lost capacity** and which fixes matter most
Bottlenecks cap annual harvests and total doses	2	**Bottlenecks removed** in priority order, with dose impact quantified
Scheduling, campaigns and changeovers consume productive time	3	**More productive time** from better scheduling and campaign design
Variable yields and inconsistent execution undermine supply	4	**Predictable output** and stronger delivery confidence
Contamination and repeat deviations disrupt production	5	**Fewer repeat events** through targeted CAPA priorities
Staffing, training and automation gaps constrain execution	6	**People, systems and production requirements** aligned
Legacy layouts, equipment and processes limit performance	7	**Targeted modifications** instead of an automatic CAPEX commitment
Improvement projects compete for limited funding	8	**A roadmap ranked by capacity gained per dollar**
Build-or-buy decisions rest on an uncertain baseline	9	**A defensible baseline**, including where perfusion or continuous processing truly pays back

PROOF POINT **30% more capacity** Mature biologics CDMO. No new footprint, and persistent biofilm contamination resolved.

BUILD | Invest in the right facility at the right time

Best for: medium-sized, mature innovators

	CHALLENGE → OUTCOME	
Facility scope advances before supply needs are clear	1	**A project basis tied to demand**, timing and the pipeline
Concepts don't reflect the manufacturing process	2	**Process, equipment, layout, utilities and flows** aligned
EPCM proposals are hard to compare	3	**A structured, like-for-like basis** for selecting the EPCM partner
Internal teams are outmatched by large EPCM firms	4	**An independent owner's-rep voice** protecting business priorities
Scope gaps and unclear interfaces create execution exposure	5	**Clear responsibilities, deliverables** and interfaces
Capital constraints force hard design trade-offs	6	**Trade-offs made with data**, through phasing, modular or shell-space options
Design overlooks maintenance and daily operations	7	**A facility built to run reliably** and adapt to change
Construction milestones overshadow manufacturing readiness	8	**C&Q and operational readiness planned from day one**
New, expanded or acquired sites lack a path into the network	9	**A practical plan** to integrate the site into the network capacity strategy

PROOF POINT **3-month EPCM lock** Large CDMO, sub-$1B greenfield campus. On time, on budget; fees under 0.25% of installed cost.

BUY | Secure external capacity that fits the program

Best for: small/medium, mature innovators

	CHALLENGE → OUTCOME	
The search starts with an incomplete manufacturing brief	1	**Technical, quality, capacity and timing requirements** set before outreach
A China-linked CDMO creates BIOSECURE, tariff or partner-diligence risk	2	**A BIOSECURE-ready second source** and transfer plan that protects the clinical timeline
Too many providers, too little comparable information	3	**A focused longlist and shortlist** matched to real program needs
Commercial claims obscure technical capability	4	**Evidence-based confidence** in modality, platform and scale fit
Quality and operational risks surface late	5	**Critical gaps found early** through structured diligence and audits
Proposals use different assumptions and scope	6	**Like-for-like comparison** of scope, costs and exclusions
Available capacity is mistaken for program-ready capacity	7	**A realistic view of tech transfer**, readiness and timelines
Selection relies on impressions, not shared criteria	8	**A documented, defensible award rationale**
Responsibilities and escalation are unclear, and needs change after award	9	**Clear governance and sponsor-side oversight** as demands evolve

PROOF POINT **21 weeks to 14** Series C mAb innovator, first DS/DP CDMO search. BRG fees about 1% of program budget.

DOING NOTHING IS NOT AN OPTION.

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

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