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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GMP IS IN OUR DNA ®

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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

OPTIMIZE | More Capacity from Existing Assets

Capacity losses are visible, but root causes are unclear
Bottlenecks limit production harvests per year / total doses
Scheduling, campaigns, and changeovers consume productive time
Variable yields and inconsistent execution undermine supply
Contamination events and repeat deviations disrupt production
Staffing, training, and automation gaps constrain execution
Legacy layouts, equipment, processes limit performance
Improvement initiatives compete for limited funding
CDMO/Expansion decision rests on an uncertain baseline

BUILD | Invest in the right facility at the right time

Facility scope advances before supply requirements are clear
Facility concepts do not adequately reflect the manufacturing process
EPCM proposals are difficult to compare
Internal teams need stronger representation with a large EPCM firm
Scope gaps and unclear interfaces create execution exposure
Capital constraints force difficult design trade-offs
Design decisions overlook maintenance and day-to-day operations
Construction milestones overshadow manufacturing readiness
New, expanded, or acquired sites lack a clear path into the network

BUY | Secure external capacity that fits the program

The CDMO search begins with an incomplete manufacturing brief
Too many providers—and too little comparable information
Commercial claims obscure technical capability
Quality and Operational risks emerge late in selection
Proposals use different assumptions and scope boundaries
Available capacity is mistaken for program-ready capacity
Partner selection relies on impressions rather than shared criteria
Sponsor–CDMO responsibilities and escalation paths are unclear
Program needs change after the award

BRIDGEONE

OPTIMIZE ✦ BUILD ✦ BUY

Biotech Resources Group (**BRG**) helps biotech companies make better manufacturing decisions at the moments that matter most:

✦Unlocking more from an existing asset
✦Building New Capacity
✦Selecting/Managing a CDMO partner

Each service is designed to reduce risk, improve execution, and turn complex GMP choices into practical next steps.

DOING NOTHING IS NOT AN OPTION

DESIRED OUTCOMES

OPTIMIZE

A clear picture of lost capacity—and which improvements matter most.
More productive manufacturing time through better scheduling.
More predictable output and stronger delivery confidence.
Fewer recurring disruptions through targeted corrective priorities.
Better alignment of people, systems, and production requirements.
Targeted modifications instead of an automatic commitment to CAPEX
A prioritized roadmap tied to capacity impact.
Adopt Perfusion technology and Continuous Manufacturing

BUILD

A capacity and project basis aligned with demand, timing, and programs
Better alignment of process, equipment, layout, utilities, and flows.
A structured basis for selecting the right engineering partner.
An independent sponsor-side voice protecting business priorities.
Clearer responsibilities, deliverables, and project boundaries.
A facility better suited to reliable operation and future change.
A practical plan for integrating the GMP asset into the Capacity Strategy.

BUY

Clear technical, quality, capacity, and timing requirements before starting.
A focused longlist and shortlist matched to the program's actual needs.
Evidence-based confidence in process, platform, modality, and scale fit.
Earlier visibility into critical gaps through structured diligence and audits.
A like-for-like comparison of scope, responsibilities, costs, and exclusions.
A realistic view of transfer requirements, readiness, and manufacturing timelines.
A documented selection and award rationale that stakeholders can defend.
Clear governance, accountability, reporting, and issue escalation.
Strong sponsor-side oversight as technical, quality, and schedule demands evolve.

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