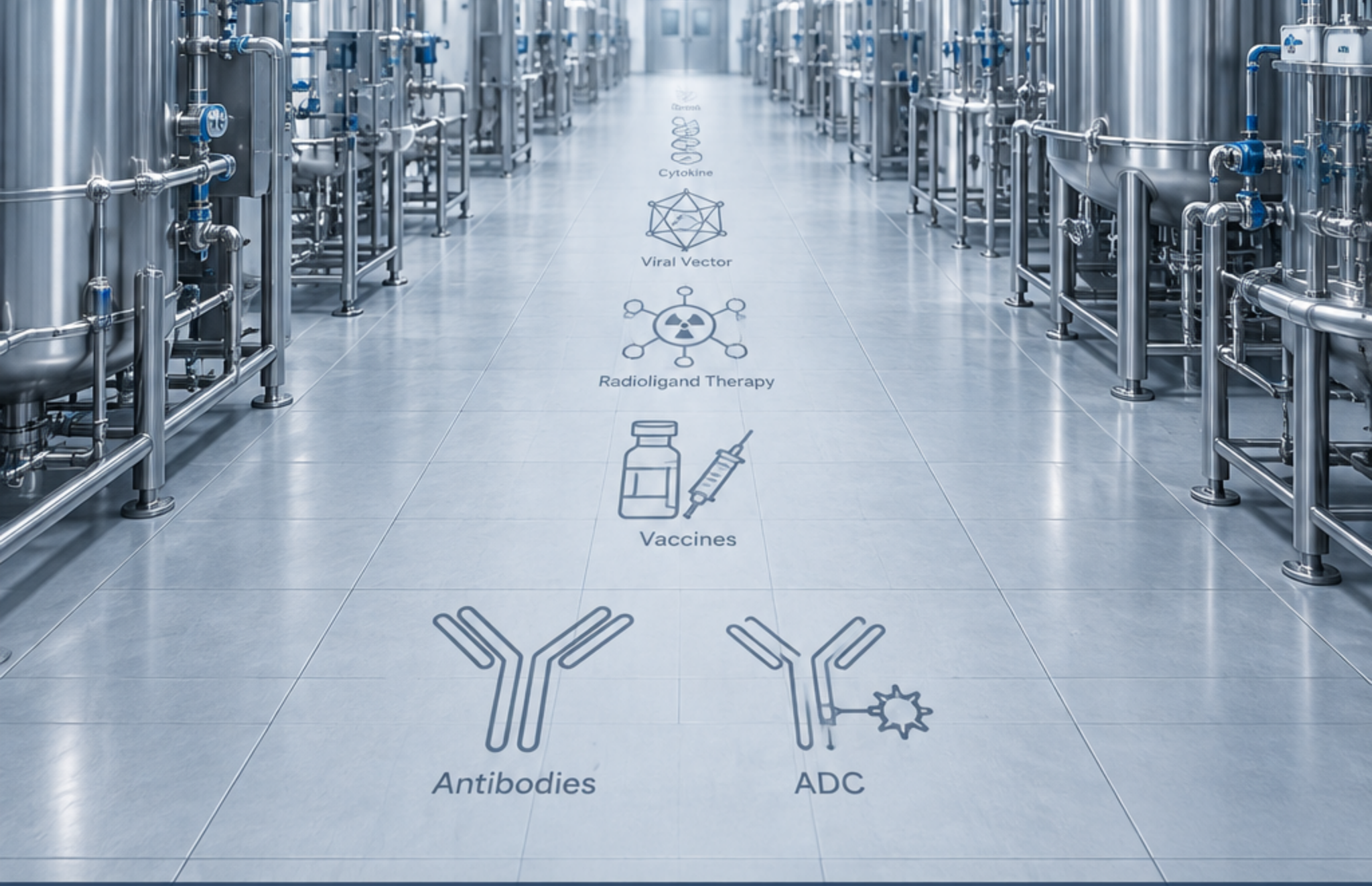
BRG
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OPTIMIZE | GMP CAPACITY STRATEGY

THE HIDDEN CAPACITY GUIDE

Understand the constraints.
Evaluate the remedies.
Define the next step.



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A practical introduction for GMP Operations leaders evaluating existing capacity and their next manufacturing investment.

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Before adding capacity, understand the gap

“Which CDMO should we qualify?”
“Should we expand or build a new facility?”

For GMP Operations leaders facing a capacity shortfall, there is an earlier question: “What is limiting the capacity we already have?”

Historical output tells you what a facility has delivered—not necessarily what it can sustainably deliver. The difference may reflect demand, product allocation, scheduling, staffing, process performance, quality-related delays, or physical constraints.

The purpose of a hidden-capacity assessment is to determine which limitations can be addressed, what additional usable supply could result, and whether that contribution can be delivered when needed.

Start with the supply requirement

• Which products, processes, and manufacturing stages are in scope?

• How much supply is required, and by when?

• Where is output measured—for example, released drug substance or released finished product?

• Which resources and production windows are available to the product?

• What decision does leadership need to make, and by what date?

Distinguish output from capacity

Design-basis capacity reflects a specified process, equipment configuration, production calendar, and operating model. Its relevance depends on whether those assumptions still fit the operation.

Demonstrated output describes what the facility has delivered under documented conditions. Historical output may reflect limited demand or allocation rather than the operating ceiling.

Estimated sustainable capacity describes expected output under explicit operating, staffing, scheduling, quality, and readiness assumptions. Proposed improvements should remain separate from the current baseline.

Usable supply is output available at the agreed boundary—for example, released drug substance or released finished product—compared on the same time basis as the supply requirement.

Keep the answer open

An assessment may identify recoverable capacity. It may also confirm the need for targeted investment, external manufacturing, or expansion. The objective is a defensible decision—not a predetermined recommendation to avoid capital spending.

Examine the connected operation

A capacity concern may appear in one department while its cause sits elsewhere. BRG examines the relevant manufacturing sequence and its supporting functions through seven assessment dimensions.

1. Upstream operations

Seed-train readiness, inoculation timing, vessel availability, harvest timing, and turnaround. What limits the planned sequence of production starts?

2. Downstream operations

Capture, polishing, filtration, buffer preparation, formulation, and storage. Can the downstream arrangement support the planned harvest profile without creating limiting queues or holds?

3. Quality and release

Sampling, testing, investigations, batch-record review, and disposition. What determines when manufactured material becomes usable supply?

4. Materials and warehouse flow

Material release, staging, quarantine, storage, cold-chain capacity, and transfers. Are the required materials and storage conditions available when the schedule needs them?

5. Facility and infrastructure

Layouts, utilities, shared systems, equipment access, and maintenance requirements. Where does the physical arrangement constrain the current operating model?

6. Automation and data

Visibility of equipment status, queues, holds, exceptions, and information handoffs. Where do information gaps or manual workflows create documented delay or rework?

7. Staffing and shift coverage

Qualified task coverage, training, handovers, decision authority, and escalation. Can the right activities and decisions occur when production requires them?

Follow the effect through to usable supply

A local improvement does not automatically create additional released output. Its value depends on the connected operation, including downstream stages, supporting systems, quality activities, and the production calendar.

These dimensions are BRG assessment lenses—not a regulatory checklist or a facility-rating system. The engagement determines the appropriate scope and depth.

How BRG works with your team

BRG works alongside the client's Manufacturing, Engineering, Quality, and other relevant functions to move from a capacity concern to an evidence-backed improvement roadmap.

1. Agree on the problem and the decision

Together, we define the supply requirement, affected operations, timing, and business decision. We agree the assessment scope, information needs, responsibilities, and success criteria before work begins.

2. Establish the baseline and investigate constraints

Through record review, cross-functional discussions, and site assessment as appropriate, we examine actual operating performance. We distinguish documented losses, suspected causes, physical limitations, and evidence gaps. Where a diagnosis remains uncertain, we identify the additional investigation or demonstration needed.

3. Develop and challenge improvement options

We work with the relevant functions to test the diagnosis and evaluate potential remedies. Options are considered for their effect on usable supply, quality risk, implementation burden, cost, disruption, and timing. Estimated gains remain conditional until adequately supported.

4. Build a prioritized implementation roadmap

We help translate findings into defined work packages with accountable owners, dependencies, decision gates, and measures of success. The roadmap distinguishes operational improvements, process changes, targeted capital projects, and any remaining need for external or additional internal capacity.

5. Support execution and review results

Where included in the engagement, BRG supports implementation planning, cross-functional coordination, issue escalation, and performance review. Results are reviewed against the agreed baseline before additional capacity is treated as established.

Agree the engagement boundaries

Assessment and implementation support may be commissioned together or as separate phases. Scope, deliverables, schedule, fees, responsibilities, and acceptance criteria are agreed in writing for the client's situation before work begins.

Ask only what each stage needs

• **Level-1, High-Level Discussion:** nonconfidential; the concern, the decision, and the fit.

• **Level-2, Focused Assessment:** after a confidentiality agreement and agreed scope; the baseline and focus areas.

• **Level-3, Departmental Investigation:** evidence from each relevant function, reconciled.

• **Level-4, Targeted Diagnostic Follow-Up:** tests competing explanations where needed.

The GMP Capacity Assessment and Diagnostic Workbook, a companion to this guide, sets out the questions, required roles, named respondents, and evidence for each level.

Turn findings into action

A constraint register is not an implementation plan. Findings need to become decisions, assigned work, and measurable outcomes.

Match the remedy to the constraint

• Operational coordination or scheduling changes.

• Staffing, qualification, or shift-model improvements.

• Process development or technology changes.

• Equipment, utility, storage, or layout modifications.

• External manufacturing or additional internal capacity.

Not every constraint can be resolved operationally. Not every technically feasible improvement can be implemented before the supply gap appears.

Make responsibilities explicit

BRG provides the assessment, technical and operational challenge, option evaluation, roadmap development, and implementation support specified in the engagement. We identify where additional specialist expertise is needed.

The client provides access to relevant information and personnel—typically beginning with an organization chart and named contacts for each function—reviews findings, appoints action owners, and retains authority for operating decisions, quality approvals, change control, product disposition, and investment authorization.

Together, we agree priorities, resolve dependencies, review evidence, and determine whether outcomes meet the agreed success criteria.

Protect quality while improving supply

Contamination events and associated investigations, repeat cleaning, holds, or equipment restrictions can affect throughput. Those effects must be considered alongside product-quality and patient-risk implications.

Throughput objectives must not override required controls. Proposed changes require the applicable site-specific technical and quality review, change control, and qualification or validation assessment.

Reassess the remaining gap

Improvement contributions should use the same output boundary and time basis as the supply requirement. Overlapping benefits should not be counted twice.

Where timing requires it, assessment, sourcing, and project definition may proceed in parallel. Optimize is a capacity-strategy lever—not a mandatory waiting period before Buy or Build can begin.

From learning to a scoped engagement

What this guide provides

An introduction to the capacity question, seven assessment dimensions, and how BRG works with a client team. It is not a facility assessment or an implementation plan.

What a paid engagement develops

Depending on the agreed scope, client-specific work may include:

• A reconciled operating baseline and time-phased capacity-gap summary.

• An evidence-backed constraint register and diagnosis, with unresolved questions identified.

• Evaluated improvement options, supply contributions, dependencies, and uncertainty.

• A prioritized roadmap with work packages, owners, decision gates, and demonstration criteria.

• Implementation coordination and performance review, where commissioned.

The guide alone does not establish recoverable capacity, verify a root cause, authorize a process change, or justify an investment decision. Those conclusions require client-specific evidence and review.

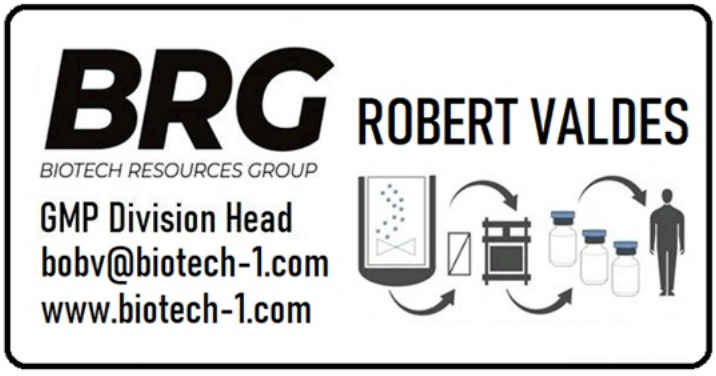
Considering your next capacity investment?

If you are responsible for GMP output and evaluating an operational shortfall, additional CAPEX, or CDMO capacity, start with a conversation about the decision in front of you.

Email **bobv@biotech-1.com** with the subject “CAPACITY,” or message Robert Valdes directly on LinkedIn.

Briefly describe the capacity concern and when you need to make a decision. Please do not include confidential product or facility information in your initial message; the first discussion uses nonconfidential information only.

We’ll discuss whether BRG’s support fits your situation and, if appropriate, define the scope of a paid assessment or improvement engagement.



The GMP Capacity Assessment and Diagnostic Workbook, a companion to this guide, supports BRG engagements. The forthcoming GMP Capacity Strategy book and its companion workbook explore Optimize, Buy, and Build.

Scope and limitations: This educational guide presents BRG assessment concepts. It does not establish a benchmark, guarantee capacity recovery or savings, demonstrate GMP compliance, or replace product-specific technical, quality, validation, regulatory, or financial review.