GMP FACILITY:

SITE SELECTION POINTS TO CONSIDER

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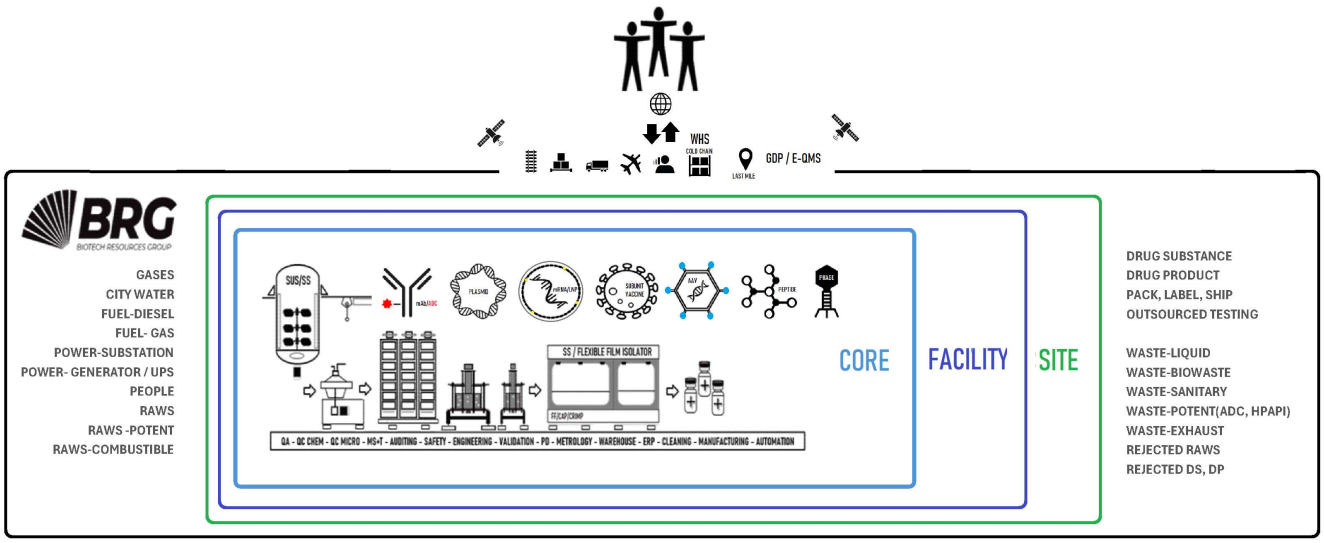

GMP Facility: Site Selection Points to Consider

Robert Valdes | Biotech Resources Group, LLC | GMP Division Head | bobv@cgmp.global

Summary

The short checklist below outlines critical factors to consider when selecting a site for a Good Manufacturing Practice (GMP) biotechnology facility. It covers essential aspects from zoning and infrastructure to workforce considerations and community impact, providing a thorough guide for decision-makers in the biotech industry. This checklist assumes that the owner has characterized their process(es) (modality, scale, biosafety, biosecurity) via feasibility study, mass balances, and/or conceptual design.

1. **Zoning and Regulations**

- Review local zoning laws and regulations specific to biotech facilities
- Ensure compliance with environmental considerations
- Verify biotech-specific land use permissions
- Analyze potential regulatory barriers

2. **Location and Accessibility**

- Evaluate proximity to transportation infrastructure (airports, highways)
- Assess distance to key scientific research institutions and academia
- Map workforce commute routes and accessibility
- Analyze public transportation options

3. **Infrastructure and Utilities**

- Conduct detailed electrical capacity analysis, including emergency power
- Ensure mechanical infrastructure supports CGMP operations
- Assess water supply and waste management capabilities
- Evaluate telecommunications and high-speed internet connectivity

4. **Facility Design and Layout**

- Ensure adequate size for current and future needs
- Plan for potential expansion
- Design to accommodate specialized equipment and systems
- Consider modular design for future flexibility
- Incorporate biosafety level compatibility features

5. **Workforce Considerations**

- Analyze availability of skilled labor pool (scientists, researchers, technicians)
- Evaluate amenities and quality of life factors to attract and retain talent
- Assess proximity to STEM graduate programs
- Consider competitive salary benchmarking for the area

6. **Clustering Effect**

- Evaluate the presence of other Biotech R&D facilities in the area
- Assess potential for knowledge spillovers and collaborations

7. **Environmental Factors**

- Analyze natural hazard risks (e.g., floods, hurricanes, wildfires)
- Develop site-specific long-term risk mitigation strategies (viral, potent materials)

8. **Logistics and Supply Chain**

- Consider proximity to patients or major transportation hubs for therapy delivery

- Evaluate access to suppliers and partners

9. **Cost Considerations**

- Analyze land acquisition costs
- Estimate development and construction expenses
- Project ongoing operational costs

10. **Sustainability and Energy Efficiency**

- Explore potential for LEED or WELL certification
- Investigate energy-efficient design possibilities
- Consider on-site renewable energy generation options

11. **Security and Safety**

- Plan implementation of necessary security measures
- Ensure compliance with biosafety requirements

12. **Community Impact**

- Assess alignment with community goals and objectives
- Evaluate potential economic benefits to the local area

13. **Facility Acquisition Options**

    13.1 **Leasing**

    - Suitable for early-stage and pre-Series A biotech companies
    - Lower initial capital investment
    - Flexibility to scale up or down
    - Typically requires longer terms (7-10 years) for biotech spaces

    13.2 **Buying an Existing Facility**

    - Advantageous for more established companies
    - Long-term control over space
    - Potential for customization to specific needs

13.3 **Building a New Facility**

- Ideal for large pharmaceutical companies or well-funded biotech firms
- Complete customization to meet specific research and production needs
- Potential for future expansion
- Highest initial cost and development time

Conclusion

Selecting the optimal site for a GMP biotechnology facility requires careful consideration of numerous factors. Companies should align their choice with their financial capabilities, growth projections, and risk tolerance. The decision between leasing, buying, or building should be based on the company's stage of development, financial resources, and long-term strategic goals.

For further assistance with GMP Facility Site Selection and Facility Design contact:

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BRG GMP Division Video (YouTube): https://youtu.be/zYW5mECaHvU

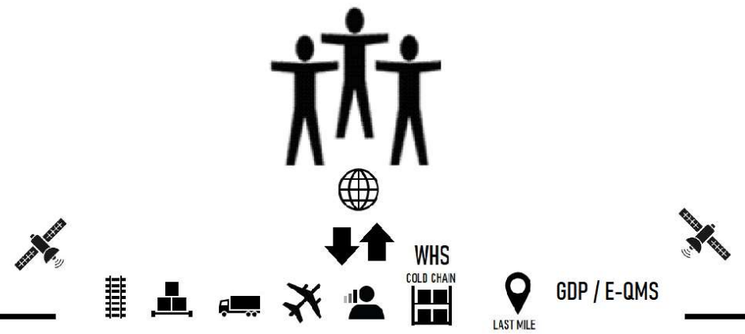
Extra Resources: Relevant Players (starter list / please amend as needed):

Real Estate	Engineering Companies
JLL (Jones Lang LaSalle)	CE&IC
Cushman & Wakefield	KBR
Colliers International	CRB
Newmark Knight Frank	AECOM
CBRE Group	HASKELL
---amend as needed---	IPS
---	JACOBS-WYPER (ARCH)
---	SYSKA HENNESSY
---	TRINITY (SAFEBRIDGE CERTIFICATION)
Owner's Rep /Advocate for Site Selection and Facility design	
Biotech Resources Group, LLC (**BRG**) | www.cgmp.global	
BRG has worked alongside most of the larger firms listed above	

ATTACHMENTS

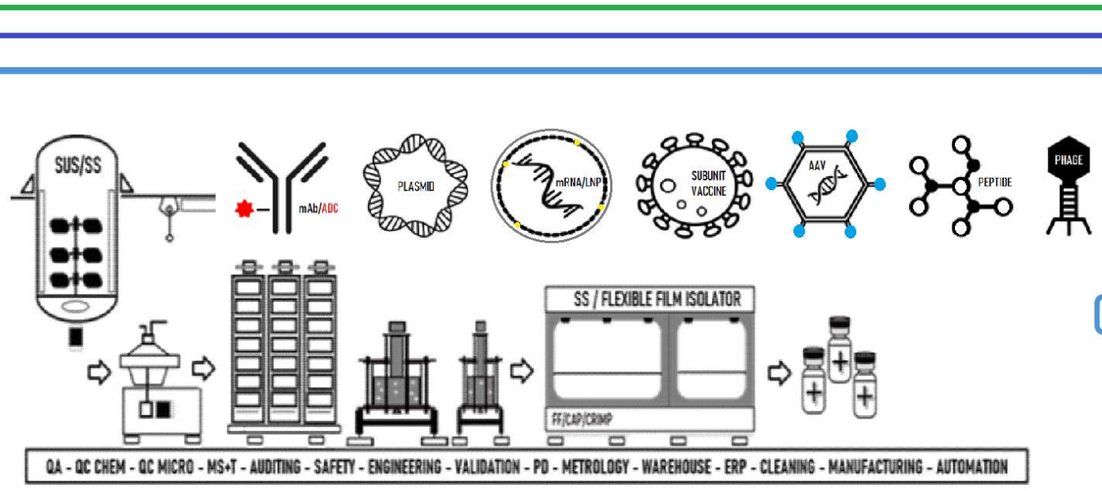
ATTACHMENT 1	SITE CASCADE: CORE→FACILITY→CAMPUS SITE→ COMMUNITY
ATTACHMENT 2	CAPITAL PROJECT PHASES (List of activities per phase) (1 page)
ATTACHMENT 3	Biotech Resources Group (BRG) Services

Notes:



BRG
BIOTECH RESOURCES GROUP

GASES
CITY WATER
FUEL-DIESEL
FUEL- GAS
POWER-SUBSTATION
POWER- GENERATOR / UPS
PEOPLE
RAWS
RAWS -POTENT
RAWS-COMBUSTIBLE



CORE

FACILITY

SITE

DRUG SUBSTANCE
DRUG PRODUCT
PACK, LABEL, SHIP
OUTSOURCED TESTING

WASTE-LIQUID
WASTE-BIOWASTE
WASTE-SANITARY
WASTE-POTENT(ADC, HPAPI)
WASTE-EXHAUST
REJECTED RAWS
REJECTED DS, DP

ATTACHMENT 1: GMP CORE-FACILITY-CAMPUS-SITE-COMMUNITY CASCADE

GMP IS IN OUR DNA ®

I. PROJECT INITIATION — 10 WEEKS

- Generate Feasibility Study per Programmatic Requirements
- Develop Scope for Concept Phase (See Phase II)
- Establish Project Goals and bridge to BD/DD/CM/Qual/GMP
- Identify/Ratify Business drivers, phases, milestones, and budget
- Create Internal Project Core Team / RACI / 2-year Hiring Plan
- Pre-Qual Questionnaire/RFI for CD Report Services
- Generate RFP for CD Scope of work
- Response Review, Clarifications, Score
- Score, Award, Kick-off

DECISION GATE

2. CONCEPTUAL DESIGN — 15 WEEKS

- Collection of information
- PFDs with material balances
- Process Model Scenarios
- Facility Layouts and General Arrangements
- Facility Flow Diagrams
- Equipment List / URS Master List & Schedule
- HVAC Design Criteria
- HVAC Classification Drawings
- Structural Assessment
- Evaluate Options: Modular, Podular, stick-built, or combination
- Generate Preliminary Site Design ✶
- Code Review, Early Constructability
- Establish Order of Magnitude Estimate
- Generate Preliminary Schedule
- Project Execution Plan and Risks
- Resource Plan and Schedule (Hire!)
- Develop of scope for BD Phase (Phase 3)

DECISION GATE

3. BASIC DESIGN — 15 WEEKS

- Approved Process and Facility Bases of Design
- PFDs (including material balances)
- 80% P+IDs
- Process Model
- Facility Layouts and General Arrangements
- Facility Flow Diagrams
- Utility Studies
- HVAC Design Criteria
- HVAC Classification Drawings
- Utility Study and Equipment Sizing
- Equipment List
- Utility use points and piping mains
- Automation Strategy
- Project Risk Assessment
- Structural Design
- Long lead construction documents (specs)
- Early equipment procurement
- Site Design ✶
- Establish Control Budget (20%)
- Establish Project Schedule
- Finalize Project Execution Plan
- Finalize Resource Plan and Schedule
- Permit Plan, Demo Plan
- Constructability Plan
- Develop Scope for Phase 4
- Project Procedures Manual for Phase 4
- Generate Scope for detailed design/construction

DECISION GATE

4. DETAILED DESIGN, PROCURE, CONSTRUCTION

- Drawings and Specs (IFP & IFC)
- Automation Contract (process and BMS)
- Procurement Packages
- Equipment Procurement/reviews/FATs/Delivery/SAT's
- C&Q plans and protocols
- Installation Verification (I.V.)
- Construction Packages
- I.V. Punchlist Generation and Closure
- Establish Mech. Completion dates for each system
- Construction Management
- Safety Management
- Construction Administration and Field Support
- ETOP Review and Punchlist
- As-built drawings

5. COMMISSIONING / QUALIFICATION

- Development of C&Q plans and protocols
- Plans and Protocols should be completed
- Delivery and SAT Execution
- Validation Protocols Executed / Reports Generated
- New Operator Training
- Transition to GMP (checklist)/ QA Mock Audit
- SOP, Batch Records
- Process Validation Protocol Review
- Master BOM review / SAP
- Plant Economics: COG's and Working Cap
- Engineering Runs

BRG BIOTECH RESOURCES GROUP

SITE SELECTION

GMP FACILITY PROJECT PHASES

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BRG
BIOTECH RESOURCES GROUP

HELPING YOU BECOME THE **BEST** BIOTECH MANUFACTURER


SITE SELECTION

BIOPROCESS / GMP OPs

QMS / AUDITS


TALENT MANAGEMENT

As global biotechnology consultants, Biotech Resources Group (BRG) helps you become the best biotech manufacturer.

Challenges & Opportunities:
Biopharma companies frequently encounter opportunities for growth/expansion as well as persistent GMP-QMS problems...often, both at the same time!

Leveraging our **BRIDGE**ONE Serivces Platform, Biopharma companies pivot to BRG to resolve problems that matter:

- Remedy Insufficient Capacity DS, DP
- Remedy Dysfunctional Capacity DS, DP
- Provide Technical/Ops Leadership
- Provide QMS Leadership
- Provide Horsepower to keep pace
- De-risk the Commercial/CDMO journey

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

Talent Management

Master Hiring Plan Creation
Hiring Plan Execution
GXP Recruiter
Staff Augmentation
Tech/Ops Leadership

Host / Modality

Mammalian, Microbial, Insect
Antibody/ADC/Cytokine/Enzyme
AAV/LV/AdV + Plasmid
mRNA, Phage,
Antibiotic, Vaccines
Enzyme, Synthetics

BRIDGEONE
BRIDGEONE is our service platform.
Flexible and always tailored to your GMP programs' goals.

Robert Valdes (Bob) GMP Consultant

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