

BIOTECH RESOURCES GROUP, LLC

OUR TALENT IS FINDING GREAT GXP TALENT

Biotech Resources Group, LLC provides strategic staffing services for clients in Clinical Research and Biologics Manufacturing.

The biotechnology economy is at full strength once again with global drivers fueling long-term growth for CRO, CMO, Innovator, and biosimilar companies. Given this, biotechnology companies are creating strategic imperatives to increase competitiveness. Specifically, each is creating a sustainable competitive advantage structured around Human Capital.

Providing staffing services for over 17 years, Biotech Resources Group (**BRG**) knows first hand that keeping pace with trials, audits, and clinical/commercial drug supply is a challenge and requires a focus on top-tier hires.

SIMPLE GOAL: FINDING THE RIGHT GXP TALENT FOR THE RIGHT JOB

KEY CLINICAL HIRES	Chief Medical Offcers Medical Directors	Project Managers Medical Science Liaison Clinical Data Manager	Clinical QA Biostatisticians Medical Writers	CRA's CRC's
PHASE I	PHASE II	PHASE III	APPROVAL ★	PHASE IV
BENCH	PILOT	COMMERICAL	STOCKPILE	2ND SITE
KEY GMP HIRES	V.P. Manufacturing Site Lead Dir./Mgr. Manufacturing Automation/Controls	Mfg. Supervisors Start-up Specialists Design-Build Specialists Engineering/Facilities	Mfg. Data Supervisors Warehouse/Shipping S&OP Planning CMO/Insourcing	Quality Assurance QC Microbiology QC Chemistry

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Since Biotech's capacity has been largely absorbed or consolidated, a new wave of capacity increase is upon us, prompting an industry-wide strategic assessment of current capacity, future capacity, technology, automation/robotics, partnerships, pipelines, de-bottlenecking, and the adjacent risk of limited owner-side (Innovator, CMO, Supplier) resources to execute, complete, operate, and commercialize Drug Substance and Drug Product facility projects.

Primary Goal: **Owner** stays ahead of the hiring curve.

First and foremost, owner's (employer's) establishment of a "**CORE GMP**" team is the #1 big scary gate to successfully keep pace and complete all subsequent capital project tasks.

When and how should the owner establish this team?

Owner: While a qualified EPCMV company can handle 80-90% of a capital projects' deliverables , the owner has a prerequisite deliverable to create a proper CORE GMP team to handle the high-horsepower output from the awarded EPCMV teams and subcontractors (20%) **(GRAPHIC A)**. Alignment around talent management should be a major component and gate of the business justification/financial modeling process. **(GRAPHIC B)**.

How/When to hire - General Rules

Owner: Do not assume the talent bullpen is full, local, cheap and easy to harvest
Owner: Do not assume that the talent lead time is short; Leverage market data. Recruiters have seen a lot of hiring plans
Owner: Perform a comprehensive Risk Assessment to uncover/prioritize challenges across the entire project span
Owner: Create a team comprised of: Owner's hiring leads, Social Media Plan, and Qualified GMP Recruiter
Owner: Owner's hiring leads must have the bandwidth to execute the plan
Owner: When assessing salary, seek market intelligence (per zip code)
Owner: Know that most qualified candidates already have jobs. Need to have an awesome value proposition
Owner: For the CORE GMP hires, the interview questions are unique
Owner: Hiring plan and tactics must be streamlined. If not, good talent will fall off (if too slow) and brand will erode.
Owner: WOM is strong/quick. Use it to your advantage
Owner: Hiring Team: Do not all ask the same interview questions. (The team should have a group discussion first)
Owner: Candidates must have the pedigree and capability; Ask, "How did you get this done?". Did they delegate or do the work?
Owner: Need to have a career plan intact (hedge against turnover). Weave-in promotions along the project path.
Owner: Cautionary Note: Screening CV's takes more time. If talent is rare, the percentage of unfit CV's will be high
Owner: Provide budget for qualified consultants/contractors before, during, and after project completion.
Owner: For bleeding/leading edge technologies, talent bullpens will be especially shallow (AAV/LV/CAR-T/Nano)
Owner: Perform a robust project assessment to reveal risks that include both internal and external resource requirements.
Owner: Create a hiring plan for the owner to systematically hire the right talent at the right time. **(GRAPHIC C1, C2)**
Owner: Leverage a recruiter that is well networked
Owner: Leverage a recruiter that has actual hands-on commercial GMP experience **(GRAPHIC D)**
Owner: Leverage a recruiter with an established presence in core biotech groups: ISPE, ASQ, PDA, ASME

Qualifying the Engineering Company/Architect

EPCMV: Be selective about the team that your EPCMV group proposes. They are under same resource constraint.
EPCMV: Qualifying/Scoring the EPCMV team is more about the specific people's capabilities/pedigree than the projects accomplished by the 2000-person company.

GRAPHIC B

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LIFE SCIENCE SERVICES: CONCEPT TO COMMERCIAL

PROJECT PROGRESS

CONCEPT

Business Justification
FCF/DCF Exercise
Plant Econ / COG's
Capacity Planning
Time-Motion Study

DESIGN

Conceptual Design
Detailed Design
PFD, P&ID, 3D's
Type C Meeting
URS / FRS/ DDS

START UP

FAT/SAT /Qualify
Master Hiring Plans
SOP / Batch Records
Ops Readiness
Protocol Execution

COMMERCIAL

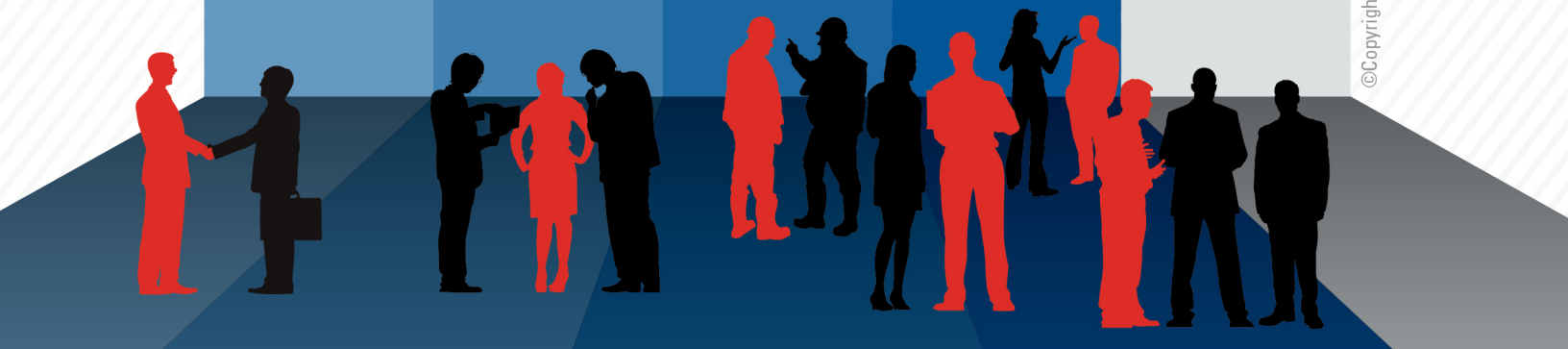
Facility Optimization
CMO Due-Diligence
KPQ/KPI Dashboards
Ramp to Full Speed

DESIGN BASIS KG/YEAR & COG'S

Commercialization of an economically viable medicine opens the door to an array of corporate opportunities. The company can now leverage its collective expertise and experience to convert new opportunities into long-term value.

Successfully establishing cGMP manufacturing capacity at the right time is a prerequisite to commercialization. It is a complex, high-horse-power event requiring subject matter expertise from a variety of fields.

The Concept to Commercial cycle starts again!



STRATEGIC HIRING PLAN EXECUTION

Creating your team to get the job done.

On-site Biotech Resources Group SME's

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GRAPHIC C1

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PROJECT STEP	DURATION	START	STOP
PRELIMINARY DESIGN	0	0	0
DETAILED DESIGN	9	0	9
CONSTRUCTION	31	3	34
CELL CULTURE COMM/VAL	8	31	39
CELL CULTURE PVAL RUNS	13	39	52

DEPARTMENT	Total Required	Currently on Staff	Needed to Hire	Staff by Grade Level
Dept 101	**4**	0	4	
Grade-1				2
Grade-2				1
Grade-3				1
Dept 101	**96**	3	93	
Grade-1			CELL CULTURE	23
Grade-2			34	8
Grade-3				3
			CC PURIFICATION	2
Grade-1			30	25
Grade-2				5
Grade-3				
			Media Prep	
Grade-1			14	11
Grade-2				3
Grade-3				
			Buffer Prep	
Grade-1			13	9
Grade-2				4
Grade-3				
Dept 101	**9**	0	9	
Grade-1				7
Grade-2				2
Dept 101	**7**	0	7	
Grade-1				6
Grade-2				1
Dept 101	**3**	0	3	
Grade-1				3
Grade-2				
Grade-3				
Dept 101	**2**	1	1	
Grade-1				1
Grade-2				
Grade-3				
Dept 101	**2**	0	2	
Grade-1				2
Dept 101	**6**		6	
Grade-1				5
Grade-2				1
Dept 101	**1**	0	1	
Grade-1				1
Dept 101	**13**	2	11	
Grade-1				2
Grade-2				7
Grade-3				2
Dept 101	**6**	3	3	
Grade-1				2
Grade-2				1
Dept 101	**5**	1	4	
Grade-1				3
Grade-2				1
Grade-3				
Dept 101	**12**	0	12	
Grade-1				2
Grade-2				9
Grade-3				1
Dept 101	**16**	1	15	
Grade-1				12
Grade-2				3
Grade-3				0
Dept 101	**44**	0	44	
Grade-1				31
Grade-2				9
Grade-3				4
Dept 101	**5**	3	2	
Grade-1				1
Grade-2				1
Dept 101	**5**	1	4	
Grade-1				4
Grade-2				0
Total Monthly				
Total	**236**	**15**	**221**	**Running Total**

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SAMPLE ONLY

NOTES:

SAMPLE ONLY SAMPLE ONLY SAMPLE ONLY

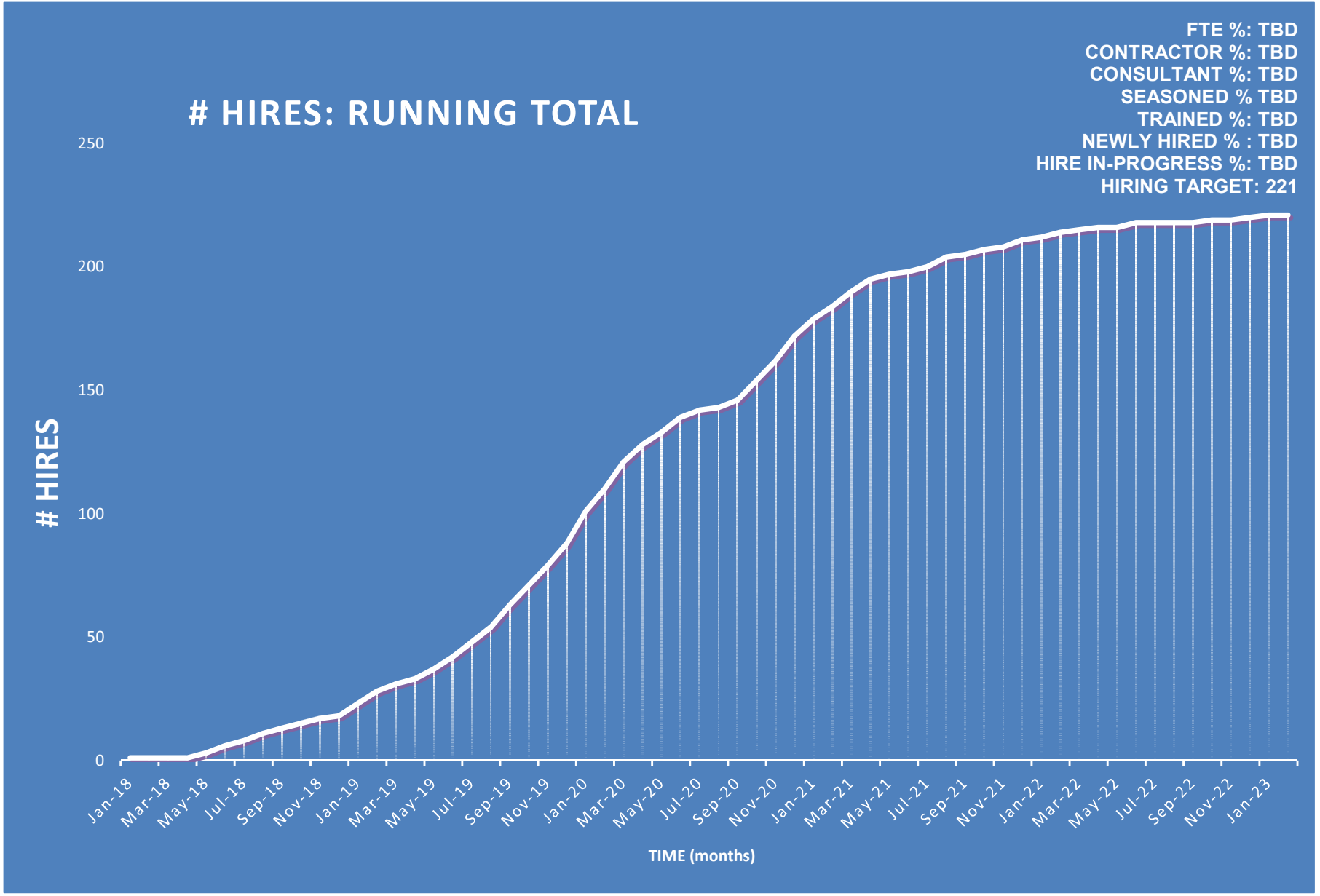
PREPARED BY: Biotech Resources Group, LLC

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DWG NAME: GMP-IN-OUR-DNA-001

GRAPHIC C2

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