

# 2 Operational Divisions: GXP Staffing and Biomanufacturing Consulting



# Susan Valdes Biotechnology Recruiter / Founder

Susan is the owner of a successful staffing agency with a background in both recruiting and small business management. Focus is currently on staffing of clinical research, quality & biologics manufacturing professionals in the pharmaceutical, biotech & CRO industries. Specific jobs filled: CRA (all levels), Clinical Project/Program Mgr, Clinical Scientist, Clinical QA Auditor, Clinical Director, Medical Writer (all levels), Clinical Supply Manager.





# Robert Valdes GMP Division Head / Consultant / Founder

Robert (Bob) is biotech leader, owner, learner, and speaker with 30+ years of experience in biopharmaceutical manufacturing and consulting. I lead the GMP BioManufacturing Services division at Biotech Resources Group (BRG), a global division that focuses exclusively on GMP. Primary goal: HELPING YOU BECOME THE BEST BIOTECH MANUFACTURER



Network: Global



# Global Network

Executing globally requires a network of pre-qualified partners across all modalities and technologies





BioTech Resources Group provides bioengineering firms with needed GMP design and operations experience

**BIOTECH RESOURCES** GROUP

GMP CONSULTING STAFFING SERVICE SME NETWORK

BioTech Resources Group augments mature and early stage **Biotech Firms** with needed, visible GMP horsepower and **GXP Staffing** Service

NOVATION FRON LIFE SCIENCE **BIOTECH ENGINEERING FIRMS** 

**FIRMS** 

©Copyright 2014. BioTech

罗伯特•无敌师 GMP资深专家顾问

# We do this for you:

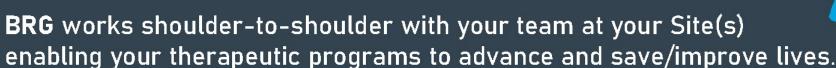


Biotech Resources Group focuses on the GMP side of things

We help clients improve their manufacturing performance & competitive position

Companies (CDMO's, Innovators, NewCo's, and JV's) turn to BRG when looking to:

- Design/Build new GMP facilities
- Remedy underperforming GMP sites
- Plan and Execute Site Selection
- Audit/Award/Replace a CDMO
- **Acquire GMP Sites**
- Create & Execute Master Hiring Plan
- Bridge Hiring Gap with SME Augmentation
- Business Development, Marketing, Trademarks
- All the above!



enabling your therapeutic programs to advance and save/improve lives.



This is a great victory for you, your teams, and patients. This victory is always GOAL#1!

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

### **Pervasive Challenge:**

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

As commercial GMP consultants, we understand how stressful this can be.

Given this, Biopharma Co's pivot to BRG to solve problems that really matter:

- ◆ Remedy Insufficient Capacity DS, DP
- ◆ Remedy Dysfunctional Capacity DS, DP
- ◆ Provide Technical/Ops Leadership
- ◆ Provide QMS Leadership

### HELPING YOU BECOME THE **BEST** BIOTECH MANUFACTURER









SITE SELECTION

**BIOPROCESS / GMP OPs** 

QMS / AUDITS

### 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 **QMS** Leadership

### **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 / Superskids

### **HOST/MODALITY**

Mammalian, Microbial Insect, Yeast, Synthetic Antibody/Cytokine/Enzyme AAV/LV/AdV + Plasmid mRNA, Phage, **Antibiotic, Vaccines** 





- ◆ Provide Horsepower to keep pace
- ◆ De-risk the Commercial/CDMO journey





HELPING YOU BECOME THE **BEST BIOTECH MANUFACTURER** 

GMP IS IN OUR DNA® GMP IS IN OUR pDNA® GMP IS IN OUR mRNA®



Robert Valdes Consultant/SME 202.738.3386 (USA) bobv@.cgmp.global

@ 2011-2024

www.cgmp.global

# WHAT'S AT STAKE?

**CHALLENGE + OPPORTUNITY** 

We know this part.

STEP

# NO BRIDGEONE

### **CONSEQUENCE OF INACTION**

Facility Shut-Down, Attrition
Loss of Patient / Community Trust
Loss of Investor Confidence
Revenue Loss / Customers leaving
Loss of Competitive Edge
Severe Regulatory Citations
Reputation with Industry Peers
Missed Opportunity for Growth
Delayed Trials / Commercialization
You get the idea

STEP

While hitting bottom and climbingout certainly builds grit, there are wiser ways to use your resources!

# **NO PRIZE**

HELPING YOU BECOME THE BEST BIOTECH MANUFACTURER



**Let's Do This!** 

202.738.3386 Ask for Bob

BIOTECH RESOURCES GROUP, LLC

MARYLAND HQ | BOSTON EU | ASIA | AFRICA bobv@cgmp.global www.cgmp.global

© 2000-2023 BIOTECH RESOURCES GROUP, LLC



Working Shoulder-to-Shoulder

## **CLIENT AS PARTNER**





