



MAKING YOU THE BEST BIOTECH MANUFACTURER



What GMP Challenges
do you have?

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



BRG

BIOTECH RESOURCES GROUP

Global Network

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



Maryland, USA

Sao Paulo

Bangalore

Malaysia

Hangzhou

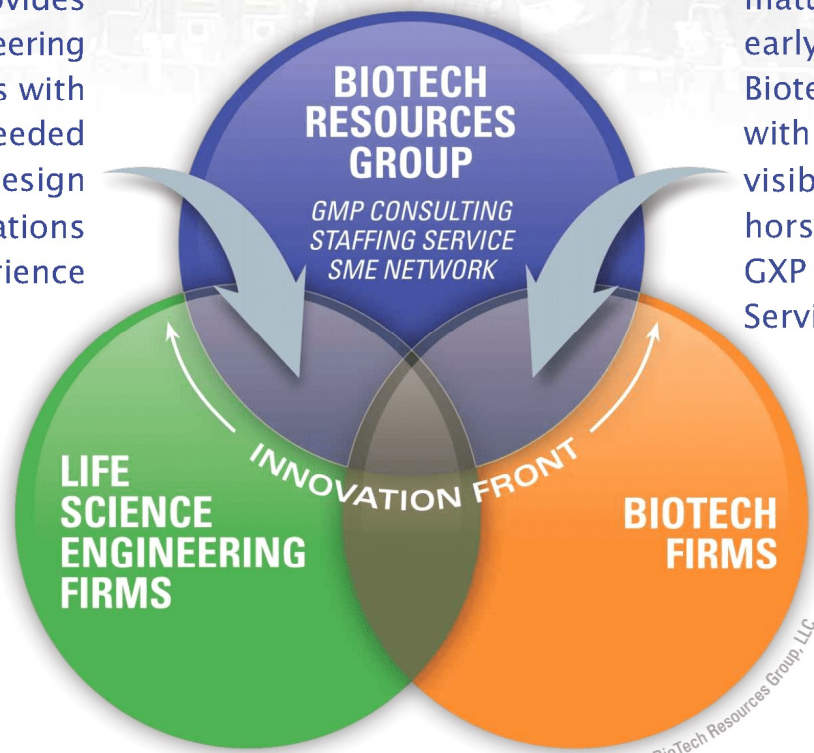


BIOTECH RESOURCES GROUP
GMP IS IN OUR DNA™

HOW WE WORK

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

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



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罗伯特·无敌师
GMP资深专家顾问

CLIENT AS PARTNER

What BRG does:



CHALLENGES & OPPORTUNITIES

Companies (CDMO's , Innovators, NewCo's, and JV's) encounter GMP challenges & Opps often at the same time.

CHALLENGES & OPPORTUNITIES

- Dysfunctional GMP Capacity
- Insufficient GMP Capacity
- Inferior QMS Stewardship
- Inadequate Technical/Ops Presence
- Staff levels too low to keep pace
- Customer Attrition, Loss Revenue
- Other?



SOLUTIONS

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





HELPING YOU BECOME THE BEST BIOTECH MANUFACTURER

CHALLENGE + OPPORTUNITY

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

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.

In response, Biopharma Co's pivot to BRG to solve 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 Tox/Clinical/CDMO journey
- ◆ De-risk the Commercial/CDMO journey
- ◆ Make Medicines that Matter



1

2

3



SITE SELECTION



BIOPROCESS / GMP OPs



QMS / AUDITS



TALENT MANAGEMENT

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



Consequences of Inaction! Scroll down. ↓

PRIZE

The diversity and breadth of the BRIDGEONE services will guide your team across the bridge.... one step at a time.

Imagine taking these steps

As you cross the bridge, you'll make substantial improvements across your entire organization and internal/external networks.

PRIZE (Consequence of Action)

- ↑ Improved GMP Performance + COG's
- ↑ Attract and Retain Customers
- ↑ Increased Factory Output
- ↑ Improved Batch Predictability
- ↑ Restored Patient/Community Confidence

GMP IS IN OUR DNA ©

GMP IS IN OUR pDNA ©

GMP IS IN OUR mRNA™

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Robert Valdes (Bob) | bobv@cgmp.global

GMP DIVISION HEAD USA EU APAC

WHAT'S AT STAKE?

NO BRIDGEONE

CHALLENGE + OPPORTUNITY

We know this part.

STEP 1

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 2

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



NO PRIZE

HELPING YOU BECOME
THE BEST BIOTECH
MANUFACTURER

STEP 3

Let's Do This!

202.738.3386 Ask for Bob

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

HELPING YOU BECOME THE **BEST** BIOTECH MANUFACTURER



SITE SELECTION



BIOPROCESS / GMP OPs



QMS / AUDITS



TALENT MANAGEMENT

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



HELPING YOU BECOME THE
BEST BIOTECH MANUFACTURER

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



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

Challenge: Biopharma companies routinely 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. We'll guide you.

Are there consequences of inaction? YES!

Given this, Biotech clients pivot to BRG to solve GMP problems that really 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 Tox/Clinical/CDMO journey
- ★ De-risk the Commercial/CDMO journey
- ★ Make Medicines that Matter

BRIDGEONE is our GMP solution platform.

GEO	ENTITY	SCALE (L)	MODALITY	SITE	SERVICES RENDERED				
					CD	BD	DD	OPS	AUDIT
USA	CDMO	4 X 2000	mAb/Cytokine	★					
USA	CDMO	10 x 15,000	mAb/Cytokine	★					
ASIA	CDMO	10 x 15,000	mAb/Cytokine		★				
ASIA	CDMO	4 x 5000	mAb/Cytokine		★	★	★		
ASIA	CDMO	4 X 300	PLASMID		★	★	★		
USA	CDMO	3 X 2000	AAV/LV		★	★	★		
ASIA	CDMO	4 x 2000	mAb/Cytokine		★	★	★		
USA/EU	INNOV	4 x 2000	AAV/LV		★	★	★		
USA	CDMO	4 X 6000	mAb/Cytokine		★	★			
ASIA	CDMO	3 X 20,000	mAb/Cytokine		★				
ASIA	CDMO	3 X 30,000	Incl. body		★				
ASIA	CDMO	4 X 2000	AAV / AdV		★				
ASIA	CDMO	10 x 10,000	Sm. Mol.		★			★	
USA	CDMO	6 x 6000	mab/Cytokine		★			★	
EU	INNOV	4 x 6000	COVID				★	★	★
EU	INNOV	4 x 2000	COVID				★	★	★
INDIA	CDMO	4 X 4000	COVID					★	
KOREA	CDMO	4 X 2000	COVID					★	
USA	INNOV	1000	Enzyme					★	
Global	INNOV	CAMPUS	AGNOSTIC					★	
RWANDA	ACAD	JOURNAL	AGNOSTIC					★	
USA	INNOV	CAMPUS	WHS-FF					★	
ASIA	CDMO	6 x 2000	mAb/Cytokine						★
USA	INNOV	Pilot	Phage						★
USA	CDMO	200 VPM	Fill Finish						★
ASIA	CDMO	10 x 60,000	Antibiotics						★
USA	INNOV	GLP LAB	Enzymes						★

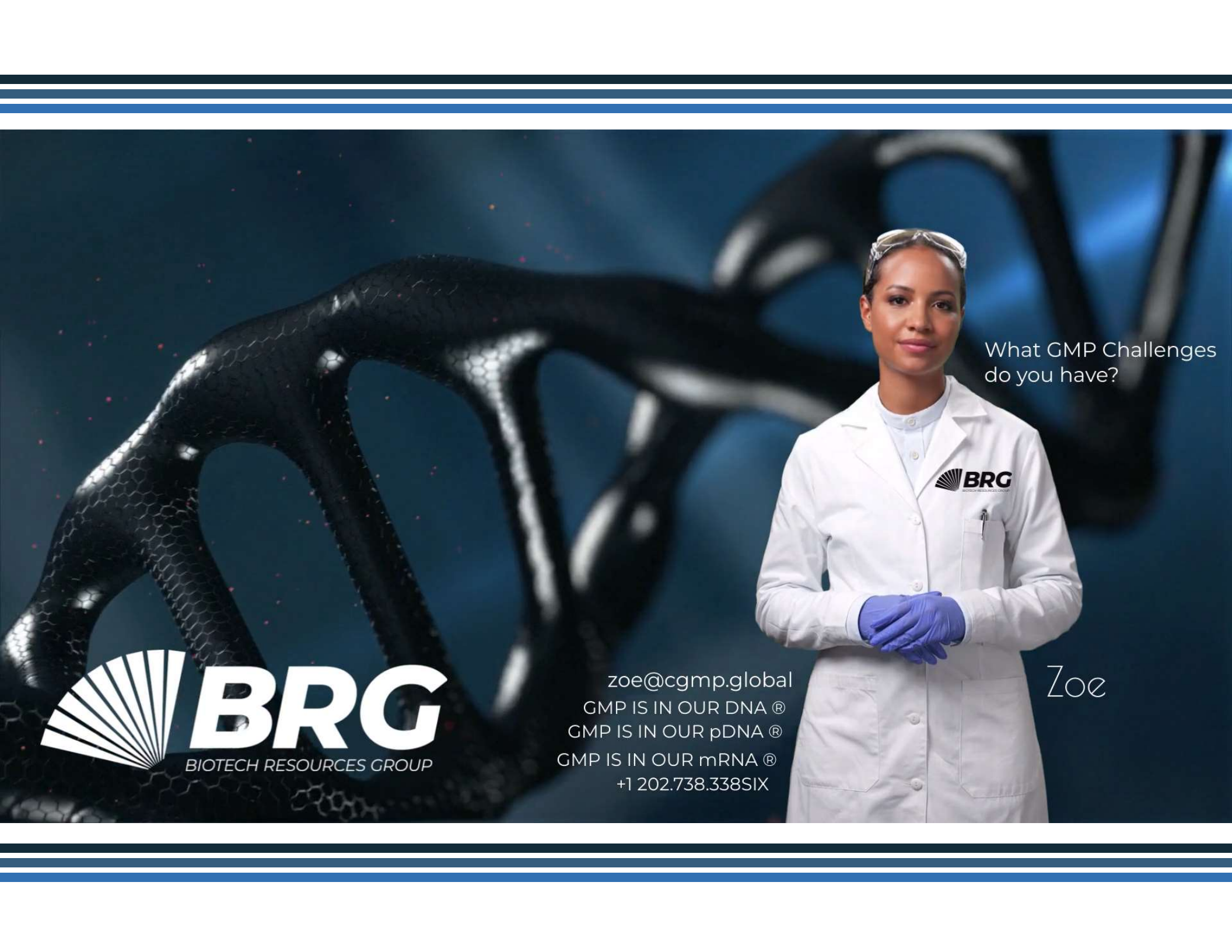
By Robert Valdes at 12:37 pm 11/14/24



PROJECT TABLE



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What GMP Challenges
do you have?



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