PACIFIC BIOMED CONSULTING

ABOUT US

Pacific Biomed Consulting (PBC) is a San Diego-based professional organization staffed by personnel with solid expertise in the area of Quality Assurance and cGMP compliance. Our approach to Quality Assurance and compliance is based on the concept of the GMP continuum (phase appropriateness). Our experience encompasses pre-clinical development through late phase and commercialization in both private and publicly held small and medium sized Biotech firms, as well as Big Pharma Companies. PBC is well versed and has experience complying with FDA, ICH, EMA, and PMDA requirements. Our staff has conducted approximately 200 GXP Audits throughout the world, including North and South America, Asia, Eastern and Western Europe and The Middle East. This has truly given us first hand opportunity in having our finger on the pulse of the Industry Standard and a solid knowledge of successful compliance approaches. The personnel at PBC have built successful Quality Departments from the ground up and also taken existing QA Departments and fine-tuned them to higher compliance levels, both of which have passed the scrutiny of Regulatory Agencies. We custom tailor our services and products to ensure that our support is commensurate with the level of development of your Company. Whatever stage of development your company finds itself in, our services will not only support your operations appropriately with that stage of development, but also prepare the foundation to grow your Quality Systems along side the growth and success of your Company. Under our Documentation and Services tabs you will find a full array of products and services available to you that will meet your specific needs. We welcome the opportunity to discuss our approach in working with to and ensure that your quality systems are robust and not only meet, but exceed Regulatory expectations.

e-mail: gusjcardenas@mac.com (858) 245-8382

PACIFIC BIOMED CONSULTING

DOCUMENTATION

- Quality Manual Development
- Policies & Directives
- Standard Operating Procedures (SOPs)
  - Training
  - QA
  - QC
  - Manufacturing
  - Clinical
  - Regulatory
  - Facilities
  - Equipment
- Master Production Batch Records
- Specifications
- Supplier / CMO Quality Agreements
- Validation Protocols
  - Process
  - Equipment (Qualification)
  - Facility Systems
  - Computer
  - Cleaning
  - Sterility
- Employee Training Files
- Stability Protocols

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SERVICES

- Remediation / Regulatory Response
  - Form 483 Response
  - Warning Letter Response

- GXP AUDITING
  - Clinical Laboratory Auditing
  - Quality Control Laboratory Auditing
  - Raw Material Supplier Qualification
  - Contract Manufacturing Organization Compliance
  - Internal Audits (Quality Systems Assessment)

- Compliance Gap Assessment for Quality Systems
  - Production
  - Facilities & Equipment
  - Laboratory Controls
  - Materials System
  - Packaging & Labeling
  - Quality

- GMP Facility Build Out Design & Planning

- Environmental Monitoring Plan Development

- Person in Plant Representation

- cGMP Training
  - New Employee Training
  - Focused Training (Specified Topics)
  - Refresher Training

- Document Control System—Implementation & Maintenance

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