



PremierC

Premier Compliance Services, Inc.
GMP Experts for the Healthcare Industry

INTRODUCING

Premier Compliance Services, Inc.

The GMP Experts for Complex Project

“The can do people - We make it happen”



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MISSION STATEMENT

We are a professional services company dedicated to providing management consulting in compliance and manufacturing operations performance in the life sciences industry and cost-effective GMP compliance and regulatory affairs related services to the healthcare industry with uncompromising quality and full commitment to our valued clients and employees.



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COMPANY INFORMATION

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Industries Served

Biotechnology
Active Pharmaceutical Ingredients
Pharmaceutical Finishing and Packaging (Sterile & Solid Dosage)
Medical Device



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INTRODUCING PREMIERC

PremierC is a management consulting firm established to service the pharmaceutical, Biotechnology, and medical device industries in the arena of GMP compliance and manufacturing of life sciences products. PremierC recognizes that cost considerations are very important in today's economy and hence focuses on providing its high quality services at the lowest possible cost through controlling overhead cost and the efficient utilization of its personnel's time. PremierC's experienced professionals and technicians focus on efficiency, responsiveness, and client service to bring projects to successful completion. PremierC provides specialized, value-added expertise in:

- GMP and GLP Compliance Consulting
- Risk Assessment and Management Programs – Risk Assessment of Compliance Status
- GMP and GLP Training
- Project Management and Owner Representation
- Regulatory Affairs Consulting
- Quality Assurance Services for Small Organizations
- Quality Assurance Audits
- Strategic Planning and Market Intelligence
- Complete Validation Services
- Process and Facility Concept development

PremierC's strength lies in our comprehensive understanding of the imperatives facing the Healthcare Industry, which has been gained from hands-on experience, and our can-do attitude. We are committed to the success of our clients through an uncompromising attention to quality that ensures cost-effective performance and mandated regulatory compliance.



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PHILOSOPHY & APPROACH

Premier Compliance Services, Inc. (PremierC) strength lies in our comprehensive understanding of the imperatives facing the **Healthcare** industry and the fact that our personnel have hands-on appreciation of the technologies involved. Through our philosophy of employing the best associates for your project, PremierC ensures that your GMP needs are met at the highest possible standard and the most competitive cost. Our goal is always to provide the most value to technologically driven projects and ensuring that our clients succeed. PREMIERC approach is based on the following principles:

- PREMIERC has a wide **range of expertise** in the regulatory compliance arena as it applies to the FDA regulated industry. We are not limited to one core competency.
- PREMIERC is focused and **experienced in FDA compliance** requirements as it relates to processes and facilities in the healthcare industry.
- PREMIERC prides itself on being a highly **enthusiastic organization**. Our pragmatic and results oriented approach ensures that our client's objectives are met in a most expedient manner.
- PREMIERC utilizes associates to ensure that the proper expertise to assist with your project is available at the most **competitive price**.
- PREMIERC remains available and **approachable** so that we may respond quickly to your changing needs and effectively integrate our personnel into your team.
- PREMIERC strictly controls its overhead cost and only utilizes associates when needed, thus ensuring that **your costs are the lowest**.

In summary: PREMIERC will add experience and depth to your staff at the lowest possible cost to you.



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HOW WE DO IT?

Our way of working with our client is simple and straightforward. It is based on total respect and the belief that without our clients we have no reason to exist, therefore we:

- Listen to our clients
- Understand their needs
- Propose solution
- Discuss the size and fit
- Perform
- Finish on time and on budget

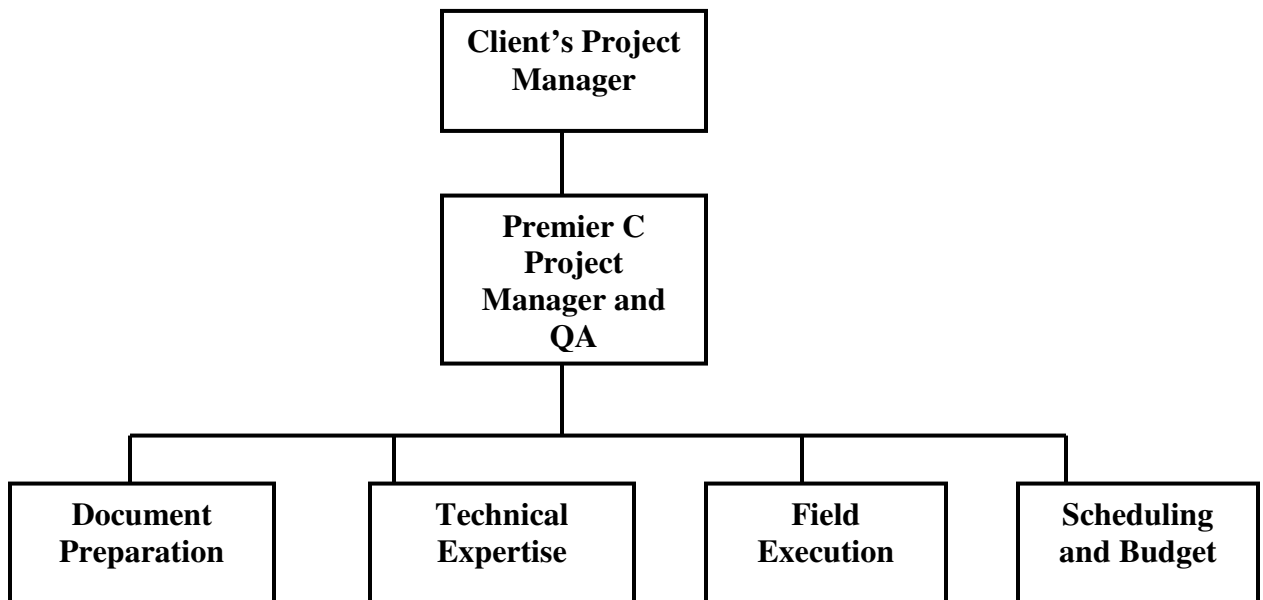


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TYPICAL PROJECT ORGANIZATION

- Client is the lead for the project
- PremierC provides the lead person reporting to Client with quality responsibility
- PremierC provides personnel with appropriate expertise for project
- Our Associates step in when ever their expertise is needed





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CLIENTS & PROJECTS

Clients

- Accugenix, Inc.
- AdiraMedica LLP
- Avid Radiopharmaceuticals, Inc.
- Citation Clinical Labeling Systems
- Executive Conferences, Inc.
- GMP Training Systems
- Kajima Corporation
- MYODERM
- ProTecs, Inc.
- Tech Manage Associates, Inc.
- Acculogix
- Advanstar
- Business Research Group
- Clinical Analysis Corporation
- Fleet Laboratories, Inc.
- Jeiven Pharmaceutical Consulting
- Mihama Corporation
- PharmaEd Resources
- Taub Pharmaceutical
- University of Wisconsin



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CLIENTS & PROJECTS

Projects

- Validation of Backup Power Supply
- Quality by Design, Risk Assessment Training
- Medical Device Manufacturing Validation
- Software validation for a medical device
- Validation of HVAC Systems for Potent Compound Manufacturing Facility
- Experimental design for proving the concept of manufacturing equipment
- Facility Systems and Utilities Validation
- In-house Training on Process validation
- Third Party Quality and GMP Audit
- Training on Cleaning Validation, Quality by Design and Basics of GMP compliance.
- Market Study of Vaccine Manufacturing in the US.



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REFERENCES

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