Our Mission

To ensure the quality and availability of life-saving and life-enhancing products to people in need.

Quality System Remediation
Staff Augmentation
FDA Audit Support
Staff Augmentation


Functional Outsourcing

Gain more freedom and retain more control of your project by outsourcing functional tasks.

Our subject matter experts will adjust to your systems and processes, serving as an internal resource that can be reallocated when priorities shift.

Staff Augmentation and Recruitment

An urgent regulatory or compliance need can strain resources, and hiring new staff takes time.

Scale your team quickly by tapping into our extensive network of quality, FDA, and compliance experts.

Our flexible, adaptable experts can get up to speed quickly in a constantly changing environment.

Managed Services/Project-Based Support

Whether managing an entire department or overseeing a project from start to completion, our industry experts work to ensure your project is delivered on time – and on budget.
In this highly regulated industry, managing the everyday manufacturing process can be difficult enough, and companies may not have the resources to properly address quality management system (QMS) issues.

We have a large network of quality and compliance experts with the knowledge and experience to identify the root cause of those issues and develop a plan to remediate them – and keep them from recurring.

**Remediation Services with Scalable Flexibility**

Whether you need one consultant to assist with determining the best approach, or several to work with your team on executing a remediation plan, we can tailor the solution to fit the unique needs of your project.

**Proactive Quality System Management**

Surviving an inspection is all about managing risk – and knowing what is important to the FDA. What's important to the FDA is a solid quality management system and documentation, and our quality and compliance experts can help you proactively develop and implement a QMS that will withstand the closest scrutiny.
FDA Audit Support

Inspection readiness. Audit preparedness. Product, systems, and facility validation and qualification.

GxP Audit Support

Our team of FDA experts understand the importance of a successful inspection, and the role that a solid audit can play in your inspection outcome.

Whether the objective is compliance with GMP, GCP or GLP, our tailored audit services help you minimize inspection risks, allowing you to focus on the big picture for your business.

Validation and Qualification Activities

- Evaluation of products, equipment and facilities
- Qualification of policies, procedures, protocols and master plans
- Computer systems and 21 CFR Part 11 Compliance
- Validation of:
  - Products, equipment and facilities
  - Manufacturing, packaging and labelling processes
  - Cleaning and sterilization systems and processes

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Why Choose Premier FDA Solutions?

WE HAVE ONE PASSION
Our sole focus is quality and regulatory compliance for the life sciences.

WE HAVE ONE FOCUS
We leverage our extensive network of FDA, quality and regulatory experts to provide the right compliance expertise at the right time.

WE HAVE ONE GOAL
Whether your need is one consultant for a day or several for a long-term project, we provide scalable staffing solutions that help you build and maintain a great quality system.

What Makes Us Unique?

- We've made the life sciences our sole focus - because the life sciences are amazing.

- We offer flexible staffing solutions so you get the expertise you need, when you need it - because compliance is not one-size-fits-all.

- We're always curating our network of regulatory and quality experts - because integrity matters.

CONTACT US

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