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The FDA Group, LLC (The FDA Group) is a world-class service organization that utilizes a proprietary talent selection process of Former FDA & Industry Experts, which is amplified by a corporate culture of responsiveness and execution. Headquartered in Westborough, Massachusetts, The FDA Group has 355 consultants (60 of whom are Former FDA Investigators) across 42 states.

Why is The FDA Group in business?

The FDA Group's purpose is to empower our clients to bring their life-changing healthcare products to the market and keep them there.

How does The FDA Group do it?

The FDA Group is able to do this by providing a world-class service experience. The way in which The FDA Group ensures a world-class service experience is by its proprietary talent selection process coupled with its deep-rooted corporate culture that includes 31 Fundamentals. These Fundamentals are the heart-beat of the organization and are focused on four areas:

1. Core Values – These values are a cornerstone to our success.
2. Focus on Service – These habits help create extraordinary service experience.
3. The Collaborative Way – These practices enable us to work powerfully together as a team.
4. Personal Effectiveness – These behaviors help us achieve great personal, and by extension, organizational success.

What does The FDA Group do?

The FDA Group is a global leader in GxP auditing & remediation and regulatory services.

GxP Auditing & Remediation

- Compliance Master Planning and Strategy
- Mock Pre-Approval Inspections (PAI) and Mock FDA Audits
- Mock Notified Body Inspections
- FDA Meetings – Represent your firm with FDA
- Assistance with the FDA: 483's, Warning Letters, Consent Decrees
- Corrective Actions and Implementation plans
- Planning and Execution of Remediation Projects
- Validation and Qualification
- Vendor / Supplier Audits
- GxP Audits (GMP, GCP, & GLP)
- Pharmacovigilance (PV) Audits
- Formal Risk Assessments & Risk Mitigation Strategies
- Quality Systems & Corporate SOP Guidance and Development
- Label, Package, Insert, Brochure, & Website Review for FDA Compliance
- Compounding Pharmacy Regulations (503A & 503B)
- Expert Witness Testimony
- Training & Development of Training Programs
- International Quality Experience (Europe & Canada)

REGULATORY SERVICES

- Investigational New Drug (IND) Applications
- Investigational Device Exemptions (IDE)
- Premarket Approvals (PMA)
- New Drug Applications (NDA)
- Abbreviated New Drug Applications (ANDA)
- Biologics License Applications (BLA)
- 505(b)(1)'s
- 505(b)(2)'s
- 510(k)'s
- De Novo Applications
- Assistance with Importation, Import Alerts, & Detention
- International Regulatory Experience (Europe & Canada)