EVERSANA'S FDA COMPLIANCE SOLUTIONS

EVERSANA solves the most complex FDA compliance challenges for reproductive establishments, including remediation and management. Whether you are starting a new donor program or looking to assess your existing program, we can guide your team to ensure proper procedures and training are in place, and address any deficiencies, before your FDA inspection.

Unique in our ability to deliver a comprehensive set of FDA solutions from preparation to onsite support, we don't just advise you on what to do, we help you do it right.

EVERSANA®

See how EVERSANA helped one client navigate a failed FDA inspection and get their business back on track.

eversana.com/fda-compliance

KEY FEATURES & BENEFITS:

EVERSANA has extensive experience in FDA-regulated industries. We provide peace of mind and ensure you will be ready for the FDA by implementing:

- Mock FDA inspections
- FDA Inspection training and support – remote or onsite
- FDA 483, Untitled Letter, Warning Letter, and Order to Cease Manufacturing response strategies and drafts
- Remediation planning and execution support

Our Human Cells, Tissues, Cellular and Tissue-based Products (HCT/P) clients rely on us for:

- Compliance with FDA's 21 CFR 1271 regulation and guidance documents.
- FDA registration
- Gap assessments and internal audits
- Procedure development and review
- Training programs
- Quality Management System creation
- Validation for processing and equipment
- Supplier qualifications

EVERSANA also has the infrastructure and expertise to provide you with electronic outsourced:

- Document control
- Training documentation and management
- Automated, web-accessible Donor Eligibility System by EVERSANA® platform