

Documents Supported

Site Audits for Clinical Trials

- Form 483 Observation report
- Site Inspection report

Site Management

- SOPs
- Quality Reviews
- Environmental Impact Audit
- Risk Assessment Audit
- 3rd Party Verification Audit
- Gap Assessments
- Post-Audit Monitoring - Remediation Check-Up
- Training Audits
- Worker Interviews
- Management Systems Audits
- Post-Auditing Performance Assessment and Planning

Customs

- County Certifications
- Labels and Packaging
- Country of Origin
- Worker Interviews
- Management Systems Audits
- Post-Trial Performance Assessment and Planning



FDA Expectations:

“Every global site I have been to for inspection, I have found issues with non compliance and enrollment.”

California based FDA Inspector

The Challenge

Biotech and Pharmaceutical Supply chains are globalizing, requiring increased scrutiny and interactions to ensure compliance with Quality, Process and Legal requirements.

Differences in standards, population genetics and environmental conditions impact FDA's confidence in global sites. Companies need well established document management, audit trail and harmonization of processes to ensure compliance.

VeriSupply™ is an online service that takes away the pain of auditing global supply chain sites. Deepen your relationship with suppliers. Using VeriSupply, you can partner with far flung companies and rest assured that your corporate risk requirements are being met.

SECURE

- Secure HTTPS based Access
- Double Encryption
- Private and Shared Folders
- Time Limited access to docs

CONTINUOUS

PROTECTION

- Email Alerts
- Notification of expiry of audits
- Confirmation of Delivery

SUPPORT FOR MULTIPLE

INDUSTRIES

- Fresh Produce
- High Tech Manufacturing
- Pharmaceuticals
- Apparel

TECHNICAL SUPPORT

- 24 x 7 Availability
- Online Help
- Trained support staff

ZERO DOWNTIME

- 99.95 uptime SLA
- Automated Monitoring

Additional Services

VeriSupply's network of partners such as certified testing labs, safety managers and logistics can provide onsite services.

For more information on any of our services please visit us on the Web at: www.verisupply.com



Enabling Fast Track through Phase II

Many global sites are held up due to language issues and lack of enrollment related documentation.

A leading Biotech company used VeriSupply.com to share translations, observation reports and PI's notes to build confidence and ensure speedy completion of their trial.



Standardizing SOP across multiple sites

For pharmaceutical companies employing contract manufacturers for Phase I and II material preparation, it is important that all the facilities follow the standard operating procedures.

VeriSupply.com can ensure that Quality, Safety and process SOPs across its global manufacturing sites are standardized. A single repository of documents increases the company's confidence in the contract facilities. Using VeriSupply, a major biopharma was able to update the SOPs across multiple sites with a single click of a button, while complying with FDA regulations.

System Requirements

- Internet Explorer or Firefox browser
- Email addresses for your safety, quality and production teams and supply chain partners.
- Access rights for sharing documents.
- Support for many formats (pdf, doc, xls)

VeriSupply Services

- ✓ Validate supply chain partners
- ✓ Securely manage documents
- ✓ Value Add Services
- ✓ Timely email alerts for audits
- ✓ Share audit information
- ✓ Industry Specific Check Lists
- ✓ Compliance Forms

How to Subscribe

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