infostrength

On-Call Quality Support

Ensure records, signatures and documentation are reliable so you're on track for meeting quality standards and bringing your product to market

It's a fact: quality and regulatory documentation is a massive undertaking. There are so many tasks that are easy to push aside… but pile up over time. Created expressly for Life Science businesses, InfoStrength's On-Call Quality Support team prepares, reviews and maintains your documents to ensure you're set up for success.

InfoStrength's combined consulting and technology solutions work to provide you with a virtual quality management and regulatory department. Our complete spectrum of quality assurance, regulatory, technology and operational services help medical device, biotech and pharmaceutical companies worldwide.

The Benefits Are Clear

Dramatically Reduce Costs

Time is money. Avoid costly mistakes by keeping documents and records in order.

Achieve Results Faster

Our team knows compliance inside and out, setting you up for success quickly.

Solve Compliance Issues

Meet challenges head on to stay on the right path for commercialization.

Manage Requirements

Get the help you need preparing, reviewing and maintaining your documents.

About InfoStrength

InfoStrength Smart Enterprise Suite (SES) is a leading quality and regulatory solution designed specifically for regulated businesses. The powerful, scalable and easy to use solution, combined with the benefits of On-Call Quality Support and experienced consultants help make FDA compliance, business process management and business communication manageable and efficient for life science companies. Businesses worldwide rely on InfoStrength to support their products in the commercialization process.

InfoStrength is a product of MethodSense, Inc. » sales@infostrength.com » 919.313.3960

Features

For a proven way to reduce risk and costs, get fast results and get the most from InfoStrength, trust our team to guide you. Your On-Call Quality Support professional will work with you to:

- Issue document numbers
- Update logs, including:
  - Document master list management
  - External documents index
  - Disposed / retired / obsolete document list
  - Quality records table / document disposition log
  - Equipment log
  - Complaint log
  - NCR log
  - Release label number log
  - Rejected label number log
  - Supplier audit log
  - Internal audit log
  - CAR log
  - RGA log
  - Other company / product specific logs
  - Training sign off logs
  - Critical software list
- Assist with Document Management and Control:
  - Upload documents into your system
  - Upload document versions into your system
  - Care and keeping of controlled document organization for easy document retrieval
- Document submittals and document change requests
- Prepare and maintain training plans and records
- Maintain job description template and records
- Maintain management review meeting schedule and agendas
- Ensure conformity to company SOPs, including:
  - Equipment qualification
  - Maintenance and calibration records
  - Executed validation
  - CAPA records
  - Non conformance reports
  - Complaint forms
  - Visitor records
  - Data analysis forms
  - Certificate of compliance
- Internal audit support with audit reports, plans, agendas and schedules
- Software development life cycle support, which may include management of and change requests for:
  - Software requirements
  - Software functional and design specifications
  - Evidence of performing software code reviews.
- Quality Management System gap assessments for:
  - 21 CFR Part 820
  - 21 CFR Part 11
  - ISO 13485
  - ISO 14971

Looking for more in depth support?

Ask about the regulatory consultants from our parent company, MethodSense. They provide a complete spectrum of quality assurance, regulatory, technology and operational services globally to medical device, biotech and pharmaceutical companies.