



Cignus Solutions
Innovative Approach Quality Solutions

OUR APPROACH

- Analyze existing QMS
- Establish Policies and Procedures required for ISO 9001:2015
- Initiate specific QMS practices geared towards R&D, contract organization (CRO), and Manufacturing sectors
- Align standards to ISO and FDA regulations
- Establish an Enterprise QMS (EQMS) with efficiency
- Oversee entire ISO certification process

BENEFITS

- Agile development model.
- One-stop shop for all your QMS compliance needs.
- On-time and on-budget project delivery.
- Standard templates and procedures for rapid implementation.
- Expertise in multiple end-to-end
- Integrate a fully scalable enterprise QMS efficiently and economically.

QUALITY MANAGEMENT SYSTEMS IMPLEMENTATION AND CERTIFICATION

Cignus Solutions offers an innovative and cost-effective approach to implement FDA-compliant, ISO-certified quality management system (QMS) for your organization. We deliver timely, pragmatic, and sustainable QMS so you can compete effectively as a global enterprise in a heavily regulated industry.



Whether you are moving from paper-based processes, upgrading an existing system, or implementing a new one, Cignus can help you select the best, most cost-effective enterprise QMS for your company. We provide industry best practices, standard templates and procedures for a rapid and effective implementation.

Cignus Solutions dedicated team of industry experts and quality management professionals have more than a decade of experience developing and integrating enterprise QMS that lead to ISO certification.

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FRONT



Cignus Solutions

Innovation - Quality

PROCESS WORKFLOWS

Our business process expertise includes in-depth knowledge of several key processes in QMS. Our process experts will identify and redesign processes and establish standardized workflows for Training, Change Control, Audit, CAPA, Supplier Quality and Complaints. Our procedure set shall include ISO compliant SIPOC and Process Flow Chart which will be utilized for QMS system design and implementation.



REPORTING

In addition to our implementation division, our team of expert report developers and process engineers takes a holistic view on the reports usage and recommend effective techniques, design practices to maximize your return on investment. Cignus uses a proprietary report requirements collection template that ensures the reports' quality and minimizes issues that interrupt data collection. We create Custom Dashboards, Trending Reports, and Operational Reports using Crystal Reports' Quality View tool to improve accessibility and provide crucial data when needed. These are just a few of the following process improvement and tracking tools Cignus can create for your business:

Dashboards

Compliance/
Submission Reports

Trending Reports

Operational Report

ISO CERTIFICATION AND AUDITING

In addition to establishing your QMS framework, we will prepare all necessary documentation needed for ISO 9001:2015 certification. We will identify and work with the ISO registrar to conduct the audit, managing the process to ensure a successful certification.

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BACK