

QUALITY MANAGEMENT SYSTEMS



Quality Management Systems

Quality Management Systems are sets of standards that have been developed by the International Organization for Standardization (ISO). CONNSTEP can assist you to achieve the industry quality system standards that will help you attract new customers, retain existing customers and compete in the global market. If you have a customer that requires you to be certified, or you just want to improve the quality of your manufacturing business, making your company more marketable, CONNSTEP can help.

CONNSTEP's Quality Management Systems specialists can assist you in becoming registered, assist with your internal quality auditing or train your internal quality auditors in the following quality standards:

ISO 9001:2000	General Quality Standard
AS 9100	Aerospace Standard
TS 16949	Automotive Standard
ISO 13485	Medical Device Standard
ISO 14000	Environmental Management Standard
NADCAP	National Aerospace & Defense Contractors Accreditation Program

When you make the strategic decision to become registered to a quality standard, a CONNSTEP Quality Systems Specialist will work with you, customizing the documentation to reflect the way you do business. We will train you and your team - not only on the requirements of the quality standard - but also on how to use the quality standard to your best advantage. Once you achieve registration, CONNSTEP will continue to work with you, helping to maintain your certification.

You'll be in good hands... CONNSTEP has assisted more than 260 Connecticut manufacturers achieve and maintain a quality certification.

"Without the initial start up and continued services provided by CONNSTEP, Colt Defense would not be in position to maintain contracts or bid on new ones. Being an ISO 9001:2000 registered manufacturer and design facility is vital to the growth of our business."

Tracey Van Flatern
Colt Defense

Quality System Implementation

CONNSTEP Mentoring Program

Once you have made the strategic business decision to become registered to a quality standard, CONNSTEP will be there every step of the way. Our customized mentoring program will assist you in preparing for and implementing a Quality Management System - to meet and sustain the requirements of your chosen Quality Standard.

Tasks include:

- Gap analysis
- Management training and employee orientation;
- Document preparation assistance;
- Internal Quality Auditor training;
- Quality mentoring; and
- Registrar selection assistance.

Stage One

Documentation Review & Implementation Verification

- Review of company's document manual and procedures;
- Assessment of company's current level of implementation of quality standard;
- Determination if Stage Two Assessment should be conducted.

Pre-Registration Audit Assessment by Registrar

- Dry run through the assessment process;
- Identification of strengths/weaknesses in the company's QMS.

Corrective Action

- Address areas of concern or NCRs from stage one;
- Identification of risk with respect to the requirements of the quality standard.

Stage Two

The Registration Audit

- Registrar audit performed on the company's quality management system against the requirements of the quality standard;
- Certification to the quality standard for three year period.

Surveillance Audits

To ensure continued compliance to quality standard, registrar performs surveillance audits every six or twelve months.

CONNSTEP Training

CONNSTEP provides training on quality techniques and methods:

- Geometric Dimensioning & Tolerancing (GD&T)
- Statistical Process Control (SPC) - basic and advanced
- Advanced Product Quality Planning (APQP)
- Failure Modes Effects Analysis (FMEA)
- Production Parts Approval Process (PPAP)
- Gauge Repeatability & Reproducibility (Gauge R&R)
- Machine capability
- Blueprint reading
- Basic inspection tools and techniques (including Optical Comparators)
- Basic math for quality inspectors

Quality Related Training

- Electrostatic Discharge Control Program (ESD)
- Root cause and corrective action (RCCA)
- Quality planning and analysis
- Basic experimental designs
- Clean room environments

Quality Training for Medical Device Manufacturers

- FDA Quality Systems Regulations (21 CFR 820 FDA)
- FDA Pre-Market Submissions (510k, PMA, registration)
- Recall regulations (21 CFR 806, Canadian, European)
- CE Marking
- ISO 14971 Risk Management
- FDA laser safety Requirements
- Clean room requirements
- Sanitation requirements
- OSHA Blood borne pathogen requirements

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