IQS
iqs.com

AN OVERVIEW OF ISO 9001 CERTIFICATION

PRODUCED BY:
OUR SUBJECT MATTER EXPERTS.

AN OVERVIEW OF ISO 9001 CERTIFICATION

The International Organization for Standardization (ISO) develops standards to help facilitate international trade. ISO 9001:2015 is the most recent series of standards that relates to the development of an ideal quality management system. The ISO 9001 series comprises the basis for additional industry-specific standards such as AS 9100, which focuses exclusively on standards within the aerospace and defense industry. Achieving ISO 9001 certification allows manufacturers to improve the quality of products or services while simultaneously lowering total cost of quality.

MANUFACTURERS AND ISO 9001.

The most important aspect that manufacturers must understand about the ISO 9001 series is that the standards encompass processes; they do not refer to the quality of the products themselves. This process-centric approach allows manufacturers to continually improve quality management systems and adapt to an ever-changing regulatory landscape.

ISO develops manufacturing standards, but enterprises must know that ISO itself does not issue certifications. A manufacturer becomes certified to an ISO standard, as opposed to being certified by ISO. This distinction is critical when considering the cost of ISO 9001 certification. Further complicating the relationship between manufacturers and ISO standards, certification procedures vary from nation to nation. Some countries have government-regu-

lated accreditation bodies; others rely on private accreditation firms to perform audits, and periodically re-access manufacturers thereafter.

THE ISO 9001 CERTIFICATION PROCESS.

ISO certifications come in three forms: first-party, second-party and third-party. First-party certifications are "self declarations" of compliance with ISO standards. Second-party certifications occur when one company wishes to audit another to ensure compliance before conducting business. Third-party certifications are by far the most common type of certification, which may or may not actually include formal accreditation. An independent mediator from a private, specialized firm conducts the review for third-party certification.

The certification process itself encompasses the same basic elements regardless of the type of certification that a company chooses. Upon applying for certification, an auditor (also referred to as a registrar) performs a document review and a pre-assessment of compliance with ISO 9001. Auditors do not focus on the quality of the products or services themselves, but rather only on process. Depending upon the nature of a manufacturer's business, auditors may interview employees and tour manufacturing sites. If manufacturers satisfy these initial stages, auditors

conduct formal assessments and issue certifications or corrective actions accordingly.

COMMON ISO 9001 PITFALLS.

Achieving compliance with ISO 9001 is a lengthy process that can take as long as six to 18 months, particularly for multinational manufacturers. Enterprises must be aware of common pitfalls when applying for certification. Primarily, the biggest challenge of ISO 9001 is negotiating the regulatory landscape among different countries. Conducting business with a new supplier may also necessitate reevaluation of certification status. Countries may choose to regulate registrars or to form a nationalized accreditation body to facilitate international trade.

Furthermore, manufacturers must understand that ISO itself does not monitor which enterprises are in compliance. ISO sets the standards, but the organization does not enforce such standards internationally. Each type of certification encompasses certain risks, as well. Companies can skew the results of first-party certifications, or can unnecessarily increase cost of quality expenses by choosing to conduct multiple second-party certifications. Thus, third-party certification is the method of choice since manufacturers can potentially achieve compliance with an accredited firm.

Satisfying ISO 9001 sets the general framework for a manufacturer's quality management system. The quality management challenges within each sector of the manufacturing industry demand flexible solutions, so at the very least, ISO 9001 should set a baseline for quality and risk management.

" *[Quality is] the totality of features and characteristics of a product or service that bear on its ability to satisfy a given need.* "

- ISO 9000 Series
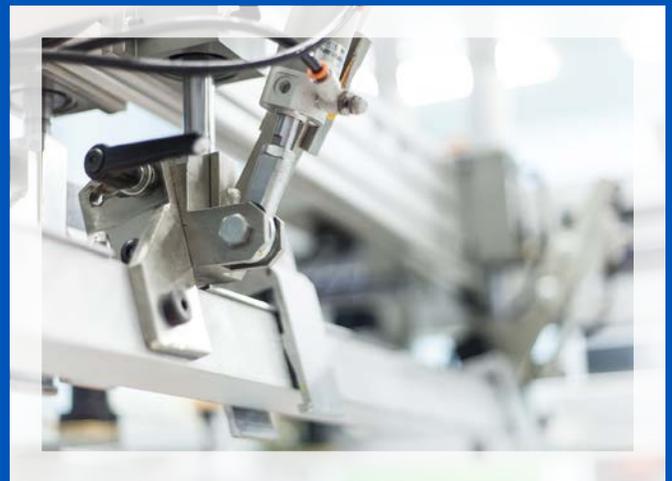
IQS

info@iqs.com

440.333.1344

24950 Country Club Blvd. #120, N. Olmsted, OH 44070 - USA

800.635.5901

iqs.com