One of the best tools pharmaceutical manufacturers have for measuring the quality management of their third party logistics (3PL) provider is through the International Organization for Standardization (ISO) 9001 certification.

The ISO 9000 suite of standards is focused on quality management and is intended to help organizations become better managed, more efficient, and more customer-focused. The U.S. Food and Drug Administration’s (FDA) current Good Manufacturing Practices (cGMP), and many aspects of FDA’s Quality System Regulations (QSR), are modeled around ISO 9000 standards.

ISO 9001 is the one standard within the ISO 9000 system that defines the requirements for a quality management system and helps businesses and organizations to be more efficient, improve customer satisfaction, and specifically for pharmaceutical manufacturers, to help improve patient safety.

Why the ISO standard was revised

The International Organization for Standardization reviews, as necessary, and updates its standards regularly to ensure they address current business and operational challenges. Increased globalization and more complex supply chain changes, coupled with increased customer expectations and more access to information, were the drivers for the new ISO 9001:2015 standards.

ISO now requires risk assessment as one of the major areas addressed in the new standard. To achieve certification, organizations must now identify and document both the positive impact of anticipating and mitigating risks before they occur, as well as identifying risks that have occurred and adjusting processes.

ICS was in an excellent position to be the first pharmaceutical 3PL to achieve certification under the new ISO 9001:2015 standards because quality management is embedded in the company’s culture. As part of their ongoing commitment to quality, ICS was already executing many of the new requirements as part of their business procedures. As a result, manufacturers are assured there is a well-documented, well-managed risk assessment process associated with every product implementation, every new client on-boarding, and every new product launch.

Benefits to pharmaceutical manufacturers

The new version of the ISO standard delivers three critical benefits to manufacturers:

- Greater emphasis on leadership engagement
- Increased prominence on risk-based thinking by addressing organizational risks and opportunities in a structured manner
- Addresses supply chain management more effectively

As the first pharmaceutical 3PL provider to receive ISO 9001:2015 certification – 18 months prior to the deadline – ICS continues to demonstrate that the company is at the forefront of improving the quality and efficiency of the supply chain for pharmaceutical products that require special handling, and is highly capable of managing complex logistics requirements.

The ICS model of excellence

ICS is the model of excellence in global healthcare logistics. In today’s highly competitive environment, ICS has demonstrated a reputation for excellence that sets it apart from other pharmaceutical providers.
ICS established its leadership in 2003, when it first-achieved ISO certification. Additionally, ICS was one of the first companies (across all industries) in the United States to be certified to the 2008 version of ISO 9001 standard.

The 9001:2015 certification extends to all ICS locations including its four fully-certified distribution centers in Reno, Nevada; Brooks, Kentucky; and Columbus, Ohio. This new certification is a clear statement to clients and the marketplace that ICS continues to be the world class, 3PL leader in quality management.

How ICS is different

The ISO 9001:2015 standards provide a framework for proving to clients and supply chain partners that ICS is at the forefront of continuous improvement in all business areas. These include:

Secure Controlled Substance Vault
Improves management of narcotics with full medication accountability by providing 24/7 inventory management, as well as an automated audit trail to comply with regulatory standards and increase efficiency.

Full Order-to-Cash for Receiving and Processing Customer Sales
Dedicated teams of logistics, accounting and customer service associates utilize their experience and extensive training to facilitate a smooth path, from order receipt to customer receipt and revenue capture.

Multiple Locations
Four fully-certified distribution centers in Reno, Nevada; Brooks, Kentucky; Columbus, Ohio; and World Courier partners in 52 countries around the globe.

Multiple Storage Sites
Fully scalable solution with state-of-the-art facilities that accommodate products of all sizes, temperatures and storage needs.

Contract Management and Chargeback Processing
Utilizing the latest, best-in-class contract management software, with online access to chargeback transaction reports that display contract, membership and pricing data.

DSCSA Readiness
ICS is working well in advance of the November, 2017 serialization deadline to help manufacturers comply from day one.
How ICS achieved certification

Certification was quickly achievable for ICS because many of the new standards were already critical elements of company-wide business processes, procedures, recruitment, and training.

This commitment to continuous improvement is exemplified in three key areas of importance to manufacturers:

1. Robust change management process leveraging input from all the stakeholders and associates that touch a business process to work through and mitigate risks to ensure a repeatable, controllable process

2. Significant investment in the quality management system, upgrading the ability to capture the data on non-conformance

3. Culturally embracing ISO as a mechanism for focusing all 500+ ICS associates on putting patients first through uniformity, consistency, and execution

Key to achieving and maintaining 9001:2015 certification are ICS associates. Any associate, at any level, can identify an area for improvement or a training need and document it for mandatory action in the ICS system.

The importance of auditing

ISO standards are reviewed and maintained through a rigorous process of internal and external audits. On any given day at ICS, the company is opening its doors for auditing by clients, prospects, ISO registrars, the FDA, or the DEA. The company welcomes audits as an integral part of its continuous improvement process for upgrading methods and systems.

The ISO audit standards require full organizational involvement in the quality assessment process. This system delivers a structure for continuous improvement and supports empowering the associates to implement change.

The bottom line for manufacturers is continued confidence in their 3PL: because they know any company with full ISO 9001:2015 certification has excellent business practices and standards in place. By providing manufacturers with truly exacting standards, ICS helps companies focus on their core goals of developing and bringing innovative drugs to market to impact patient lives.

ICS is the first to meet the standards because we live them

As Peter Belden, President of ICS said, “Quality is part of our DNA. We are committed to continuous improvement throughout our organization. Each of our associates are responsible for identifying areas in which we can improve our processes and deliver quality.”

Stay informed

For more information on our unique approach to third party specialty logistics, please visit our website: icsconnect.com

These are trending topics of interest to manufacturers:

- Is ICS Title Model Right for you?
  icsconnect.com/strategic-planning/title-model
- Are you ready for DSCSA serialization?
  icsconnect.com/integrated-logistics/dscsa
DAN FIELDING, ASQ CPGP, CMQ/OE, CQE, CQA, CBA, CQIA & CQI

Dan Fielding is Senior Director, Quality for ICS and has been with the company since September 2002. He holds seven American Society for Quality (ASQ) certifications including Certified Pharmaceutical GMP Professional, Certified Quality Engineer and Certified Biomedical Auditor. Dan has successfully implemented ISO9000 programs in a variety of industries and has more than 25 years of quality and process improvement experience.

ENABLING GLOBAL COMMERCIALIZATION

The U.S. pharmaceutical sector is one of the last industries to embrace the concept of an internationally-recognized quality standard. However, manufacturers that distribute product internationally, hold their 3PL providers to the strict ISO international requirements. The first 9001:2015 certification awarded to a 3PL extends to all ICS locations in the U.S. Additionally, its World Courier partners in 52 countries around the world are also ISO certified.

ICS was certified by DQS Inc., a division of Underwriter's Laboratory (UL), one of the leading certification bodies for management systems in the world.
ABOUT ICS

ICS, a business unit of AmerisourceBergen, partners with pharmaceutical manufacturers to deliver third-party logistics services that improve the quality and efficiency of their supply chains. As the pioneer in the specialty logistics market, ICS has helped bring hundreds of specialty pharmaceutical products to market and served as an integral component in their growth.

ICS was founded in 1997 and since then, has organically grown to become the industry leader in outsourced logistics and distribution services for pharmaceutical manufacturers. From strategic program design to enhanced 3PL and performance analytics, ICS goes the extra mile to ensure increased supply chain efficiency, maximum return on investment and enhanced patient care. ICS is the model of excellence in global healthcare logistics.