# UNDERSTANDING ISO 9000 CERTIFICATION

**By Dan Fielding**

This is the second in a four-part series looking at ISO 9000 certification.
To read the first part, "ISO 9000 Certification: Quality infusion for 3PL providers," click here.

Pharmaceutical manufacturers often hear the term "ISO certification," but they might not fully understand what this means to their business. The ISO 9000 certification is established through the International Organization for Standardization (ISO) and is inclusive of the U.S. Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMP). Many aspects of FDA's Quality System Regulations (QSR) were actually modeled around ISO standards.

These certifications provide a framework for demonstrating to clients that a documented Quality Management System (QMS) exists throughout an entire organization. The initial certifications are only the beginning of a committed process; the standard also sets requirements for continuous improvement that are verified through rigorous third-party audits.

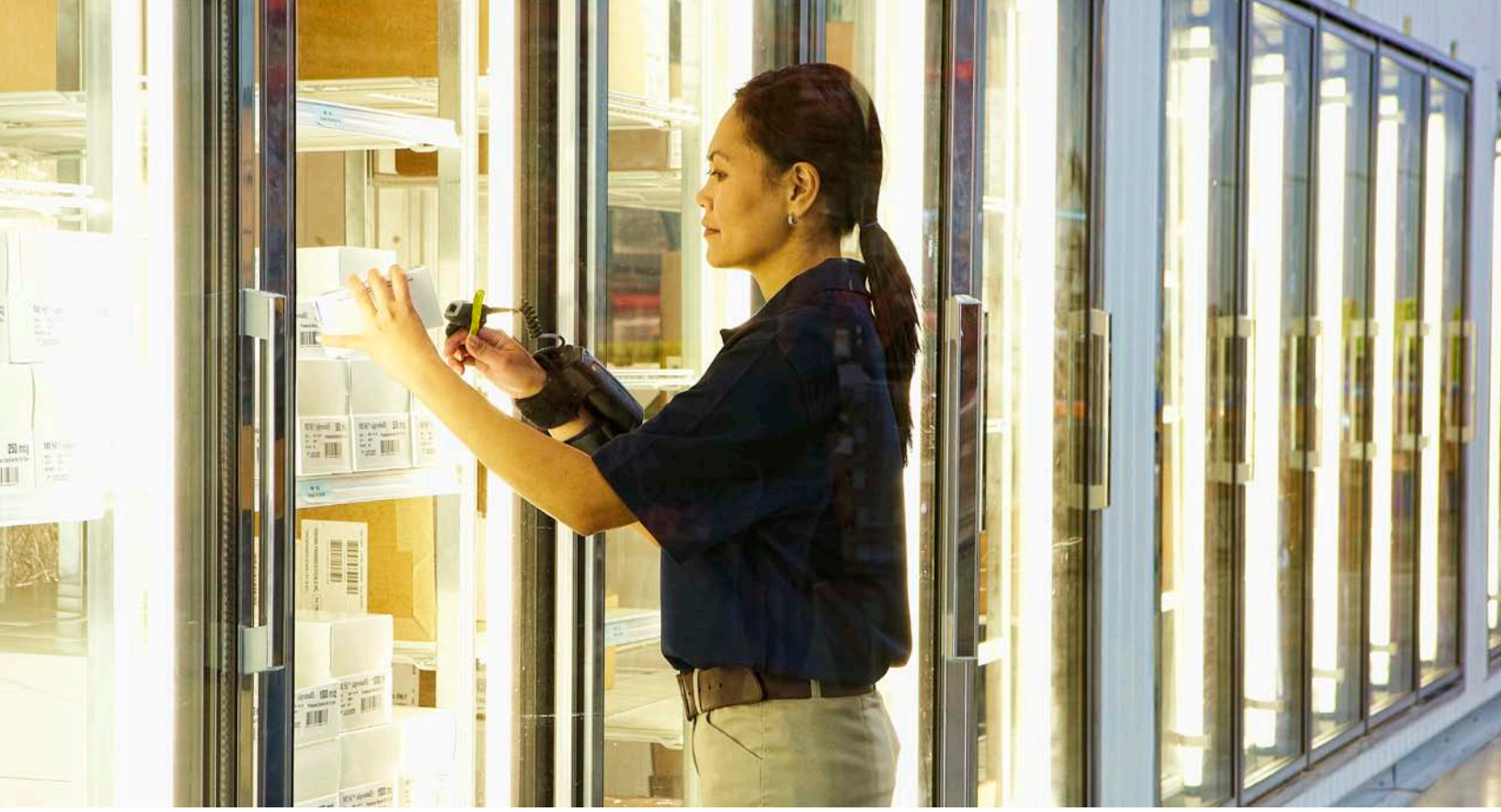

## WHY DOES CERTIFICATION MATTER?

When a pharmaceutical manufacturer works with a third-party logistics (3PL) provider to handle their products between production and sale to consumer, they need to be assured that their products and customers will receive the highest care.

Some companies have received some sort of certification for parts of their business — an example might be a distribution center that is Verified-Accredited Wholesale Distributors (VAWD) certified. ICS maintains VAWD certification for our Distribution Centers and have also chosen to ISO certify every aspect of their service offering. Their customer service, training, program management, accounts receivable and information technology groups etc. are all subject to the same third-party audits as their distribution centers.

ICS, a division of the AmerisourceBergen Specialty Group is the leading 3PL provider for the pharmaceutical manufacturing industry, focused on continuously improving the quality and efficiency of their supply chain for pharmaceutical products that require special handling.

A little history: When the FDA embraced the use of "modern quality management" in September 2003, ICS identified that need. ICS wanted to define a standard of excellence in their market space. In a highly competitive environment, it's the ability to establish a demonstrated reputation for excellence that sets companies apart. By providing high-quality service, ICS demonstrates to clients it is prepared and highly capable of managing



complex commercialization requirements. In addition, these standards are entirely consistent with the vision, mission and values of its parent company, AmerisourceBergen.

ICS was one of the first companies (across all industries) in the country to be certified to the 2008 version of ISO 9001 standard. The certification also extends to all locations where the organization is represented, including its three fully certified distribution centers in Reno, Nevada and Brooks, Kentucky, and its World Courier partners in 52 countries around the world.

ICS has been ISO-certified since 2004, and is the only known pharmaceutical company offering our full suite of services to maintain such certification. This sets us apart and offers value to manufacturers. ISO certification coverage includes DEA Class I-V vaulting/caging/shipping, a full order-to-cash process including chargebacks and multiple locations as a component of a comprehensive disaster recovery plan.

## CERTIFICATION ITSELF

Certification is performed by an external registrar and is a rigorous process. ICS receives assessment audits every six months. In addition, there is a "ground-up" re-certification every three years where all aspects of the company are examined for continuous improvement and compliance with the standard. These stringent audits mean that certified companies must be constantly "polishing" their methods and systems.

The standards in place through ISO are generic in scope, requiring full organizational involvement in the quality assessment process. This system delivers a structure for continuous improvement and supports empowering the associates to implement change.

Certainly, when ICS received high ratings from its triennial audit, this good news was shared with clients. But it's not the specific number that clients care about. To them, ISO represents a standard of excellence. When ICS carries the ISO certification logo, it means that there's a level of discipline that competitors don't have.

The bottom line for manufacturers is confidence in their 3PL: because they know any company with full ISO 9000 certification has excellent business practices and standards in place. By providing manufacturers with truly exacting standards, ICS helps companies focus on their core goals.

In part three of this series, we will look at why ISO 9000 is critical to manufacturers.

Part One

## ABOUT ICS

ICS partners with pharmaceutical manufacturers to provide third-party logistics (3PL) that improve the quality and efficiency of their supply chain for products that require special handling. From controlled substance storage and handling to business processes, ICS is the industry's only 3PL service provider to carry best-in-class ISO certification for its full scope of service. ICS is a division of the AmerisourceBergen Specialty Group, part of the AmerisourceBergen Corporation, and is able to connect customers with expanded services to improve performance at every stage of the product lifecycle.

For more information on ICS, go to **icsconnect.com**

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