

THE SPECIFICS OF ISO 9000

By Dan Fielding

This is the final in a four-part series looking at ISO 9000 certification.

To read the third part, "Why ISO 9000 certification matters to manufacturers," [click here](#).

We opened this series with a quote from the father of total quality management, W. Edwards Deming, who said, "If you can't describe what you're doing as a process, you don't know what you're doing."

The International Organization for Standardization (ISO) has that as its basic philosophy, stating, "The adoption of a quality management system should be a strategic decision of an organization." ICS, a division of the AmerisourceBergen Specialty Group, has adopted such an approach in designing its systems to serve its clients through its ongoing ISO 9000 certification and scope of services.

ISO 9000 certification is all about preparation: It requires a rigorous pre-assessment process to determine the level of the organization and a continuous follow-up process. ICS, a third-party logistics (3PL) provider, has designed and created its processes and systems with its clients clearly in focus.

HOW DOES ICS COMPLY AND EARN CERTIFICATION

While ICS has multiple business focuses, continuous improvement is a basic underpinning of all operations. Continuous improvement is taught as a cornerstone of new associate training and is incorporated into the culture throughout the organization.

Continuous improvement is most often conveyed through the idea of "plan, do, check and act."

- **PLAN:** A plan is developed around any potential service offering



- **DO:** The planned activity is then performed
- **CHECK:** An in-process evaluation or audit is performed to measure the efficacy of the planned activity
- **ACT:** Based on the outcome, appropriate action is taken

The most important attribute of this is that the process must always continue. And it always does at ICS.

THE ROLE OF INTERNAL AUDITORS

The internal audit function at ICS reflects the continuous improvement ethos within the organization. Auditors are developed within different operational areas of the company. Those who are able to pass multi-phased credentialing administered by the American Society for Quality (ASQ) become part of the internal auditing team.

ADDITIONAL STANDARDS OF EXCELLENCE

Key to identifying and driving training requirements are the associates of ICS themselves. 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. Supervisory personnel approve all submitted requirements.

In addition, ICS utilizes an integrated documentation application to store and update its training and process documentation across the enterprise, from top to bottom.

We hope this four-part series has helped you better understand ISO 9000 certification, the specifics of its application and why it matters so much that pharmaceutical manufacturers demand full certification of their 3PL providers. ICS takes their ISO 9000 certification seriously, and takes pride in the continuous improvement the process requires.

[Part One](#)

[Part Two](#)

[Part Three](#)

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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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Dan Fielding has been with ICS since 2002 and currently serves as the Senior Director of Quality. He has implemented and maintained ISO 9000 systems in a variety of industries. Dan currently holds seven American Society for Quality credentials, including Certified Pharmaceutical GMP Professional and Certified Manager of Quality/Organizational Excellence.