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ZeptoMetrix Receives ISO 13485 & ISO 9001 Certifications

ZeptoMetrix Corporation is a life sciences company that develops, manufactures and sells products for scientists. The company's primary focus is on products used in the research of infectious diseases and oxidative stress including HIV, hepatitis, SARS, various cancers, Avian influenza, West Nile virus and numerous primate viruses. In addition, many of these products are packaged into test kits used for disease control and sold to major pharmaceutical and diagnostic companies.

ZeptoMetrix was founded in 1982 and has been under its present ownership since 1999. Its employment has grown to 35 people, including five PhDs. Company headquarters are located within the burgeoning medical research complex in downtown Buffalo, NY, where ZeptoMetrix has maintained active collaboration with several renowned area institutions including Roswell Park Cancer Institute, SUNY at Buffalo and Hauptman-Woodward Medical Research Institute. In recent years ZeptoMetrix's sales have grown significantly as its products are marketed globally (about 30% of its sales volume is exported) to many diagnostic companies, as well as numerous universities, hospitals, research centers and government agencies. Its major customers include such high-profile accounts as the National Institute of Health, the Center for Disease Control and the New York State Department of Health. In addition, because of its level 3 safety laboratory, ZeptoMetrix has received a "select agent permit" from Homeland Security to work with bio-terrorism agents.

Situation

Despite being both GMP and FDA compliant, one of ZeptoMetrix's customers, a major diagnostic company, insisted that future business

was incumbent upon ZeptoMetrix becoming ISO 9001:2000 registered. The company's senior management determined that it would not only pursue this registration, but also become certified in the ISO 13485:2003 medical standard as well. This certification is an enhanced version of the world-wide ISO standard with specific provisions uniquely applicable to the life sciences industry. It was believed that this certification was closely related to the company's primary business and could provide a competitive advantage as few other manufacturers were registered to this extent. Unfortunately, due to business demands, limited internal resources and an unfamiliarity with the specifics of the standard, ZeptoMetrix management did not feel prepared to achieve registration within a reasonable time frame.

Solution

The company subsequently engaged the services of Insyte Consulting to support the upgrade of the quality system to the above

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Tricia Hoover performs Coxsackie virus purification inside a Biological Safety Level-3 laboratory at ZeptoMetrix's Buffalo Facility.

What's Next for WNY Manufacturing

The manufacturing world is in transition. Lean manufacturing and information technology have caused unprecedented productivity gains; the relaxation of trade barriers has opened global markets; and on-line communication has enabled international outsourcing and sales. The U.S. is losing much of its commodity manufacturing to lower cost labor markets overseas, so the future success of U.S. manufacturers depends on their ability to innovatively differentiate their products and services to provide additional value for their customers.

As WNY manufacturing suffers through this transition, our community wonders which industries and companies will survive. We are betting big that life sciences companies will be an important part of WNY's future — we have placed hundreds of millions of dollars on that bet. WNY already has a higher concentration of medical device companies than most areas of the country and has a small but growing pharmaceutical industry. These life science companies are particularly important to our future because they align with our strong life sciences research and clinical capabilities. The growth of these industries must be supported.

In our concern for the future, we must not forget our current manufacturers. Although some of them will close, unable to successfully reinvent themselves, others will manage the transition and thrive. WNY will continue to have auto, aerospace, food and defense companies. The survivors will emerge from the intense global manufacturing shake-out, stronger and wiser. Insyte Consulting helps companies with their transitions.

To respond to the needs of our next generation manufacturers, Insyte Consulting will maintain its strong base of productivity-enhancing services including lean manufactur-

ing and quality systems; expand its strategic services in marketing, IT, strategy and enterprise-wide supply chain development; and build on its innovation services such as new product development and technology diffusion. Additionally, Insyte Consulting will continue to provide capital and business assistance to support the growth of high tech start-up companies.

The next generation manufacturing in WNY can be a blend of new industries and companies with today's reengineered companies. Our community's challenge is to support the transition of our existing companies while we position our research and clinical resources to support new regional business development. If we support a balanced approach to the transition, we are more likely to be rewarded with a new generation of globally competitive manufacturers that provide good jobs and generate community wealth.

Robert J. Martin

Increase Your Company's Profitability through Waste Elimination

Does the current state of your manufacturing processes result in over-production or excess inventory? Do you have too much scrap due to quality issues or inefficient processing? Are you spending too much time and money moving information, material or product through your processes? These are some of the many forms of waste that are a drain on profitability for area manufacturers and the target of a new program supported by New York State.

The application of lean thinking to a review of your production and new product development processes can identify these and other forms of waste. The implementation of appropriate lean tools can be a means of eliminating these wastes.

NYS Department of Economic Development Partners with Insyte Consulting

Insyte Consulting and the New York State Department of Economic Development (DED) are partnering to help companies identify and reduce sources of waste in their production and new product development areas. Insyte Consulting will provide the assessment and implementation expertise; DED will provide matching funds to underwrite the cost.

This program is unlike other state assistance programs because participating companies are not required to complete lengthy applications or seek reimbursement of expenses from the state. Insyte Consulting manages all state program requirements.

How to Participate

Companies wishing to qualify for this program will undergo 40-hour assessments to identify the amount and dollar value of waste currently generated. The company's adaptability to lean thinking will be evaluat-

ed during the assessment stage. The result of the assessment will be a report, which will include a prioritized list of improvement recommendations. Most of the cost of the assessment will be paid under this program by DED.

Companies that have the potential to substantially reduce or eliminate waste and are capable of adopting lean thinking and practices will qualify for implementation projects with Insyte Consulting. DED will pay for over 75% of the implementation project costs.

Contact Insyte Consulting

If you are interested in this program, contact Phil Celotto or John Murray at 716.636.3626. You can also reach them via email at pcelotto@insyte-consulting.com or jmurray@insyte-consulting.com. ❖

Economic Indicators

International Measure	Previous Year	Last Month/Quarter	Current Month/Quarter
Trade Balance - Trade with World, seasonally adjusted, in millions of U.S. dollars	— 60,716 — 5/05	— 68,267 — 4/06	— 68,669 — 5/06
National Measures			
Gross Domestic Product - Current dollars and "real" Gross Domestic Product (seasonally adjusted annual rates) in billions of chained 2000 dollars	11,001.8 — 2nd qtr 2005	11,316.4 — 1st qtr 2006	11,385.3 — 2nd qtr 2006
Producer Price Index (PPI) - by stage of processing, seasonally adjusted, Durable Goods	136.5 — 1/06	137.5 — 5/06	137.8 — 6/06
Manufacturing Employment - all employees, thousands	14,233 — 6/05	14,236 (p) — 5/06	14,251 (p) — 6/06
Productivity - Manufacturing output per hour, at annual rate, % change qtr. ago	4.8% — 1st qtr 2005	4.7% — 4th qtr 2005	3.8% — 1st qtr 2006
Wages - Manufacturing average hourly earnings of production workers, seasonally adjusted	\$16.56 — 6/05	\$16.79 (p) — 5/06	\$16.82 (p) — 6/06
Manufacturing Sentiment - National Purchasing Managers Index (PMI)	56.4 — 7/05	53.8 — 6/06	54.7 — 7/06
Prime Rate - Bank prime loan rate	6.01 — 6/05	7.93 — 5/06	8.02 — 6/06
Local Manufacturing Measures			
Employment - Buffalo-Niagara Falls, NY Manufacturing employment in thousands, not seasonally adjusted	64.5 — 6/05	62.5 — 5/06	62.4 — 6/06
Manufacturing Sentiment - Buffalo Purchasing Managers Index	60.5 — 6/05	63.6 — 5/06	64.5 — 6/06

P: preliminary, Sources: U.S. Census Bureau, Bureau of Economic Analysis, Bureau of Labor Statistics, Institute for Supply Chain Management, Federal Reserve, New York State Department of Labor, National Association of Purchasing Management - Buffalo Inc.

Understanding ISO and Industry Specific Standards

By Philip Celotto

The ISO 9000 standard, initially released in 1987, was developed to create a standardized approach to quality management. The rapidly expanding international trade market made it imperative to establish a standardized methodology for developing and defining a quality management system (QMS).

The ISO 9000 standard has been revised twice since the initial release, with the latest version being issued in 2000. Each new version has followed the continuous improvement model, becoming more flexible and providing greater benefit. The most recent release focused on:

- Adopting a process-oriented approach,
- An increased emphasis on meeting customer needs,
- Allowing small businesses to use the standard and
- Assisting organizations in improving their business.

The benefits of an ISO certified QMS are numerous. First and foremost is that the management system will continually improve the quality of product and processes within an organization. In addition, the standard presents a benchmark for quality improvement, provides the appropriate control of firms' processes and requires self-evaluation to drive improvement. As a result of the improvement cycle, the costs associated with poor quality will be reduced, there will be an increase in employee involvement and ownership of processes and customer confidence will be increased. Finally, the attainment of an ISO certification can open up new opportunities in markets or regions of the world which were previously unavailable.

Industry Specific Standards

In addition to the ISO 9000:2000 standard, there are industry specific standards that have requirements above and beyond those defined in ISO 9000:2000 but are based on and build upon that standard. The industry specific standards most often required are:

- Aerospace: AS9100
- Automotive: ISO/TS16949
- Medical Devices: ISO 13485

Each of these standards employs the core concept of the Plan-Do-Check-Act cycle which focuses the organization on its key processes. The model also builds in the ideas of planning



and reviewing and the foundational concept that organizations should continually improve (see diagram above).

Many factors must be considered when deciding to obtain an industry specific certification. Does the standard add value to your business? Will there be significant improvements to the business? Will the time and cost to achieve the certification be rewarded with additional opportunities? Is this a customer requirement?

Although not intended to provide an exhaustive review of the additional requirements associated with each of the industry specific standards, the following identify some of the major requirements.

Aerospace: AS9100

AS9100 is the U.S. version of a globally harmonized standard. There are supplemental requirements to ISO 9000:2000 which are clearly distinguished within the standard. The focus of AS9100 is on the unique, complex and highly regulated nature of the aerospace industry. There is an emphasis on identifying critical aspects of key characteristics as well as a need to satisfy internal, governmental and regulatory requirements.

Automotive: ISO/TS 16949

Additional requirements are throughout the standard, but are concentrated within the following clauses:

- 7.3 Design and Development (including FMEAs,

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- APQPs and PPAPs for all parts)
- 7.5 Control of Production and Service (including Control Plans)
- 7.6 Control of Monitoring and Measuring Devices
- 8.2 Monitoring and Measuring

As an example, the basic ISO 9000:2000 standard, as well as ISO/TS 16949, require a documented process for measuring customer satisfaction. TS 16949 additionally requires that companies determine a method for monitoring customer perception as to whether requirements have been met, requires that data be evaluated continuously and requires that companies must demonstrate compliance with customer requirements and efficiency of process.

In addition to the requirements listed within the standard, it is the organization's responsibility to also satisfy customer specific requirements as listed by GM, Ford and DaimlerChrysler.

Medical Devices: ISO 13485

The additional requirements to the ISO 9000:2000 document are clearly identified within the standard and can be substantial depending on the type of devices manufactured. There are significantly more required procedures in the medical device standard, and it has additional stipulations for existing requirements such as traceability, labeling and packaging, cleanliness, installation activities and servicing. Customer satisfaction has been replaced with customer feedback.

There are new requirements for risk management as well as sterile medical devices and implantable medical devices.

Although based on the ISO 9000:2000 system, there is a distinction in ISO 13485 that requires that the suitability of

the system be maintained as opposed to continuously improved.

Summary

The additions described here for each of the industry specific standards can be minor or significant from ISO 9000:2000 depending on the product and application. The benefits of pursuing registration for any of these standards must take many

factors into account. If you are considering pursuing any of these quality systems please contact Insyte Consulting at 716.636.3626 for a more in-depth discussion.

Philip Celotto is a manufacturing consultant with Insyte Consulting. Phil is certified as an ISO 9000 Lead Auditor. ❖

Suggested Reading

The Toyota Way: 14 Management Principles From The World's Greatest Manufacturer*

by Jeffrey K. Liker

Publisher: McGraw Hill ©2004

The Toyota Way reveals the management principles behind Toyota's worldwide reputation for quality and reliability. Dr. Jeffrey Liker, a renowned authority on Toyota's Lean methods, explains how you can adopt these principles-known as the "Toyota Production System" or "Lean Production"-to improve the speed of your business processes, improve product and service quality, and cut costs, no matter what your industry.

Drawing on his extensive research on Toyota, Dr. Liker shares his insights into the foundational principles at work in the Toyota culture. He explains how the Toyota Production System evolved as a new paradigm of manufacturing excellence, transforming businesses across industries. You'll learn how Toyota fosters employee involvement at all levels, discover the difference between traditional process improvement and Toyota's Lean improvement, and learn why companies often think they are Lean—but aren't.

The fourteen management principles of the Toyota Way create the ideal environment for implementing Lean techniques and tools. Dr. Liker explains each key principle with detailed examples from Toyota and other Lean companies on how to:

- Foster an atmosphere of continuous improvement and learning
- Create continuous process "flow" to unearth problems
- Satisfy customers (and eliminate waste at the same time)
- Grow your leaders rather than purchase them
- Get quality right the first time
- Grow together with your suppliers and partners for mutual benefit

Dr. Liker shows the Toyota Way in action, then outlines how to apply the Toyota Way in your organization, with examples of how other companies have rebuilt their culture to create a Lean, learning enterprise. *The Toyota Way* is an inspiring guide to taking the steps necessary to emulate Toyota's remarkable success. ❖

*Source: www.amazon.com

Understanding the Phases of Six Sigma - Part I: Define *by Steve Diloia*

These days it seems like company management may be pursuing Six Sigma without understanding what it really is or what it can offer. Unfortunately, as many organizations hurry to join in the call for Six Sigma or Lean Six Sigma they end up asking themselves, "Why are we calling for it? How would we use it? What will it gain for us?"

This is the first article in a five-part series to help you become better equipped to answer these questions. Each article will explain one of the process phases used in the Six Sigma methodology and provide you with a better understanding of what is needed to successfully implement Six Sigma in your organization.

Introduction

The Six Sigma methodology follows the DMAIC principle of problem solving. The acronym is taken from the first letters for each phase: Define, Measure, Analyze, Improve, and Control. The DMAIC methodology provides a structure for logic progression through a problem solving activity. The focus of this article will be on the Define phase. (A basic overview of Six

Sigma was provided in the September/October 2005 issue of the Affiliate News which can be found at www.insyte-consulting.com.)

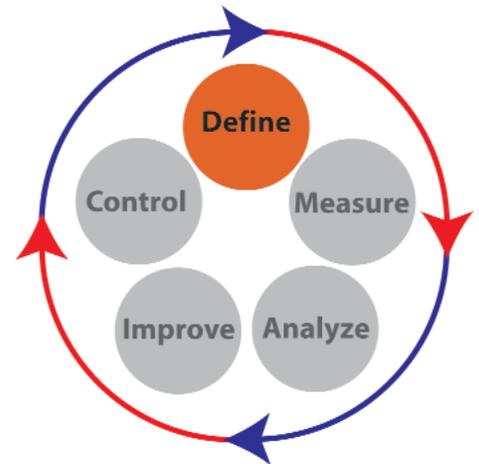
First Step of Define - When should we use Six Sigma?

The very first step is to define your problem. By asking some basic questions and analyzing the current issues, a fundamental understanding can be gained to assist in choosing the correct methodology to solve the problem. Perhaps a full blown Six Sigma project is not needed; instead implementing Lean Manufacturing tools or TOC may solve the issue.

Define the Problem

Once it is determined that it is necessary to utilize the Six Sigma approach there are some key elements in defining the problem that ensure success.

1. Prioritize opportunities for improvement. What are the issues and their impact within the organization? The impact should be evaluated from different functional areas ranging from financial to strategic goals of the organization.



2. Select the appropriate project based on the data collected in step one and management's acceptance.
3. Create a project charter covering the project statement, project scope, business impact, goals, timeline, project team, and management commitment.
4. Finally, recruit a dedicated cross-functional team comprised of stakeholders to find a solution to the problem.

The Define phase is where an individual needs to realize that the Six Sigma methodology might not be the best way to resolve the problem. This expertise comes through training and experience. Insyte Consulting's Six Sigma training or Six Sigma services can provide your organization with the knowledge, experience, and training to ensure that the proper methodology is utilized. Our unique training develops Black Belts that not only view the world through the eyes of Six Sigma; but through the eyes of a problem solver. Ultimately, if you properly define the problem, you define the proper course of action, resulting in a bigger return on investment spent to solve the problem. Our next issue will focus on the "Measure" phase. Contact us at 716.636.3626 for help in determining if Six Sigma is right for your organization.

Steven Diloia is a manufacturing consultant with Insyte Consulting. Steve was trained and certified through Motorola as a Six Sigma Black Belt and certified through SixSigma.US as a Master Black Belt. ❖

American Society for Quality Conference

Date:	Thursday, September 21, 2006
What:	EBAJ (Erie, Buffalo, Allegheny Mountain, Jamestown ASQ sections) Conference
Theme:	21st Century Quality: Taking the Lead
Where:	Ambassador Conference Center, Erie, PA (conference rates available)
Format:	A one day conference with 3 tracks: Technical, Survival Skills, Leadership
Time:	7:45 am registration — 4:15 pm wrap-up reception
One CEU credit Cost:	\$145/person early bird til Sept. 8, 2006 (a bargain—same cost as last year) or mention this newsletter
More information:	Contact Rose Ann Dulski, 716.827.1467

ZeptoMetrix continued from page 1

standards. ZeptoMetrix's management believed that Insyte Consulting's trained staff could work effectively with their employees to develop and implement the enhanced quality processes. Insyte Consulting's intent was to clearly link the quality system, including the manual, processes and procedures, to the company's business structure and operations. A joint

ZeptoMetrix/ Insyte Consulting team was formed to implement the elements of both these ISO standards. An initial review of existing procedures and documentation was conducted at the outset in order to develop a realistic project plan. An overview of the ISO 9000 standard was presented to all employees. This

overview set a strong, common foundation of understanding across the organization and validated the importance of the ISO implementation to the company's future.

The management team developed a quality manual, along with a quality policy and quality objectives to provide the structure for a quality system that was aligned with the company's vision. Personnel were trained in process mapping to assist in developing internal procedures. Teams were assigned to develop area and process specific procedures, while Insyte reviewed the created documentation and coached the team to ensure compliance to the ISO standard.

Internal auditor training was subsequently completed. The internal audit schedule was created and one complete audit cycle implemented. Review of the quality system was done through weekly meetings with the project management team. Management reviews were initiated and conducted at specified intervals. This aided in the system implementation while developing the practice of man-

agement reviews required by the standard.

Additionally Insyte Consulting worked with ZeptoMetrix's internal team to address specific nuances of the ISO 13485 standard including risk management, advisory notices, traceability requirements, cleanliness of product and contamination control, and status identification.

“Achieving certification just eleven months after starting is a remarkable accomplishment. We are now very well positioned to accelerate growth and effectively compete with the major players in our industry.”

**James C.D. Hengst, PhD
President & CEO**

Finally, an ISO registrar was selected and scheduled for the formal audits. Of particular importance is that company personnel assumed ownership of the quality system at this time and have been effectively maintaining it after formal registration (and subsequent surveillance audits) and completion of Insyte Consulting's involvement.

ZeptoMetrix achieved both ISO 9001:2000 and ISO 13485 registration in June, 2005, just eleven months after project initiation. Since then the company has gained access to numerous new accounts because of the ISO certifications. This has helped support a 20% increase in sales during that period along with the opportunity to significantly accelerate growth over the next several years. Due to recent business growth, employment has increased proportionately by 20% as well. From an operational perspective the quality processes have supported improved internal documentation and structure, both of which were good before, but now meet or exceed prevailing industry standards. In addition many customers no longer need to perform quality audits at ZeptoMetrix, as the ISO registrations sufficiently attest to product quality and the adherence to a formal quality process with documented corrective action procedures in place. ❖

Firm Benefits

- Obtained certifications for ISO 9001:2000 and ISO 13485:2003 within 11 months providing the opportunity to:
 - Access numerous new accounts
 - Increase sales by 20%
 - Increase employment by 20%
- Improved internal documentation and structure
- Customers no longer need to perform quality audits



Laura Wolfe removes HIV culture from incubator.

Affiliates News

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ly reflect the views of NYSTAR.

Insyte Consulting assists WNY manufacturing and technology companies to overcome their strategic and tactical business challenges. Whether it's a short-term engagement or a long-term commitment, we create positive change.

Because our employees have hands-on experience, we can help our customers see the opportunities and threats that lie ahead. We're always ready to roll up our sleeves to help get results — results you can measure.

We also place a strong emphasis on teaching our customers proven methods for maintaining and replicating the success that has been achieved. Knowledge combined with common sense — that's how our experience improves your business.

Our experience improves your business



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