



# AQA INTERNATIONAL NEWSLETTER

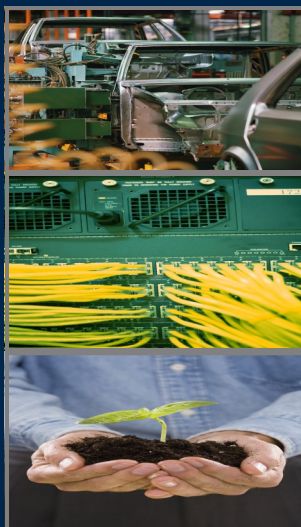
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## Featured Client:

Headquartered in El Paso, Texas, ReadyOne Industries provides employment opportunities to individuals with significant disabilities in an environment that inspires and nurtures self

determination and success. They take great pride in providing a safe, caring, and welcoming environment for their nearly 1,250 workers. With 75% of the direct labor performed by employees who are blind or severely disabled, ReadyOne Industries has built a solid reputation for manufacturing a variety of apparel and related products, corner board, boxes and other items for the United States government as a participant in the Ability One program.



ReadyOne Industries also provides services beyond manufacturing and government contracts; having ventured into a variety of commercial enterprises, document management and destruction, warehousing, vehicle storage, fleet management and creative products. They are an ISO 9001:2008 certified company and are committed to a management process with quality as the foundational business principle. The core of the process is achieving customer satisfaction by meeting their internal and external customer requirements on time every time. Employee participation within a continuous improvement effort develops, reviews, and implements the quality assurance system, procedures, and practices needed to meet the highest standards. The end goal is to continue meeting world-class standards for the mutual benefit of their customers and employees.

For more information regarding ReadyOne Industries and the services and products they provide, please check out their website: [www.readyone.org](http://www.readyone.org)

## Supplier Evaluation for Medical Device Manufacturers

*Article Written by: Ahmet Faruk Taka*

Medical Device Manufacturers (MDM's), have full responsibility for each clause of their Quality Management System and can not delegate their responsibility to any supplier of a product and service according to Annex II, V, VI of EU Directive 93/24/EEC. In effect, MDM's should have a sound system to ensure that products or services purchased meet the relevant regulatory requirements.

Having a system in place for purchasing does not necessarily mean that MDM's need to have second party audits at the premises of their suppliers. Following the steps as described in NBOG BPG 2010-1 Appendix 1 can help out MDM's to manage this challenging process successfully.

The NBOG document outlines important steps of purchasing activity such as the following:

1. Planning: Setting Objectives, Identifying Controls, Identifying Potential Suppliers and Risks
2. Selection of Suppliers: Investigating Capabilities of Potential Suppliers
3. Supplier Evaluation & Acceptance: Setting Evaluation Criteria, Communication with suppliers
4. Finalization of Controls: Establishing Purchasing Information and controls
5. Delivery, Measurement & Monitoring: Carrying out acceptance activities, related measurements, re-evaluation of suppliers
6. Feedback & Communication: Corrective & Preventive Action Process, Re-evaluation of suppliers.

## The 8-D Process, Discipline 2

*Article Written by: Richard Everhardt, AQA Auditor*

The second discipline in the problem solving process, D2, is to describe the problem. Before we can attempt to find a root cause and then alternative corrective actions, the problem must be described clearly and accurately. Sounds simple, right? Not always as we will explore.

It is important to state the problem precisely because all of the work to follow— all of the description, analysis, and explanation we will undertake will be directed at correcting the problem as it has been described. Just as presenting physical ailments to your physician completely so that a proper diagnosis can be made the problem definition must contain the same detail. Telling your physician that you don't "feel well" and then expect him or her to make a proper diagnosis and recommend corrective actions will seldom produce favorable results. Or, if you tell your auto technician that you have a "noise" under the hood and expect him or her to correct the problem would not produce favorable results. In both of these cases you could end up with a lot of new parts and still have the same problem! Countless hours and expense has been incurred in organizations trying to solve problems that have not been properly defined.

The end result of an analysis of the symptoms and outcomes of a flaw in the operating system must be an operational definition of the problem. The operational definition consists of verifiable criteria that have the same meaning to all stake holders and a basis of comparison - that is, the situation had to be "right" at one point in time. If a machine or process has never produced favorable results the current situation of a customer complaint is not the problem. The problem lies much deeper and must be resolved so that the process or machine is capable of producing favorable results.

In defining the problem you are studying, consider these guidelines:

- Define the problem in measurable terms. How much and how many must be included in any problem statement.
- Specify the internal and external customer. Who is affected internally and externally as a result of the situation?
- Be very specific. Look for answers to "When was the problem first identified?"; "Who discovered the problem?"; "Why was the problem not reported earlier?"; "Where in the process does the problem first become evident?"; "What specifically is the unacceptable deviation?"; "Why is this occurring now?" This last question may provide the most insight as through the problem solving activity you are looking for "what has changed"? For a problem to be present in a proven process or method, something must have changed!

The end result of this line of questioning will be a concise problem statement that compares what is occurring to what should be occurring. For example to simply say "bad parts were shipped to the customer last week" is not adequate and will not provide much assistance as you research the situation. Instead, something like: "Between May 1-May 4, 2010 10,000 pieces of part number 13536 that were .020 out of tolerance were sent to Acme Stamping but not to other customers" will guide you much more completely.

As you and your team complete this step in the 8-D process, strive to avoid these pitfalls:

- Vaguely defined problems. If the problem description is not presented in enough detail your team can be misled.
- Problem described incorrectly. A clear, thorough description of the problem is required. Answering the "who", "what", "when", "where", "why", "how much" and "how many" questions will help you to be accurate.
- Lack of communication. The actions of the problem solving team must be communicated throughout the organization or you may find "push back" or defensiveness as the team seeks answers to their questions. Everyone in the organization must understand that you are not seeking to blame anyone, but to solve the problem.
- Jumping to early conclusions. Team members, armed with some preliminary facts, often are tempted to jump to solutions too quickly. Do not shortcut the 8-D process. You must work through all of the steps to verify what you have found and to find solutions that will truly solve the problem.

Take your time to fully understand the scope and complexity of the problem you are faced with. The time invested here will pay important dividends later.



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## AQA Newsflash:

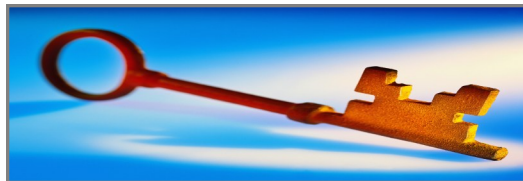
AQA International will be attending the Medical Design and Manufacturing Exposition and Conference in Orlando, FL from March 16-17, 2011. MD&M Florida is a part of the nation's premier event for design, engineering, manufacturing and regulatory affairs within the medical manufacturing industry. We are excited to attend and look forward to meeting our clients in Orlando!

## Meet the Staff:

Born and raised in Burlington, Ontario Canada, Brad Kitchen has been with AQA Toronto since 2008 and currently holds the title of President of AQA Canada as well as being an ISO 9001:2008 Lead Auditor. Prior to coming to work for AQA, Brad was Vice President of Sales & Marketing with AQSR International and has spent over 25 years in sales; 15 of that in third party certification. In his free time Brad enjoys spending time with his wife and four children. When asked what his favorite thing about AQA was thus far, he mentioned that "The people are what make AQA a great organization to work for." We are very glad to have Brad Kitchen on board and we look forward to many more years of working together!



## AQA Training... The Key to Success



Come join us for public training courses geared to meet your needs!

<u>Month</u>	<u>Date</u>	<u>Class</u>	<u>Days</u>	<u>Cost</u>	<u>Location</u>
April	4-6	AS9100 Internal Auditor	3.0	\$975	Ann Arbor, MI
	13-15	ISO 9001:2008 Internal Auditor	3.0	\$975	Columbia, SC
May	9-11	TS 16949 Internal Auditor	3.0	\$975	Ann Arbor, MI
June	13-15	ISO 9001:2008 Internal Auditor	3.0	\$975	Ann Arbor, MI
	22-24	AS9100 Internal Auditor	3.0	\$975	Columbia, SC
July	20-22	ISO 9001:2008 Internal Auditor	3.0	\$975	Columbia, SC
August	17-19	Integrated Management System Internal Auditor	3.0	\$975	Columbia, SC
September	7-9	ISO 9001:2008 Internal Auditor	3.0	\$975	Columbia, SC

Any of the above referenced courses can be customized to fit any of your training needs with onsite training. For more information regarding any of our classes or how to sign up, please contact Ansley Whiteside at 800-281-4384 or check out training updates on our website!

[www.aqainternational.com](http://www.aqainternational.com)