Quality Corner

3 Ways MDSAP Improves Audit Effectiveness

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What is the MDSAP program?

In Singapore in 2012, the International Medical Device Regulators Forum (IMDRF) began development of a Medical Device Single Audit Program (MDSAP). MDSAP allows approved auditing organizations to conduct a single regulatory audit of a medical device manufacturer. This single audit expands the scope of the audit to previously unaudited areas of large organizations, standardizes a consistent auditing model, and replaces as many as five separate audits. It also satisfies the regulatory requirements of the authorities participating in the program – even ISO 13485:2016. MDSAP focuses on defined and linked processes and is based on requirements for risk management. The goals of MDSAP are:

1. to improve audit effectiveness and the influence the audit can have on outcomes that improve patient safety
2. to reduce the resource demands on both regulatory bodies and auditees in organizations having to comply with a variety of global standards

The core processes in scope for the MDSAP audit include:

- Management
- Measurement, Analysis and Improvement
- Design and Development
- Production and Service Controls
- Purchasing

MDSAP also extends to the critical supporting activities that directly impact public safety, including: Device marketing Authorization and Facility Registration and Medical Device Adverse Events and Advisory Notices Reporting. Organizations can work with an authorized Auditing Organization (AO) to perform the single Quality Management System (QMS) audit and address the requirements of all participating regulatory bodies.

Currently, MDSAP includes the following regulatory jurisdictions and agencies:

1. Australia: Therapeutic Goods Administration or TGA (TG(MD)R Sch3)
2. Brazil: Agência Nacional de Vigilância Sanitária or ANVISA (RDC ANVISA 16/2013)
3. Canada: Health Canada or HC
5. United States: Food & Drug Administration or FDA (Quality System Regulation 21 CFR Part 820)

Notable observers in MDSAP include the World Health Organization (WHO), Medicines and Healthcare Products Regulatory Agency (MHRA), and Health Products Regulatory Agency (HPRA).

The IMDRF conducted a three-year pilot project from January 1, 2014 to December 31, 2016 to assess the viability of MDSAP globally. The findings from that project are available on the FDA website. These findings demonstrate that the MDSAP initiative is a viable one and that it has the support it needs to improve patient safety.

3 Ways to Improve Audit Effectiveness:

Improved Product Quality and Patient Safety

Prior to MDSAP, multi-national corporations or organizations sometimes overlooked parts of their businesses for auditing simply because the business was too large to account for every area. Since they can’t audit everything, these

Interested in submitting your article for next month’s Quality Corner? Below are some helpful guidelines for Quality Corner submissions:

1. Email submissions to communication@asqtoronto.org by the 15th of the month.
2. Maximum 500 words.
3. A small image (4 cm x 6 cm) can be included.
4. Submission of an article will not guarantee publishing in a given month’s newsletter and may be published in a subsequent newsletter.
5. If your submission is selected, the Newsletter Editor will contact you directly.
6. Your submission will be reviewed for clarity, readability, grammar, spelling, etc. and may require revisions prior to publishing in the newsletter.

If you have any questions, please contact the Communications Chair at communication@asqtoronto.org or speak with Sanaz Ghazi at the next section meeting.
organizations perform audits on a sample basis, so it’s critical that audits verify that processes work as expected and that the QMS is performing up to expectations while satisfying regulatory and customer requirements. With MDSAP, the increase in available resources and capacity among the shared global regulatory agencies enables them to audit previously untouched areas of the business and provides the additional scrutiny needed to ensure that independent third party assessments improve product quality and patient safety. Audits now penetrate more deeply into an organization while following the defined audit model and audit sequence. This helps organizations uncover hidden connections between processes, such as those between the measurement, analysis and improvement processes of Medical Device Adverse Events and the reporting processes of Advisory Notices.

Standardized Audits
The MDSAP audit model ensure consistency in the processes that will be assessed, evaluation of linkages between processes, and expectations for both auditors and auditees. The specific audit sequence, supporting guides, and checklists help to remove ambiguity in the process and ultimately save time during preparation, planning, and execution phases of the audit. This also ensures that everyone across a variety of organizations can incorporate and incrementally improve upon industry best practices as they use the tools. As an example, the FDA’s MDSAP QMS Implementation Assessment checklist is available for any organization to use. Proven and templated tools like this go a long way in helping organizations achieve the MDSAP goals of reducing risk associated with patient safety, improving QMS effectiveness, and making better use of auditor and auditee resources.

Improved Resources Management
Harmonization of the requirements across 5 regulatory agencies is no small feat. As such, MDSAP is a significant advancement in auditing as a general practice. The audit model allows medical device manufacturers to undergo a single regulatory audit rather than 5 separate audits, depending on the geographic regions in which they operate. Just think of all the work involved in preparing for and responding to an individual audit and multiply that effort by a factor of five! Now think of the savings in effort and cost in going from five audits performed by different global agencies to a single standardized audit. The significant reduction in business disruption for both authorized Auditing Organizations (AO) and auditees brings lasting benefits to medical device manufacturers around the world. Thanks to MDSAP, organizations will only need to go through a single audit at recurring review periods.

Last Thought
The MDSAP model could also potentially help in other audit activities such as supplier audits, internal audits, and even dock audits. Could a similar approach be applied as part of your audit program planning? Is there an opportunity for you to consolidate internal audits to help maximize the impact of your process outputs? These best practices would help suppliers become more effective and to focus on what matters most – delivering products and services for their end customers.

We want to hear from you, our members and recognize those of you doing great work in the Quality community. We would like to help promote our valued and trusted members so that each of us can get to know another a little better while recognizing the expertise that is part of our community. We will be featuring a section in the monthly newsletter for someone that made a great contribution to the quality world. If you are interested in being featured, please visit https://goo.gl/forms/9Cewa17TZwaUDZIS2 and submit the required information by the deadline.

ASQ Toronto is looking for members to participate in a quick 2 minute testimonial that we will use to promote the ASQ Toronto community via our new ASQ Toronto YouTube channel. Video recordings will take place at the end of the monthly ASQ section meeting or remotely. To participate, go to https://goo.gl/forms/27ZMDg4Ilp3VLbnn2. You will need to answer the following in the 2 min video testimonial:

1. What is your name, job title, and how long have you been a member of ASQ?
2. What is 1 thing you learned from the section meeting?
3. What do you enjoy the most as an ASQ Toronto member?
On March 29th, ASQ Toronto section held the first ever webinar via Webex regarding the Value of Integrating Risk Management into existing Quality Systems.

On April, ASQ Toronto section held two outstanding events; one on April 11th by John Nasar talked about six sigma methodology and its application in manufacturing industries and another one was the annual section Spring Seminar on April 18th.

**ASQ Toronto Section’s first Webinar on March 29:** "Value of Integrating Risk Management into existing Quality Systems" by Dr. Chaitanya Baliga.

Dr. Baliga provided a well-researched and comprehensive presentation covering multiple perspectives on the risk management principles. In this webinar, he provided some key elements for organizations to consider in areas of strategic and operational risk. The event was well attended considering this was the first ASQ Toronto Webinar with by 75 containing 72 ASQ members and three non-members. Attendees found the topic useful and wanted more webinars in future.

**About the Presenter:**

Dr. Chaitanya Baliga serves as Chair-Elect of ASQ Section 402 (Toronto), Deputy Regional Director (Canada), and Vice Chair of Social Responsibility Technical Committee. He has over 20 years of experience in implementing and executing risk management processes for aerospace, medical devices, pharmaceuticals, consumer products and logistics. Chaitanya has presented at various ASQ forums on risk management/ tools related to supplier management and medical devices.

**Webinar Summary:**

Businesses of any size have to manage risks, and this is true throughout the business lifecycle. Risk management is an essential business activity for enterprises of all sizes. Enterprises both small and large need to identify, understand and manage the uncertainties or risks that are critical to achieving success. New regulations, standards, and risk concepts add complexity, and challenge companies to wrestle with the practical application of risk management tools. Focus on benefit-risk concept throughout their product/service lifecycle is overlooked. This webinar focused on the value of integration of risk management principles and tools within existing quality management systems to provide risk assessment and mitigation within their process controls.

For full presentation of this webinar, please visit ASQ Toronto YouTube channel at: https://www.youtube.com/channel/UCQ29qVwKG0OldZ8cX4nSJQg
Six Sigma applications in Manufacturing Quality Control, April 11:

This event was held on April 11th at SpringHill Suites by Marriott Hotel Vaughan. The guest speaker was John Nasar, P.Eng., M.Eng., ASQ-CSSBB, CQE. He talked about Six Sigma applications in Manufacturing Quality Control.

About the Presenter:


Event Summary:

He explained DMAIC in detail and provided different tools and techniques that he is using in Ford Motor Company to manage Six Sigma projects.

Voice of customers, critical to quality (customer requirements), defect definitions for Y (objective metrics), cost of poor quality and problem statement scope and goals are key tools in Define step of six sigma projects. In Measure phase, key process inputs need to be defined and Measuring System Analysis and baseline process capability requirements are essential.

In Analysis phase ANOVA is the most important tool to understand data and finding solutions.

In improvement phase, implementation work plan needs to be established and by using hypothesis testing effectiveness of solutions can be evaluated. Applying SPC and studying trends are the keys to sustain improvements.

He also provided case studies about robust design application in improving quality of the products.
This event was held on “Risk Management Principles” at Edward Village Markham, Toronto. BSI (British Standard Institution and PLATO (web-based platform developer in risk management) were two main sponsors of this seminar. The event held in two steams simultaneously from 8:00 AM to 5:00 PM. (EDT).

**Presentation Topics and Speakers:**

- What Quality Professionals Need to Know about Managing Risk to Them Sleep Better at Night by *Michael Stanleigh*, CEO of Business Improvement Architects

- Risk Management Approach to ISO 9001:2015 and Management System by *Glen Clarke* and *Matthew Mac Neil*

- Effective Risk Management Aligned to Operational Excellence by *Mark Chambers*

- Risk Management Tools for New Product Launches by *Lorraine Fraser*

- Never Miss an Opportunity; ISO 50501 Innovation by *Peter Merrill*

- Risk Based Thinking by *Michael Mladjenovic*
Did You Know?

Upcoming events

An Opportunity to Recruit Quality Professionals!

Annual Employment Job Skills Event
Wednesday May 9th, 2018

As a global community of people passionate about quality, we are excited to announce that ASQ-Toronto annual employment event will be held on May 9th, 2018 at Edward Village, Markham. It is an ideal opportunity for quality professional candidates to meet employers/Recruiters, and for organizations/recruiters to meet quality professionals from GTA area.

Additional, it is an excellent opportunity to meet job search skills professionals and attend their presentations.

Agenda:
5:45 - 6:00pm Sign-in
Presentations topics
6:15- 6:45pm: Are we ready for tomorrow- Do we know where we are and where are we going
7:00- 7:30 pm: Interview Skills
7:45- 8:15pm: Lead With "You" Not Your Resume

Exhibit Booth and Display:
Training,
Education,
Aerospace,
Manufacturing,
Recruiters and more

Event to be held at the following time, date, and location:

Time: Wednesday, May 9, 2018 from 6:00 PM to 8:30 PM (EDT)

Location: Edward Village Hotel Markham
50 East Valhalla Drive
Markham, ON L3R 0A3
Canada

- Admission is free to all ASQ Toronto members. A $10 fee will apply for non-members who intend to apply their attendance towards recertification units.
- Parking is free

Registration at:
https://asqtontomay918.eventbrite.ca

For any Further Details, Question or Concern, please contact Employment Assistance Team at jobs@asqtonto.org

Fast Fact

A new version of the Recertification Journal was released on January 1, 2018. This version contains more information on ways to earn recertification units (RUs) and has a simplified layout, table of contents, and contains the updated ASQ Code of Ethics. Recognizing the high value of professionally based sessions at clinics, workshops, and section and division meetings for development, there was an adjustment from 0.3 RUs to 0.5 RUs in the meetings section of the journal. The change took effect January 1, 2018, and includes meetings attended so far this year and those in the future. For more information please visit:

Did You Know?

Upcoming events

- **Webinar; Disruptive Analytics in Quality 4.0**
  **May 15, 2018- 7:00 pm (Eastern time zone)**

  Speaker:
  **Jim Duarte** is a Fellow of ASQ as well as being Certified as a Quality Engineer and Six Sigma Black Belt who also holds certification as a Lean Six Sigma Master Black Belt.

  **Learning Objective:**
  - Evaluate methods for analyzing 'high volume', 'high velocity' data vs. 'low volume', 'low velocity' data
  - Recognize the proper methods to analyze 'data at rest', 'data in motion' and 'analytics at the edge'
  - Understand the importance of machine learning for predictive models
  - Recognize the importance of working with Information Technology (IT) and Operational Technology (OT) to acquire the best analytical software

  To register for the online event:
  1. Go to [https://asq.webex.com/asq/onstage/g.php?MTID=ec3692052feb97db391a104282fb19f1](https://asq.webex.com/asq/onstage/g.php?MTID=ec3692052feb97db391a104282fb19f1)
  2. Click “Register”.
  3. On the registration form, enter your information and then click “Submit”.

  Once the host approves your registration, you will receive a confirmation email message with instructions on how to join the event.

  For assistance, you can contact ASQ Toronto Section at: [program@asqtoronto.org](mailto:program@asqtoronto.org)

- **Study Groups**

  ASQ Toronto Certification Committee volunteers help in organizing study groups for the candidates who have registered to write any of the following exams:

  - Certified Quality Engineer - CQE
  - Certified Quality Auditor - CQA
  - Six Sigma Green Belt - CSSGB
  - Manager of Quality / Organizational Excellence (CMQ/OE)

  The study group start date will be finalized once we have six or more interested candidates for a certification exam type.

  Please e-mail to: [studygroup@asqtoronto.org](mailto:studygroup@asqtoronto.org) for more information.

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For more information please visit:

Section Executives

To better understand the ASQ Toronto Section leaders, we are kicking off the introduction of section executives consecutively in each issue of upcoming newsletters to our readers.

In this issue we introduce Desmond Mahadeo as Special projects Co-Chair of ASQ Toronto Section. Special projects committee is responsible for Project Manages special projects SLC may require to fulfill a section directive.

Desmond Mahadeo is a Mechanical Engineer, a Certified Quality Engineer, a Lean Six Sigma Black Belt, and a Senior member of the ASQ, with more than 20 years of membership.

He is Deputy Regional Director (ASQ) for Section 0400, member of the ISO TC179 committee representing Canada in the development of the International Standard for Innovation, current co-chair of Special Projects and was the past Employment Assistance chair of Section 402, from 2006-2012.

Desmond has a passion for excellence and improvement, is outspoken, believes in helping others; serves the industry with his knowledge and experience and has been volunteering on several committees from the inception of his ASQ membership. He pioneered and championed the Annual Employment Event and has been playing a key role with the success of the Annual Spring seminars since 2004.

Quality Spotlight

This month we introduce ISO 31000: Risk Management Standard. This standard covers ISO Risk Based Thinking; risk based, problem solving; risk based, decision making; and Enterprise Risk Management.

ISO 31000: ERM offers the following value:

- Explains the 11 critical risk management principles that should be integrated into each ISO risk initiative.
- Explains the structure and purpose of the ISO 31000 Risk Management Framework.

Reference: https://asq.org/quality-press/display-item?item=P1606
ASQ Statistics Webinars

The ASQ Statistics division has several free webinars available for its members to learn more about risk-based statistics for product testing, process capability analysis, DOE, and paired t-tests. To watch any of the webinars visit https://www.youtube.com/ASQStatsDivision today.

Volunteers Needed:

Deputy Treasurer

Section Deputy Treasurer is responsible for oversee section funds. Maintain accurate section financial records. Report on financial condition of the section at times directed by the bylaws and policies and procedures.

Education Co-Chair

Education committee Coordinates and manages section educational programs including conferences and/or special seminars.

If interested, please reply with resume to chair@asqtoronto.org.

Change in Exam Format

ASQ has moved from the traditional “pencil and paper” exam format to computer-based testing (CBT). Detailed information is available on ASQ’s website at http://asq.org/cbt/. Since this exam format is still new, please visit the website from time to time as ASQ provides new updates.
Job Postings

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There are no new job postings for February. Stay tuned!

ASQ Toronto Leadership Team

Executive

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Committee Chairs

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Committee Co-Chairs

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Senior Advisors

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Feedback

Please let us know your opinion about the newsletters. What would you like to see in the newsletter and how we can make it better? Your ideas are most welcome.

Please email your comments to the Communications team at communication@asqtoronto.org.