Session #: I1 **Date: Friday, October 18, 2019** **Time: 9:45 – 10:30**

Speaker Name: Mark Durivage

Session Title: Understanding the Medical Device Single Audit Program (MDSAP) Audit Nonconformity Grading Methodology

Session Summary: Traditionally, audit findings have been graded qualitatively using the generally accepted and widely used qualitative terms minor and major. With the launch of the Medical Device Single Audit Program (MDSAP), there has been a shift in the traditional qualitative audit finding methodology to a new system developed by the Global Harmonization Task Force (GHTF) which quantitatively grades audit findings with a numerical score based upon product impact and other pre-established criteria. This presentation will provide an overview of the quantitative nonconformity grading system used by MDSP.

Session Abstract: The International Medical Device Regulators Forum (IMDRF) which succeeded the Global Harmonization Task Force on Medical Devices (GHTF) acknowledged that to improve medical device safety and oversight that a harmonized global system was necessary for auditing, inspecting, and monitoring medical device manufacturing facilities. To address those objectives, the Medical Device Single Audit Program (MDSAP) was launched. MDSAP currently has five participating health authorities including; Australia's Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada/Santé Canada, Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and The United States of America's Food and Drug Administration (FDA).

MDSAP utilizes the Global Harmonization Task Force (GHTF) *Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange* authored by Study Group 3. The grading systems breaks with the traditional qualitative model of minor and major audit findings and grades audit findings with a quantitative numerical score based upon product impact and other pre-established criteria.

The GHTF scoring system separates the ISO 13485 standard into two discrete components, clauses having an indirect and direct quality management system (QMS) impact. Clauses 4.1 through 6.3 are the foundation of the QMS which indirectly influence medical device safety and performance. Clauses 6.4 through 8.5 are considered to directly impact medical device safety and performance.

This presentation will explain how the MDSAP audit grading system functions and will provide examples demonstrating how to quantitatively grade audit nonconformities. The session will also demonstrate how to use the MDSAP audit grading process to comply with ISO 13485 internal audit obligations requiring the organization when planning the audit program take "into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits."

Speaker Bio: Mark Allen Durivage has worked as a practitioner, educator, and consultant. He is Managing Principal Consultant at Quality Systems Compliance LLC, ASQ Fellow, and SRE Fellow. He holds several certifications including; CRE, CQE, CQA, CSQP, CSSBB, RAC (Global), and CTBS. He has written several books available through ASQ Quality Press, published articles in Quality Progress, and is a frequent contributor to Life Science Connect.

Mark primarily works with companies in the FDA regulated industries focusing on quality management systems including internal and external audit support as well as FDA 483 and Warning Letter response and remediation services.

Session #: I2 **Date: Friday, October 18, 2019** **Time: 10:45 – 11:30**

Speaker Name: Cathelene Compton

Session Title: After the Audit: Auditing Current Trends in Cleaning Validation

Session Summary: Fifteen percent of all US FDA 483 observations are related to Cleaning Validation. The current trends in US FDA 483 issuance has been related to lack of appropriate Cleaning Validation programs including but not limited to lack of proper acceptance criteria, lifecycle, campaign studies, and lack of swab data. This presentation will guide an auditor on how to effectively audit a cleaning validation program when there is limited time. This presentation will steer the auditor to specific areas to tackle when looking at Cleaning Validation documentation including how to cite the observations when found to CFR references.

Session Abstract: The presentation is focused on key areas to audit for Cleaning Validation. The current trend in FDA 483s has been Cleaning Validation. Mylan received a 32 page 483 in April of 2018 and 50% of the observations were targeted at Cleaning Validation. With the restructuring of FDA's Office of Regulatory Affairs, more FDA investigators are focused on Validation and the implementation of the Agency's guidance. Numerous trends have emerged with new Agency Guidance on how to calculate acceptance limits for Cleaning Validation. This presentation will guide an auditor through the trials and tribulations of finding and determining if a company has an acceptable Cleaning Validation program. Sustainable Validation programs are key to compliance success for any audit. The presentation is tailored towards areas of concern when an auditor has limited time. These areas of concern include periodic review, continued process verification, and surveillance programs. The presentation is concentrated on where to get started when auditing Validation programs during a general inspection audit or a 'for cause' audit, when there is limited time.
This presentation will help the attendee or auditor prepare for an audit when there is limited time. The presentation will also guide the auditor on how to write up the observations to specific CFR references to demonstrate to the site or facility that this observation could result in a FDA 483. Additional guidance and perspective will be provided in this presentation will include expectations detailed from guidance documents and observations from US FDA, EU, Health Canada, TGA, ANVISA, and more.

Speaker Bio: Cathelene Compton is a dedicated consultant to the Pharmaceutical, Nutraceutical, Medical Device and Food Industries with specialized experience in Consent Decree, Warning Letter Remediation and Third-Party verification, specifically Quality System and Validation program development. She has worked in the FDA and EU regulated industries for over twenty years specializing in Validation, Quality and Compliance. She holds multiple certifications including HACCP, Certified BRC GFSI Third Party Auditor, and ASQ CQM/OE. She is also the recipient of the ASQ FDC Shirl Furger Leadership and Meritorious Awards.

Session #: I3 **Date: Friday, October 18, 2019** **Time: 1:45 – 2:30**

Speaker Name: Dr. Ahmed Mubarak

Session Title: RISK: HSE Audits

Session Summary: The scope, objective, philosophy and dynamics of conducting HSE audits at the OIl and Gas industrial operations, both onshore and offshore, as well as the chemical industry as a whole, is here presented and discussed. Auditors qualifications, pre-audit information, critical audit areas. and statistical analysis of audit findings based on real time audits are analyzed and audit durations are determined.

Session Abstract: HSE auditors often mix between Asset Integrity resource elements (comprising mainly trade assets; mechanical, electrical, civil and instruments) with straight up HSE management system elements (including pollution, waste management, ergonomics, BBS, etc.,). While asset integrity Management System (AIMS) audits would address, to a large extent, equipment behavior and catering practices, traditional HSE audits would concentrate more on human behavior based elements. Meanwhile, Management Indicators (i.e., management commitment, training, communication, monitoring, auditing, etc.) are fairly common to both audits.

In this presentation, HSE audit metrics are reported and discussed.

Speaker Bio: Dr. Mubarak is an IRCA and PECB certified lead auditor for QMS, EMS and SMS ISO management systems. He also has extensive auditing experience in conducting HSE as well as Asset Integrity type audits at oil, gas, chemical and energy installations, in general, including nuclear and wind turbine operations. Dr. Mubarak worked in manufacturing / operational industries for over 25 years; holds six sigma black belt and the rank of a full professor.

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Session #: I4 **Date: Friday, October 18, 2019** **Time: 2:45 – 3:30**

Speaker Name: Dennis Welch

Session Title: ISO 26000, Guidance on Social Responsibility – A Business Perspective of How to Do the Right Things

Session Summary: ISO 26000 Guidance on Social Responsibility has been around as an international standard for nine years. It seems to have gained traction over the last few years as OEM's integrate it into their systems and then push it down to their supply base. Also, if you are considering implementing ISO 26000, keep in mind it is a guidance standard. You cannot be registered to it, because it has no requirements, no "shall's."

ISO 26000 revolves around six topics called core subjects. In addition, each core value is broken out into its basic components. You will probably find that you have many of these integrated into your system already, e.g. specific clauses from your employee handbook for instance. The rest of the core subjects will fit easily into your business model. They are:

A. Rights
- Due diligence
- Human rights risk situations
- Avoidance of complicity
- Resolving grievances
- Discrimination and vulnerable groups
- Civil and political rights
- Economic, social and cultural rights
- Fundamental principles and rights to work

B. Labour Practices
- Employment and employment relationships
- Conditions of work and social protection
- Social dialogue
- Health and safety at work
- Human development and training in the workplace

C. The Environment
- Prevention of pollution
- Sustainable resource use
- Climate change mitigation and adaptation
- Protection of the environment, biodiversity, and restoration of natural habitats

D. Fair Operating Practices
- Anti-corruption
- Responsible political involvement
- Fair competition
- Promoting social responsibility in the value chain
- Respect for property rights

E. Consumer Issues

- Fair marketing, factual and unbiased information and fair contractual practices
- Protecting consumers' health and safety
- Sustainable consumption
- Consumer service, support, and complaint and dispute resolution
- Consumer data protection and privacy
- Access to essential services
- Education and awareness

F. Community Involvement and Development

- Community involvement
- Education and culture
- Employment creation and skills development
- Technology development and access
- Wealth and income creation
- Health
- Social investment

Of course, the guideline drills deeper into each core subject above and Clause 4 elaborates on the principles of social responsibility. There are two annexes and a bibliography. Purchase a copy of ISO 26000 Guideline on Social Responsibility from www.iso.org if you don't already have it.

What I have found over time working on social responsibility and sustainability is that the guidance from ISO 26000 is the right thing to do for all of those interested parties involved.

Speaker Bio: Dennis Welch has spent his career helping businesses build management systems beginning with QS-9000 in 1995. He has been the risk management auditor for Madison Precision Products for the last three years and built a social responsibility system that won their OEM customer's prestigious sustainability award. Dennis is currently retired, but still consults with companies to build management systems.