Session #: D1 **Date: Thursday, October 17, 2019** **Time: 9:45 – 10:30**

Speaker Name: William Taraszewski **Session Title: First Impressions: The Myth of the Objective & Impartial Audit**

Session Summary: Studies have shown that you make judgements on the trustworthiness and competence (among other traits) of other people after looking at their faces for 100 milliseconds. How then does an auditor maintain objectivity and impartiality for the remainder of an audit? This session will examine the science behind first impressions; how they can be both advantageous and disadvantageous during an audit; what to do to attempt to overcome them; and perhaps most importantly, how to create better first impressions as auditors to enhance the overall effectiveness of audits.

Session Abstract: You've driven to your audit site, parked the car, entered the building, signed in, and met your host. Within those first minutes, you have already formed impressions about the company, its commitment to quality, and the competence, likability, aggressiveness, and trustworthiness of the people who work there. And the data suggests that these impressions may persist, in spite of available information that contradicts your first thoughts. How then do you conduct a fair, objective, and impartial audit?

In this presentation, we will discuss the science behind first impressions. Numerous examples will be presented, highlighting the types of things people decide within seconds – and there are many! The effects of similars and dissimilars, such as cultural influences, accents and speech, will be presented. Research on the relative importance of verbal and non-verbal cues is will also be shown.

Because there are differences in perceptions of video vs. in-person contacts, the particular risks of remote or virtual audits will be addressed.

Given the apparent persistence of first impressions, the need and ability to overcome a first impression, particularly with regard to audit performance, will be discussed in detail. Strategies such as finding areas in common, and how to proactively tackle assumptions, will be shown.

In addition, it is particularly important that auditors also present and portray desirable first impressions to the auditee, so as to set the stage for a productive audit. Discussion of several key, controllable ways to make a positive first impression as an auditor will conclude the presentation.

Speaker Bio: Dr. William Taraszewski is an independent consultant and quality systems auditor. He is a member of the Food, Drug, & Cosmetic, Audit, Biomedical, Quality Management, and Lean Enterprise Divisions, and is an ASQ Fellow. Bill has been on the Executive Team of the FDC Division since 2015 and was Chair in 2018. He holds the CQA, CMQ/OE, and CPGP certifications from ASQ, and Certified QMS Auditor and Certified Management Systems Specialist certifications from Exemplar Global.

Session #: D2 **Date: Thursday, October 17, 2019** **Time: 10:45 – 11:30**

Speaker Name: Randall Pittman

Session Title: Understanding ISO 45001, a Safe and Healthy way to realize Profit and Productivity.

Session Summary: Occupational Health and Safety programs directly impact an organizations' working environment, quality program and financial capabilities. Direct and indirect costs associated with even a single injury can cost millions in sales dollars, delaying allocation for planned improvements. Replacing experienced injured employees introduces new risks, which could lead to reduced quality or even more injuries. Maintaining a safety management system is a great way to take control of these risks and opportunities.

ISO 45001 is the latest occupational health and safety (OSH) management system standard designed to integrate seamlessly with ISO 9001. This session makes a business case for ISO 45001 and highlights the benefits and efficiencies of integration. This session is presented by a technical expert and 3rd party auditor who will share auditor resource documents that are essential to the proper assessment of ISO 45001 and explain the intent of certain requirements based upon the specific language used.

Session Abstract: It is assumed that most in attendance are already familiar with ISO 9001. A very general overview regarding the value of an implemented management system and how an implemented safety management system like ISO 45001 can also drive positive performance and operational excellence will be described. The session progresses by presenting a business case for adopting a safety management system by providing a couple of real-world scenarios regarding the costs, risks and opportunities to an organization when an injury occurs. This information is based upon the most recent data available. Then there is a brief interaction regarding the top injuries in the workplace which then includes the opportunity for selected attendees to describe how an injurious event impacted their company. ISO 45001 is then introduced with a brief explanation regarding its evolution and the eventual retirement of OHSAS 18001. The main areas of change will be highlighted to include the gaps between the two standards while sharing the high-level structure to illustrate the alignment to ISO 9001 for easy integration and discuss the benefits of integration. The last part of the session dives a little deeper into how to identify specific key words within the standard which unlock the process approach for auditing ISO 45001. This involves introducing resources beyond the standard that each and every auditor should be aware of and also know how to gain access to them. Throughout the presentation the importance of understanding entire ISO45001 document from introduction to bibliography and not just the auditable sections is emphasized.

It is expected that Attendees will walk away with an understanding of what ISO 45001 is intended to achieve, why the standard is structured the way that is, and how to achieve understanding of the intent for each requirement for maximum auditing effectiveness and performance.

Speaker Bio: Randy Pittman is the Business Unit manager for Environmental Health and Safety Standards with NQA. For over a decade, Randy has conducted and led teamed audits around the world for ISO 9001, ISO 14001, OHSAS 18001, & ISO 45001. He presents technical material to 3rd party auditors and participates as a technical expert to various industry groups.

Randy Acquired his skills while supervising commercial and residential construction projects within his family business. Attaining a degree in Geo-Physical Science he re-entered the workforce in the environmental industry. Certificate course within MSHA, OSHA, NEBOSH, ASP, RCRA, contribute to his professional portfolio.

Session #: D3 **Date: Thursday, October 17, 2019** **Time: 1:45 – 2:30**

Speaker Name: Maribel Colon

Session Title: Bringing Excellence to the Cannabis Industry through the Auditing and Self-Inspection Path

Session Summary: Get on the pulse of the billion-dollar state-sanctioned but highly legislated cannabis consumer products and therapies industry. Discover the new policy landscape with FDA approvals and licenses to make cannabis-derived pharmaceuticals and learn the benefits of developing effective self-inspection programs and compliance auditing systems that mitigate risk while delivering better quality products and excellent services. While the approval and commercialization of cannabis offer a multitude of new opportunities, quality management systems deliver a competitive advantage, inspire trust in brands, and attract potential investors. Learn the necessary strategies to begin the audit path.

Session Abstract: Used for over 3,000 years for its health benefits, today cannabis is one of the most highly-legislated fields with massive growth potential. Amid conflicting state and federal laws is an increasing awareness and demand for quality and safe cannabis consumer products and therapies. The landmark FDA approvals of Marinol, Syndros and Epidiolex have helped securely establish cannabis in the US market. Along with licenses for authorized manufacturers of cannabis plant extracts and CBD that are approved to make cannabis-derived pharmaceuticals

Amid the exponential growth of CBD and cannabis industries is the increasing widespread issue of safety and quality risks. One solution is to create a robust cannabis quality management system and develop an effective self-inspection program and compliance auditing system from cultivation and manufacturing to retail.

Being a fairly new industry, cannabis brings challenges for both organizations and auditors. But the benefits of developing quality management systems offer excellent benefits. Along with mitigating risk, organizations can stay ahead of the competition by offering better customer services and quality.

The growing state-sanctioned U.S. cannabis industry needs effective self-inspection programs and compliance auditing systems to reach its full commercial potential in all verticals. Strategies to begin the audit path have tremendous payoffs for quality, risk management, innovative processes, and potential market share.

This session will provide the basic steps on how to develop, implement, and conduct a cannabis industry auditing and self-inspection program to deliver on the promise of safe and reliable cannabis while achieving full commercial potential. Discussed will be the primary reasons why to consider implementing an effective self-inspection and auditing program, including the primary risks, credibility, and sustainability of an organization. The unique factors to consider when developing and conducting an auditing program for the cannabis industry will also be examined.

Acquiring an effective auditing and self-inspection program is the foundation on how to create a culture of business excellence in organizations that are passionate about becoming a profitable, transparent, and trusted leading brand for quality cannabis. Effective programs are also highly desirable to create trust with potential investors.

Speaker Bio: An active member of the ASTM D37 Committee developing the first cannabis industry self-inspection and auditing standard, Maribel Colón is a bilingual results-driven engineer. Working with fortune 500 companies in quality management systems and remediations, auditing, cGMP, ISO and FDA readiness, risk management, new process development, process improvement, and lean manufacturing, Colón's experience includes the heavily regulated industries of biotechnology, radiopharmaceutical, medical devices, APIs, the food industry and cosmetics/OTC in the U.S. and Latin America. A certified Lead Auditor, Colón holds a Chemical Engineering degree with a concentration in Industrial Biotechnology. She's also a Lean Six Sigma Black Belt.

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Session #: D4 **Date: Thursday, October 17, 2019** **Time: 2:45 – 3:30**

Speaker Name: Jeremiah Genest

Session Title: Lessons on Change Management from a Consent Decree Site

Session Summary: Drawing on the experiences of a company under a FDA consent decree, this session will consider change management and change control, and how they are improved upon by a grounding in knowledge management and risk management. The lessons learned and applied are relevant not only to the pharmaceutical industry, but to other FDA industries (medical devices, cosmetics, food, etc.), and to other heavily regulated industries (energy, mining, financial services and beyond). It is easy for a company in these situations to focus on change control and forget the wider scope of change management. During this session we will share improvements made in our processes as a result of being under the consent decree, as well as several templates, and tools to enable good change management, and change control activities.

Session Abstract: The Pharmaceutical Quality System described by the International Conference of Harmonization (ICH) is a holistic approach which facilitates the consistent development and production of high quality pharmaceutical products. It aims to support innovation and continual improvement of products, processes, and methodologies using knowledge management and quality risk management. Providing a lifecycle approach to pharmaceuticals, change management is a key element to this approach.

The Pharmaceutical Industry is one of the most regulated industries. In the US, the Food and Drug Administration (FDA) often uses the consent decree as the ultimate enforcement tool for those who break the rules. A company under consent decree needs to prove, via third party, that it has achieved and can sustain regulatory compliance. Companies under a consent decree must break down and build up their entire quality system.

After this session attendees will be able to:

- Evaluate lessons learned from a consent decree and building a robust pharmaceutical quality system for your use.
- Explain how the pharmaceutical experience can deepen your understanding of ISO 9001:2015, especially risk based thinking
- Identify how change management fits into a culture of quality
- Understand how the change management system increases compliance
- Use a few simple but effective tools for change management.

The ICH quality approach developed from ISO 9001:2008 but in many ways preceded the risk based thinking pivotal to ISO 9001:2015. Utilizing a matrix of similarities and differences between traditional GMPs, the ICHs and ISO 9001:2015, we will explore several lessons learned from consent decree activities, and demonstrate principles of change management.

This session will explore change management from the three lenses of science, regulation and risk, with a focus on knowledge management and risk management as enablers of successful change management. Several examples will be shared to demonstrate the fundamental connections between these systems.

The basis of this session will be change management as a fundamental part of a culture of quality. We will share best practices based on lessons learned from the consent decree around the impact of cumulative changes and large-scale versus incremental change.

Compliance for change management necessitates clear accountabilities, prioritization of changes, and the role of the quality unit – including the importance of a change champion or steward. This session will explore the relationship between change control, which often refers to the execution step of an individual change, and change management, which is a more systematic, holistic approach to the review and management of a portfolio of changes and the change process

Speaker Bio: Jeremiah Genest is an Associate Director of Quality Systems at Sanofi and has 20 years quality systems experience in the energy and pharmaceutical industry, with over a decade's experience implementing and running quality systems in the biotech field. He has experience implementing change management and data integrity at a consent decree site. He is a Certified Manager of Quality/Operation Excellence and Pharmaceutical GMP Professional.

Session #: D5 **Date: Thursday, October 17, 2019** **Time: 3:45 – 4:30**

Speaker Name: Denis Devos

Session Title: Outsourced Internal Audits – Changing Attitudes

Session Summary: Outsourcing internal audits is not a new phenomenon, but as QMS standards evolve and internal resources become more scarce, organizations are taking a new look at how outsourcing audits can benefit them. In 2007, the author conducted a survey to examine experience with and attitudes towards outsourcing internal audits. In 2018, the survey was conducted again, and this session shows the changes in attitudes over the past 10 years.

Session Abstract: This paper examines a growing trend among ISO 9001 and IATF 16949 registered companies toward outsourcing their internal audits. With the publication of the latest edition of ISO 9001 in 2015, companies are moving in greater numbers toward the outsourcing of their internal audits. A survey was conducted by the author to explore attitudes toward this issue between January 2018 and October 2018. The survey presents the experiences and attitudes of organizations toward outsourcing internal audits.

This paper presents a unique insight into this phenomenon, as the same survey was conducted by the author in 2007. The paper compares and contrasts the changing attitudes over those 10 years. The paper also examines the changes in ISO 9001 as a possible reason for the increase.

Survey results point to a growing tendency for organizations to rely on the services of professional auditors to perform their audits. Across all sectors, the two pressures of employees being expected to do more with less and the expectations of registrars for a very high level of internal auditor competency are discouraging organizations from doing their own internal audits.

Organizations are almost twice as likely to outsource their internal audits as 10 years ago, and those who have used professional audit resources in the past to perform their internal audits report the same level of very high satisfaction. Among companies who have adopted a strategy of on-going outsourced internal audits, a majority report very high satisfaction and an intention to continue.

Our conclusions are that many companies have decided to outsource their internal audits and have been very pleased with the results. The rise in use of outsourced auditors over the past 10 years is influenced by the changes in ISO 9001 and IATF 16949. As professional auditors, we should consider our role in advising our own companies and clients of the options available to provide the best internal audit solution for their needs.

Speaker Bio: Denis Devos is a professional engineer with a long career providing QMS training and advisory services. He is a Fellow of the ASQ and is a recognized expert in the application of the ISO 9001 and IATF 16949 Standards. Denis was the developer of the Risk is the Compass risk-based audit model in 2001. He works with clients in a variety of industries, providing internal audit services and training for QA practitioners and internal auditors Denis is a regular contributor to ASQ conferences at the Audit Division, Management Division, and the World Conference on Quality and Improvement.