



**Session #: A1**

**Date: Thursday, October 17, 2019**

**Time: 9:45 – 10:30**

**Speaker Name: Jay Arthur**

**Session Title: The Language of Motivation**

**Session Summary:** Ever have trouble with leadership, project teams, family, friends or people in general? You know they're speaking English, but you can't understand what they're saying? There are three types of team members and each has their own way of talking. Learn how to influence your team's dreamers, realists and critics by using *their* language. Using the language of influence, you'll learn a handful of questions to discover each person's style and motivating/influencing language for each one

**Speaker Bio:** Jay Arthur teaches people how to Turn Data Into Dollars® using Microsoft Excel and the Magnificent Seven Tools of Lean Six Sigma. Jay helped one healthcare system reduce denied claims by \$5 million per year and rejected claims by \$24 million.

Jay is the author of *Lean Six Sigma Demystified (2<sup>nd</sup>)*, *Lean Six Sigma for Hospitals*, and the QI Macros SPC Software for Excel—a software package that automates all of the charts, graphs, and documents required for quality improvement.

Jay holds a BS in Systems Engineering from the University of Arizona.



**Session #: A2**

**Date: Thursday, October 17, 2019**

**Time: 10:45 – 11:30**

**Speaker Name: Erin Wright**

**Session Title: Audit Readiness – Take the Pain out of Audits**

**Session Summary:** Are you being audited frequently by clients, notified bodies, or regulatory agencies? Want to learn a few tricks of the trade to make those audits as painless as possible? This session will focus on delivering practical tips and tricks throughout all stages of the audit, including audit preparation, audit hosting (facilitation), and audit remediation.

**Session Abstract:** Do you deal with frequent audits by clients, notified bodies, or regulatory agencies? Would you like to learn a few hints on how to make those audits as painless as possible? Undergoing an audit can be a nerve-wracking experience, but it doesn't have to be. In this session, expert Jake Walton will share practical tips and tricks for all stages of the audit process, including audit preparation, audit hosting (facilitation), and audit remediation. You will learn pointers on how to get your organization into an audit-ready state, and you will be given actionable tools that you can take back to your company and start implementing immediately. This session will provide attendees with universal principles that can be applied to any industry and to any audit. The presenter will go beyond the audit itself to teach guidelines on how best to interact with the auditor before, during, and after the audit. Discover how to create an environment for the auditor that builds a constructive relationship while also protecting your company. The tips and tricks from this session will teach you how to take the sting out of the auditing process, so you can focus on creating a positive outcome for everyone involved.

**Speaker Bio:** Erin Wright, MasterControl's validation product manager, has supported regulatory audits for customers throughout her career and is an expert in quality and validation as they apply to regulated industries. She has hosted and participated in hundreds of audits for regulated software, including high-risk trial software for patient randomization and drug-dispensation to low-risk automated test software.

She joined MasterControl in 2013 as a professional services consultant and worked closely with hundreds of regulated companies, including the FDA's Center for Drug Evaluation and Research (CDER), Ancestry.com, Abbott Point of Care, Institute for Transfusion Medicine (ITxM), and the University of Utah, in conducting custom validation implementations. Her extensive experience in quality, validation, and regulatory compliance includes working for an automated-testing software company and several clinical-trial software providers.

Wright graduated summa cum laude from West Chester University with a degree in psychology.

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**Session #:** A3

**Date:** Thursday, October 17, 2019

**Time:** 1:45 – 2:30

**Speaker Name:** Marty Cronin

**Session Title:** Auditing Around the Edges

**Session Summary:** How to audit around the edges is about auditors having their eyes open to the things that aren't found via questions – the posters on the wall, the subtle signs that there are gaps in the firm's ability to rely on their process instructions.

**Session Abstract:** Almost always, when auditing, I run into "signs" that tell me there are challenges with following work instructions or process maps. These are often in the form of special "reminders" or instructions "above and beyond" that are posted on the walls, the bulletin boards, etc. in a workplace. If something is happening often enough to warrant such special attention, it surely is something that should be noted and followed. Special notes, either handwritten in work instructions or in an employee's special "documentation", there are often clues that should be investigated right there in plain sight.

**Speaker Bio:** Marty Cronin, who has been working in the standards world since the UCC project to define the attributes of the UPC code for the retail industry, has taught EDI 101 to thousands of participants in user group conferences. She teaches ISO 9001, IATF 16949, ISO 14001, ISO 45001 and Internal Auditing to hundreds of new and experienced managers every year. She conducts approximately 25 pre-assessment or gap analysis audits yearly.

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**Session #: A4**

**Date: Thursday, October 17, 2019**

**Time: 2:45 – 3:30**

**Speaker Name: Colleen McGuigan**

**Session Title: Baldrige-inspired Audits: A Case Study and Lessons Learned**

**Session Summary:** Asked to conduct a Baldrige-inspired assessment of one of the company's Business Units, the presenter was excited to bring comprehensive assessments to her company but found herself pushing against current state inertia once the report was published. This case study examines the excitement and pitfalls of initiating a sudden switch to Baldrige-style assessment in an environment used to ISO 9001-based audits.

**Session Abstract:** Asked by senior leadership to do a deep-dive audit into one business unit as the result of multiple quality issues, I chose to use a modified Baldrige methodology going beyond ISO 9001:2008's requirements and moving toward identifying root cause issues. I was incredibly excited to finally use my Baldrige experience at my place of employment. We called it a deep-dive audit rather than using the word Baldrige because it was easier for people to understand and didn't carry the same baggage. This deep-dive started with marketing, continued through design and manufacturing, and finished with sales and remanufacturing. To accomplish my assigned task, I chose a small group of experienced internal auditors who had an inclination to go farther than an ISO 9001:2008 audit would allow. We focused on the key business indicators of that business unit, evaluated on the effectiveness and efficiency of the processes we reviewed, and looked at hand-offs between functional groups. To evaluate what we saw, we looked at the process as it was defined, the deployment of that process, improvements made to the process, and the results of the process. We worked hard to ensure our report reflected what we saw and learned and were excited to present it to management. It was then that I realized there was more to this assessment than just presenting the report—I should have spent more time preparing the business unit and its leadership for the differences between an ISO 9001 audit and a Baldrige-type assessment. Now that I have moved through this experience, I can look back and see a better path. That is what I will share with you.

**Speaker Bio:** Colleen McGuigan has been working at Rockwell Automation for 16 years and during that time her ISO 9001 responsibility has increased from a single facility to encompass the entire company. She was a Baldrige Examiner, Senior Examiner, and Alumni Examiner for 10 years, during which time she also volunteered with the Wisconsin Forward Award.



**Session #: A5**

**Date: Thursday, October 17, 2019**

**Time: 3:45 – 4:30**

**Speaker Name: Mark Rohlfing**

**Session Title: Auditing for Business Excellence: Lessons from the Operations Side**

**Session Summary:** Audits are a valuable management tool, used to assess operations against expected business performance and quality standards. Audits that are effectively planned and executed can provide great value to an organization and help drive business excellence. Conversely, if done poorly, audits add waste, thereby weakening an organization's ability to compete.

In this talk, a seasoned quality manager who is now responsible for overall site operations for his company will provide his unique insight into the business benefits and risks of quality auditing.

Learning Objectives:

- Create a better audit strategy by considering key needs and motivations of the executive and operations teams
- Recognize positive and negative aspects of audits in order to optimize continuous improvement and business excellence initiatives
- Improve career development as an auditor by being a better team member and problem solver

**Session Abstract:** Audits are a valuable management tool, used to assess operations against expected business performance and quality standards. Consequently, an audit is not an activity onto itself, but a key strategic investment. Audits that are effectively planned and executed can provide great value to an organization and help drive business excellence. Conversely, if done poorly, audits add waste, thereby weakening an organization's ability to compete.

This talk will provide unique insight into the benefits and risks in quality auditing taken primarily from the operations side of the business. While working in quality management for over 20 years, Mark Rohlfing performed and hosted hundreds of quality audits. In his current role as the head of operations at a leading clinical trial supplies manufacturer, he continues to work with quality and operational managers to optimize the business benefits of his company's customer and internal audit programs.

By the end of this session, attendees will be able to:

- Create a better audit strategy by considering key needs and motivations of the executive and operations teams
- Recognize both positive and negative aspects of audits and how they can accelerate or dampen meaningful continuous improvement and business excellence initiatives
- Develop a list of suggestions on how being a successful auditor can help advance career opportunities in both quality and operations

**Speaker Bio:** Mark Rohlfing is Vice President of Operations at Almac in Souderton, PA, leading site operations in clinical supply chain management, manufacturing, packaging, and global logistics. Mark was previously Director of Quality at Almac and has 25 years of experience within GMP/GCP Operations, QA/QC, and Regulatory Compliance including positions at Cell Pathways Inc. and Teva Pharmaceuticals USA.

Mark holds a BS degree in Biology from Millersville University and a MS degree in Biology from Villanova University. He is an ASQ Certified Manager of Quality/Organizational Excellence, ASQ Certified Quality Auditor, and ASQ Certified Six Sigma Green Belt.