

# ASQ - NEQC 58<sup>th</sup> Conference Program – Tuesday, October 19, 2010

7:00 – 7:45					REGISTRATION - REFRESHMENTS - EXHIBIT HALL				
7:45 – 9:00					<b>OPENING REMARKS</b> <b>KEYNOTE SPEAKER – John Bergeron, Director Six Sigma – Raytheon Company</b> <b>TOPIC: Quality, Reliability &amp; Risk Management During Product Life Cycle</b>				
9:00- 9:10					BREAK - EXHIBIT HALL				
TRACK		TRACK 1 MANAGEMENT SYSTEM		TRACK 2 PEOPLE		TRACK 3 MEDICAL		TRACK 4 SOFTWARE	
9:15- 10:15		<b>11A</b> Jim August, Director of Quality Management, American Biltrite Inc. Barbara August, Literacy Staff Developer, Livingston Public Schools  <b>Improving the Effectiveness of Change Management Approaches</b>		<b>12A</b> Rob Peck, Founder of Zestworks  <b>Keeping All The Balls In The Air (How to Make a Living...&amp; Still Have a Life!)</b>		<b>13A</b> Dan O' Leary, President of Ombu Enterprises, LLC  <b>A Unified Approach to Complaints, Servicing, and FDA</b>		<b>14A</b> Scott Davis, Director, Global Documentation Systems, Symmetricom  <b>PLM Integration and Change Management – Technology, Chaos, Culture</b>	
10:20-11:20		<b>11B</b> Jim August, Director of Quality Management, American Biltrite Inc.  <b>Critical and Creative Thinking: Getting “outside the box”</b>		<b>12B</b> Wang Wilhelm, Managing Director at TransReg, LLC  <b>Think Business Sustainability! Evolution of Sustainability Management from Quality Thinking</b>		<b>13B</b> Liz Markewicz, Sr. Principal Engineer, Raytheon Company Don Restiano, Sr. Principal Engineer, Raytheon Company  <b>Risk Management Pro-active Principles</b>		<b>14B</b> Mona Lane, Sr. QA Project Manager, AETNA  <b>Testing Center of Excellence (COE) – solving the dilemma of testing consistency</b>	
11:25-12:25		<b>11C</b> Sandy Liebesman, President; Sanford Quality Consulting, LLC  <b>The Advantages of Linking Management Systems</b>		<b>12C</b> Jay P. Patel & Larry Schworer, Consultants at Quality & Productivity Sol.  <b>Making Improvements through Kaizen - Workshop</b>		<b>13C</b> Steven Rakitin, President Software Quality Consulting Inc.  <b>How Clinicians and Device Manufacturers Can Collaborate to Reduce Risk</b>		<b>14C</b> Brian Le Suer, CEO of Zeenyx Software, Inc. David Laroche, CTO of Zeenyx Software, Inc.  <b>Minimizing Maintenance in Test Automation</b>	
12:30- 2:30					<b>LUNCH &amp; KEYNOTE SPEAKER: Steve Wrenn, Vice President Corporate IT and Shared IT Services – CVS Caremark</b> <b>TOPIC: Quality &amp; Continuous Improvement in the Service Industry, Why it's all About the “Outside” in.</b>				
2:35 - 3:35		<b>11D</b> Kenneth Rispoli, Sr. Principal Engineer, Materials Engineering, Raytheon Company Lee Gould, Sr. Electrical Engineer, Materials Engineering, Raytheon Company  <b>Physics of Failure (PoF)-Tools and Methodologies</b>		<b>12D</b> Bob King, CEO & Founder, GOAL/QPC  <b>Integrating Innovation with the Voice of the Customer</b>		<b>13D</b> Joe Azary, Manages the Quality & Regulatory Consulting Division at Orchid Design  <b>CE Marking Medical Devices - Changes to the European Medical Device Directives</b>		<b>14D</b> David Dwyer, Principal Software Engineer, BAE Systems  <b>“Downs &amp; Tractenberg” – Foundation for Software Reliability Engineering</b>	
3:40 -5:00		<b>11E – Jim Whitman – Sr. Consultant, Quality &amp; Productivity Solutions, Inc.</b>  <b>Workshop: Gauge R &amp; R Analysis</b>		<b>12E</b> Tim King, Quality & Leadership Manager, Tupelo Group, LLC  <b>Workshop: Delivering Quality Training Using Virtual Classroom Techniques</b>		<b>13E</b> Jeff Boatman, Quality System Sr. SME, QPharma  <b>FDA's Quality System for Pharmaceutical Manufacturers Guidance</b>		<b>14E</b> Madhav S. Phadke, PhD, President Phadke Associates, Inc Kedar M. Phadke, Vice President, Phadke Associates, Inc  <b>Utilizing Design of Experiments to Reduce Software Testing Cost in the Financial Services Information Technology (IT) Industries</b>	
5:00 - 7:30					<b>RECEPTION, ENTERTAINMENT, AWARDS, AND \$2000 worth of PRIZES;</b> <b>Host: Jay P. Patel, ASQ NEQC Chair</b>				

## TUESDAY - OCTOBER 19, 2010 SESSIONS

### Track 1- Management System

Session 11A - Jim & Barbara August show you how **“Improving the Effectiveness of Change Management Approaches”** affects how people and personality differences impact learning. They also review some of the basics of Adult Learning Theory based on the Knowles approach.

Session 11B – Jim August explores **“Critical and Creative Thinking: Getting “outside the box”** and the use of four tools to step outside the box: formal logical argument, TRIZ, Edward deBono’s “Six Thinking Hats”, and *reduction ad absurdum*. You learn how to incorporate these concepts into your everyday responsibilities.

Session 11C – Sandy Liebesman discusses **“The Advantages of Linking Management Systems”** and how important it is to improve the dialogue between financial, quality, IT and environmental management systems as well as the 8 step value proposition that provides a basic philosophy for organizations developing a linked management system. He also discusses support of Sarbanes-Oxley compliance by linked management systems.

Session 11D – Kenneth Rispoli and Leroy Gould talk about **“Physics of Failure (PoF) Tools and Methodologies”** and how failing to understand the basic mechanism for part and system failures is at the heart of some very expensive, high profile warranty claims. This presentation details the application of the PoF approach to hardware design as a preventive and failure analysis tool.

Session 11E – In Jim Whitman’s **Workshop**, he discusses **“Gauge R&R Analysis”**. He helps you understand the measurement system methodologies including the measurement process, variation, MSA studies, and the improvement of measurement systems.

### Track 2 - People

Session 12A - Rob Peck shares with us his concept of **“Keeping All The Balls In The Air (How to Make a Living...& Still Have a Life!)**. You experience a greater sense of optimism that allows you to stay focused and committed, still have fun and understand the link between broader perspectives and more flexible thinking and its positive impact on team chemistry.

Session 12B – Wang Wilhelm speaks about **“Think Business Sustainability! Evolution of Sustainable Management from Quality Thinking”** and how business risks that are embedded either a directly or indirectly in companies’ activities, products and services are derived from inferior quality or limited functionality.

Session 12C – Jay Patel & Larry Schworer **“Kaizen Workshop”** teaches you the concepts of a culture based quality and how you can learn to implement powerful kaizen techniques by involving employees to reduce waste in the organization at a low cost.

Session 12D – Bob King provides an understanding on why **“Integrating Innovation with the Voice of the Customer”** is critical. For this, the organization needs to understand the customer’s environment, converting understanding into customer requirements and then generating concepts. Integrating creativity, Lean Six Sigma & other techniques during the development process is essential.

Session 12E - Tim King’s **“Workshop – Delivering Quality Training Using Virtual Classroom Technologies”** demonstrates the do’s and don’ts of using technologies like WebEx Gotomeeting, and iLinc for delivering training on quality topics.

### Track 3 – Medical

Session 13A - Dan O’ Leary shows how **“A Unified Approach to Complaints, Servicing, and FDA Reporting”** brings together servicing, complaints, corrective action, and other processes through a unified system. He explains the regulatory requirements for both record keeping and reporting to the FDA. Dan provides you with the information to implement an effective system for managing and reporting adverse events.

Session 13B – Liz Markewicz and Donald Restiano explains **“Risk Management: Pro-active Principals for Project Success”** They describe how Risk Management is expected to ensure a successful program and the on schedule and within budget delivery of a system that meets the customer’s requirements.

Session 13C - Steve Rakitin talks about **“How Clinicians And Device Manufacturers Can Collaborate To Reduce Risk”** by designing, deploying and maintaining medical devices that are safe and connected to ever changing networks, creating safety challenges for clinicians and device manufacturers.

Session 13D – Joe Azary discusses **“CE Marking Medical Devices – Changes to the European Medical Device Directives”**. He provides an overview of what the changes to the European MDD in value, their relationships to other directives, the restrictions regarding the use of carcinogenic materials and the changes that are impacting medical device companies.

Session 13E – Jeff Boatman talks about **“FDA’s Quality System for Pharmaceutical Manufacturers Guidance”**. He covers the expectations that are already required under ICH Q10 and 21 CFR 820.1(b), which directly affect drug firms. Many FDA District Offices are conducting site inspections under the Quality System Inspection Technique, which this guidance mirrors.

### Track 4 – Software

Session 14A – Scott Davis covers **“PLM and Change Management – Technology, Chaos, Culture”** Scott’s presentation outlines the change management process used in the acquisition and implementation of Oracle-Agile Product Lifecycle Management (PLM).

Session 14B - Mona Lane speaks of **“Testing Center of Excellence (COE) – Solving the Dilemma of Testing Consistency”**. She discusses the tools necessary to conduct effective reviews, including developing the processes that your COE team will follow, along with the detailed checklists used to conduct their reviews of testing organization.

Session 14C - Brian Le Suer and Dave Laroche discuss **“Minimizing Maintenance in Test Automation”**. In this presentation, you learn: How to select application features for automation; a notation for creating automation-ready to use test plans; methods for dynamically identifying application objects and much more.

Session 14D – David Dwyer discusses **“The Papers of Downs and Tractenberg”**, an approach to the problem of modeling software testing in which the mathematical requirements for relaxing the various assumptions.

Session 14E – Kedar & Madhav Phadke discuss the **“Utilizing Design of Experiments to Reduce Software Testing Cost in the Financial Services and Information Technology (IT) Industries”**. They describe the change management process, case studies, and the basics of the OA-based testing process.

# ASQ - NEQC 58<sup>th</sup> Conference Program – Wednesday, October 20, 2010

7:30 - 8:00					REFRESHMENTS - EXHIBIT HALL				
8:00 – 9:00					KEYNOTE SPEAKER – Larry Acquarulo, CEO - PolyMedex Discovery Group TOPIC: Quality & Performance Journey to Operational Excellence				
9:00 – 9:10					BREAK - EXHIBIT HALL				
TRACK	TRACK 1 LEAN SIX SIGMA		TRACK 2 PROCESS		TRACK 3 MEDICAL		TRACK 4 RELIABILITY		
9:15 - 10:15	21A Steve Hodlin, Principal- Steven F. Hodlin & Associates  Lead With Lean, Follow with Six Sigma		22A Jack Reardon, Sr. Consultant, Quality & Productivity Solutions, Inc.  Transitioning to ISO 9001:2008 and Improvement		23A & 23B Jeff Boatman, Quality System Sr. SME, QPharma  FDA's Incoming Bombshell- the new Process Validation guidance		24A Aaron DerMarderosian, Sr. Electrical Eng. II with honors, Materials Eng. Raytheon Company Kenneth P Rispoli, Sr. Principal Engineer, Materials Engineering, Raytheon Company  Detection & Prevention of counterfeit Commercial & Mil-grade Electronics		
10:20-11:20	21B Jay Patel, President & CEO, Quality & Productivity Solutions, Inc.  Beyond Lean Six Sigma		22B Alex Elentukh- Sr. Engineering Program Manager, Computer Associates Corp.  Implementing Process Architecture				24B Harry Saraidaridis, Lead Reliability Engineer, iRobot  Service life estimation for electronic equipment		
11:25-12:25	21C Dr. Philip J. Ramsey, Professor at University of New Hampshire & operates the North Haven Group  Visual Six Sigma: Making Data Analysis Lean		22C Angelo Scangas, President Quality Support Group, Inc.  Supply Chain Risk Management: A Delicate Balancing Act		23C Jay Patel, President & CEO, Quality & Productivity Solutions, Inc.  ISO 13485 Auditing & Improvement		24C James Perreira, Engineering Fellow, WLED, Raytheon Company Philip Bedard, Engineering Fellow, Raytheon Company  Benefits of Collaborative Approach to RAM and Supportability Modeling		
12:30- 2:30					LUNCH & KEYNOTE SPEAKER: Bob Faw, Chief Ignition Officer - Matchbox Group TOPIC: Language of Influence (Ignite, Inspire & Influence People)				
2:35 - 3:35	21 D & 21 E – Jack Reardon, Sr. Consultant, Quality & Productivity Solutions, Inc.  Workshop: DOE		22D Bob Faw, Chief Ignition Officer, Matchbox Group  Workshop: Creating Passion for Change		23D Joe Azary, Manages the Quality & Regulatory Consulting Division at Orchid Design  Design Controls		24D Philip Scarff, Senior Reliability Engineer, Alcatel-Lucent  A New Approach to System-Availability Analysis: An Integrated Hardware, Software, and Procedures Model		
3:40 -5:00			22E Jason Krasowitz, Sr. Sales Rep., Minitab  What's New in Minitab 16		23E Dan O' Leary, President of Ombu Enterprises, LLC  Medical Device Production, Excel Spreadsheets, and Part 11 Compliance		24E David Cadge, Industry Lead- Electronics & Consumer Products, SIMULIA-Dassault Systemes Mark Kerrigan, Sr Business Development Mgr. SIMULIA-Dassault Systemes  Workshop – “Simulation & Reliability Prediction Utilizing Simulia for Electronics”		

## WEDNESDAY – OCTOBER 20, 2010 SESSIONS

### Track 1- Lean Six Sigma

Session 21A – Steve Hodlin describes how “**Lead With Lean, Follow with Six Sigma**” can improve processes by first applying lean thinking. His presentation focuses on the key concepts of lean, its benefits, as well as how to identify lean projects. Other topics Steve covers are Kaizen, 5S, continuous flow, and value stream mapping.

Session 21B – Jay Patel talks about “**Beyond Lean Six Sigma**”. He explains some of the advanced techniques that you need to compete in today’s market place, and how you can be proactive rather than reactive. He emphasizes the criticality of determining what is needed, and then discusses how to deploy these techniques.

Session 21C – Dr. Philip Ramsey speaks about “**Visual Six Sigma**”. Visual Six Sigma (VSS) is the next generation of Six Sigma. By using cases studies from healthcare, engineering, and manufacturing, he illustrates the three main stages of this new and powerful tool.

Sessions 21D & 21 E - Jack Reardon, through his “**Workshop – DOE**” presents you with the principles and the hands-on experience that you require to design experiments and apply DOE. This is a workshop that everyone can participate in.

### Track 2 – Process

Session 22A – Jack Reardon presents “**Transitioning to ISO 9001:2008 and Improvement**”. Jack gives you the techniques you can use to improve your Quality Management System, and shows you how to transition to ISO 9001:2008. Come and learn from Jack how to systematically manage the process approach, and how to transform ISO compliance into business performance excellence.

Session 22B – Alex Elentukh discusses the “**Implementation of a Process Architecture**”. The role of the Process Architect has grown into a mandatory part of software corporate culture. Architecture is defined as an interconnection among standard process elements, and then implemented using the SharePoint Process Asset Library.

Session 22C – Angelo Scangas talks about “**Supply Chain Risk Management: A Delicate Balancing Act**”. During his session, he emphasizes the shifting of geographical sourcing of supply towards outsourced, contracted manufacturing, and supply shortages. Angelo also examines direct and indirect suppliers, and discusses the additional risks they impose, along with some of the benefits they offer.

Session 22D – Bob Faw, during his “**Workshop- Creating Passion for Change**”, teaches you the Matchbox method of “*ignite, involve, inspire*”. He shows you how to create empowering partnerships with leaders, how to get everyone thinking, how to learn and contribute, and finally how to spark energy, creativity and productivity using fun.

Session 22E- Jason Krasowitz will provide information on the new “**Minitab 16**” The latest version includes more than seventy-two features & enhancements, including greater statistical power, a new menu – The Assistant- to guide you through your analysis, and increased speed.

### Track 3 – Medical

Session 23A & 23B – Jeff Boatman describes the “**Incoming Bombshell: FDA’s New Process Validation Guidance**”. In this session, Jeff discusses how the FDA stated that nothing from the new standard currently exists under Parts 211 & 820. Jeff also discusses how CDRH and the Medical Device division have aggressively moved ahead with its own process validation requirements under the separate authority granted by 21 CFR 820.75.

Session 23C – Jay Patel talks about “**ISO 13485 Auditing & Improvement**”. Jay demonstrates how to understand the auditing process under the ISO 13485 requirements, what audit trails are required, and how to conduct system, process, and product audits.

Session 23D – Joe Azary discusses “**Design Controls**”, what they are and what you need to know about them. Joe gives an overview of the design control process, including design planning, design organizational interface, design input/output, as well as verification and validation. He also talks about clinical evaluation, efficacy, safety, and design risk management.

Session 23E - Dan O’ Leary talks about “**Medical Device Production, Excel Spreadsheets, and Part 11 Compliance**”. In this session he discusses the pitfalls, and how to recognize when you are using software in production or the quality system. Dan also teaches you how to use Excel tools, about FDA requirements and expectations, the implications and requirements of Part 11 for electronic records, and the current guidance document.

### Track 4 - Reliability

Session 24A – Aaron DerMarderosian and Kenneth Rispoli discuss “**Detection & Prevention of Counterfeit Commercial & Mil-grade Electronics**”. Aaron and Kenneth cover the definitions of counterfeit electronics and its impact on the trade industry. During the session, they provide examples of counterfeit electronics, and present an overview of best practice strategies, best practice supplier selection, and in-coming inspection analysis.

Session 24B – Harry Saraidaridis explains “**Service Life Estimation Analysis**” by providing guidelines for performing a service life estimation analysis. He talks about establishing service life requirements and goals, and also discusses key factors and field system usage, as well as how these factors can influence a systems’ service life.

Session 24C – Philip Bedard and James Perreira talk about “**Benefits of Collaborative Approach to RAM and Supportability Modeling**” by highlighting the sensitivities and the relationships between the RAM and supportability parameters. They discuss the omissions and the pitfalls of common assumptions, make a case for a more collaborative approach, and introduce process flow.

Session 24D – Philip Scarff explains “**A New Approach to System - Availability Analysis: An Integrated Hardware, Software, and Procedures Model**”. He discusses system and model, comparisons to field data, analysis, sensitivity analysis, along with applications and comments. Finally, Phillip provides a summary of future work.

Session 24E – David Cadge presents “**Workshop: SIMULIA Analysis Toolset for Electronics (Dassault Systemes)**”. David focuses on the capabilities of the Abaqus Unified FEA product suite. During the session, you learn more about how the Abaqus Unified FEA product suite improves a company’s workflow.