

Conference Agenda

2016 Conference and Expo, Annapolis, MD

Track 1	Specialty Training
Track 2	Quality & Regulatory Compliance
Track 3	Multi-Platform Training



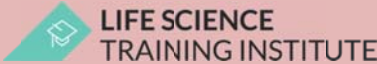
Learning Tracks Sponsored by








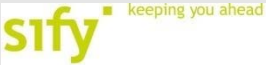





SUNDAY, September 25, 2016

6:00 pm - 8:00 pm	Registration (Main Concourse)
7:00 pm - 10:00 pm	<p>Welcome Reception Guitarist/Musician - Tyler Carson (Mainsail East)</p> <p>Sponsored by </p>

MONDAY, September 26, 2016

7:30 am - 8:30 am	Registration (Main Concourse)			
7:30 am - 8:30 am	<p>Continental Breakfast (Main Concourse and Mainsail Main & West) (Mainsail Main & West)</p> <p>Sponsored by </p>			
8:30 am - 10:00 am	Exhibits Open	<p>Opening Ceremonies / Keynote Address</p> <p>"Think Like An Olympian – How to Overcome Life's Obstacles!"</p>  <p>JOHNNY QUINN THINK LIKE AN OLYMPIAN (Mainsail Main & West)</p> <p>Sponsored by </p>		
10:15 am - 11:30 am		<p>The Many Voices of Instructional Content Daniel Duncan, Rowan Tree Studio (Mainsail East)</p>	<p>Onboarding Programs for GXP, Maryann Fox, Training Specialist (Mainsail Main)</p>	<p>Industry Best Practices for SOP Writing & Training Terry McGinn, VP - Skillpad (Mainsail West)</p>
11:45 am - 12:30 pm		<p>Lunch Break (Leeward)</p> <p>Sponsored by </p>		
12:45 pm - 2:00 pm	<p>Investigating Operator Errors Brian Krenc, Director, Learning and Development, Renaissance Pharma (Mainsail East)</p>	<p>The Challenges of Writing in FDA-Regulated Industry Jack Garvey, Founder and CEO, Compliance Architects LLC (Mainsail Main)</p>	<p>E-Learning in a GXP Environment Susmit Banerjee Director Business Development Sify Corp (Mainsail West)</p>	

MONDAY, September 26, 2016 (cont.)


<p>2:15 pm - 3:30 pm</p>	<p>Training for the Pharma Labs: Would the Pokémon GO Model Work? Kim Huynh-Ba Pharmalytik (Mainsail East)</p>	<p>The Evolution of the R & D Qualified Person Phillipe Dekeyser, QA Director, EU Qualified Person, BMS (Mainsail Main)</p>	<p>Training Effectiveness and the Brain Chrissy Frey, Associate Director, Compliance Learning, PTC (Mainsail West)</p>
<p>3:45 pm - 4:45 pm</p>	<p>Serialization Overview and Operator Readiness Patrick Boyle, President Skillpad (Mainsail East)</p>	<p>3D Printing, John Padfield, Professor, Purdue University (Mainsail Main)</p>	<p>How Effective are You With Your Training? Ken Petelinkar Associate Director Compliance Systems BMS (Mainsail West)</p>
<p>5:00 pm - 6:00 pm</p>	<p>Vendor and Networking Reception with Prize Baskets (Main Concourse) Sponsored by</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  </div> <div style="text-align: center;"> <p>Performance. At a higher level.</p>  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div>		
<p>6:30 pm - 8:30 pm</p>	<p>Theme Dinner - Murder Mystery Co. (Mainsail East) Sponsored by</p> <div style="display: flex; justify-content: center; align-items: center;">   </div>		

TUESDAY, September 27, 2016

7:30 am - 8:30 am	Registration (Main Concourse)		
7:30 am - 8:30 am	Continental Breakfast (Main Concourse and Mainsail Main & West) Sponsored By 		
8:30 am - 10:00 am	<p style="text-align: center;">Leadership and Communication Landmines</p> <p style="text-align: center;">Marty Clarke Author & Motivational Speaker (Mainsail Main & West)</p> <p style="text-align: center;">Sponsored by </p> 		
10:15 am - 11:45 am	Situational Awareness for Manufacturing Personnel Patrick Boyle, President, Skillpad (Mainsail East)	Device Regulations and their Impact! Himanshu Naik, QA Manager, BMS (Mainsail Main)	Data Integrity <i>John Lewis, Assoc. Dir. Operational Excellence, Merck & Co., Inc. and Jack Garvey, Founder and CEO, Compliance Architects LLC</i> (Mainsail West)
12:00 pm - 12:45 pm	Lunch Break (Leeward) Sponsored by 		
1:00 pm - 2:15 pm	<p style="text-align: center;">FDA G-SRS: Developing Global Data Standards and Systems to Define Substances and Specifications Larry Callahan, FDA Chemist FDA -Office of Health Informatics, Office of Chief Scientist, Office of the Commissioner (Mainsail Main & West)</p>		
2:15 pm - 3:30 pm	<p style="text-align: center;">FDA New Inspection Protocol Project (ORA and CDER) Ernie Bizjak, Regulatory Compliance Officer FDA -Office of Regulatory Affairs (ORA) (Mainsail Main & West)</p>		
3:45 pm - 5:00 pm	Designing an Interactive Professional Development Workshop for the Learning Professional: A Case Study Sara Baletsa, Learning Manager, R&D Learning, Bristol Myers Squibb & Cate Fry, Learning Manager, R&D Learning, Bristol Myers Squibb (Mainsail East)	USP Compendial Approaches to Characterization of Biologics and Training Opportunities Maura C. Kibbey, Ph.D., Director of Science & Standards, USP Global Biologics, U.S. Pharmacopeial Convention (USP) (Mainsail Main)	SIGMA Tools Used in the Compliance World, John Padfield, Professor, Purdue University (Mainsail West)
	Free Night - Dinner on Your Own		

Exhibits Open

WEDNESDAY, September 28, 2016

7:30 am - 8:45 am	Registration (Main Concourse)		
7:30 am - 8:45 am	Continental Breakfast (Main Concourse and Mainsail Main & West)		
8:15 am - 8:45 am	Prize Awards (Mainsail Main & West) Sponsored by  <small>Web-based Mentoring Tool</small>		
9:00 am - 10:15 am	<p>Lab Analyst Training & Certification Program Vincent Ranieri, J&J</p> <p>(Mainsail East)</p>	<p>Regulatory Trends & Updates for 2016 (Mainsail Main) Maryann Fox, Training Specialist</p> <p>(Mainsail Main)</p>	<p>Engaging the Modern Learner Elena Coarse, Director of Business Development, SCRIMMAGE, and Tammy Cullen, Learning and Development Manager, Eli Lilly</p> <p>(Mainsail West)</p>
10:30 am - 11:45 am	<p>A System Model for the Learning Function Brad Shike, Principal, Polyhedron Performance Solutions LLC</p> <p>(Mainsail East)</p>	<p>Maximizing the Business Value of Your Compliance Training Sheri Winter, Dir. Client Development, Caveo Learning</p> <p>(Mainsail Main)</p>	<p>Industry Best Practices for SOP Writing & Training Terry McGinn, VP - Skillpad</p> <p>(Mainsail West)</p>
11:45 am - 12:15 pm	<p>Closing Ceremonies (Mainsail Main & West)</p>		

Johnny Quinn is a professional speaker and travels the globe to inspire audiences by delivering thought-provoking and action-packed messages to businesses, schools and organizations. He is a United States Olympian in the sport of bobsled and competed at the 2014 Winter Olympics in Sochi, Russia. Johnny is also a former professional football player spending time with the NFL's Buffalo Bills, Green Bay Packers and Saskatchewan Roughriders of the CFL. He is one of three people to have played in the NFL and competed in the Winter Olympics. Johnny is the founder of TheAthleteWatch.com, an online pro-active leadership course that helps student-athletes and their families search for scholarships.






Marty Clarke

As a wickedly funny and painfully honest professional speaker, Marty Clarke's compelling keynote speeches, workshops and seminars continue to draw large and enthusiastic audiences worldwide. As a Leadership consultant Marty and his team work closely with leadership teams who have the vision and backbone to make the changes that yield material improvements in real time.

Marty is the founder of Martin Productions (www.martyclarke.com), a highly successful consulting firm, through which Marty and his staff focus on keynote speeches, live training events, custom curriculum development and on-line training programs.\

Marty received his BA in English from Lafayette College, Easton, Pa.

	<p style="text-align: center;">Sara Baletsa, Learning Manager, R&D Learning, Bristol Myers Squibb</p> <p>Sara is a Learning Manager at Bristol-Myers Squibb in the R&D Strategy & Planning organization. In her role, Sara partners with internal and external stakeholders to identify organizational learning needs, design and develop creative learning solutions. Sara holds a Masters Certificate in Instructional Systems Design from the University of Maryland Baltimore County and is currently pursuing her Master's in Business Administration at the University of Connecticut.</p> <p><u>Designing an Interactive Professional Development Workshop for the Learning Professional</u></p> <p>Instructional designers and other training professionals focus their time on developing the knowledge and skills of employees but they also need to take the time to develop their own knowledge and skills. How do you create an engaging learning experience to develop the skills of a team training professionals with varying degrees of experience and expertise? That's the question that Bristol-Myers Squibb's (BMS) R&D Learning team faced. The solution was the "Learning Lab" a hands-on, immersive workshop for building capabilities of R&D Learning's team of training professionals through practice and peer knowledge-sharing. In this experiential learning program, teams worked together to on a fictional scenario to bring a training project through the entire project lifecycle, from identification of a need through implementation and evaluation. This presentation will review the Learning Lab strategy and model, share lessons learned from implementation, and discuss how the model can be applied to diverse audiences to onboard, upskill and expand job development.</p> <p>Tuesday 27Sep2016 3:45 pm - 5:00 pm Mainsail East</p>
	<p style="text-align: center;">Susmit Banerjee Director Business Development Sify Corporation</p> <p>E-Learning in a GXP Environment</p> <p>Monday 26Sep2016 12:45 pm - 2:00 pm Mainsail West</p>
	<p style="text-align: center;">Ernie Bizjak, Regulatory Compliance Officer FDA -Office of Regulatory Affairs (ORA)</p> <p>Ernie Bizjak joined the U.S. FDA in June 2001 and began as an Investigator in the New Jersey District - North Brunswick Resident Post, primarily focusing on drug manufacturing/CGMP inspections. After a brief two and half year transfer to the Detroit District - Indianapolis Resident Post, he became a Drug Specialist in the Baltimore District in February 2008. He achieved Level III/Pharmaceutical Inspectorate certification in July 2010. In February 2012, he accepted a Compliance Officer position in the Baltimore District. He handles many complex cases for all commodities regulated by FDA. These cases have resulted in regulatory actions such as a Consent Decrees, seizures, and Warning Letters. He continues to participate in domestic and foreign inspections whenever possible. Ernie graduated from the University of Wisconsin - Madison with a B.S. degree in Pharmaceutical Science (Go Badgers!).</p> <p style="text-align: center;">New Inspection Protocol Project (ORA and CDER)</p> <p>Tuesday 27Sep2016 2:15 pm - 3:30 pm Mainsail East & Main</p>



**Patrick Boyle,
President Skillpad**

Patrick Boyle spent 13 years in the Canadian Air Force, with two active duty tours flying jets in Training and Combat Support roles. He then joined a major aircraft manufacturer and spent the next 15 years as an instructor pilot, check pilot (examiner/inspector) and test pilot, with the final 3 years as manager of a flight test center in an aircraft production facility. During that time, Patrick designed and certified aircraft pilot training programs where complex technology and human factors had to be combined for effective and safe operations. In 2014, Patrick joined Skillpad, a leading Life Sciences Knowledge Management company, and began working on Serialization, which had been implemented in the Aerospace Industry since 2002, to combat the problem of counterfeit aircraft parts. Patrick brings the Aerospace Industry's proven Situational Awareness approach to the challenge of training Pharmaceutical and Biotech plant employees for the realities of working in the world of complex automated and interdependent systems.

Serialization Overview and Operator Readiness

Starting on 27 November, 2017 the Drug Supply Chain Security Act will require all prescription drug products in the United States to have unique serial numbers so they can be tracked and traced from the Manufacturer through to the Wholesalers, Distributors and Dispensers. This regulation introduces new systems and processes that touch many aspects of pharmaceutical manufacturing - not just the packaging lines and warehouses, but other departments like Quality, Production, IT, Maintenance, and Engineering. The industry effects will be felt from the Corporate and Enterprise levels all the way to Contract Packagers and Manufacturers. Pharmaceutical manufacturing employees will need to understand the new regulations, technology and terminology in order to function effectively and consistently in this new environment.

Monday 26Sep2016 3:45 pm - 4:45 pm Mainsail East

Situational Awareness for Manufacturing Personnel

This presentation on Operator Readiness suggests using the proven concepts of Situational Awareness, borrowed from the Best Practices of the Aerospace industry, to address the needs of today's Pharmaceutical plant personnel.

Tuesday 27Sep2016 10:15 am - 11:45 am Mainsail East



**Larry Callahan, FDA Chemist
FDA -Office of Health Informatics, Office of Chief Scientist, Office of the
Commissioner**

**G-SRS: Developing Global Data Standards and Systems to Define Substances
and Specifications**

Tuesday 27Sep2016 1:00 pm - 2:15 pm Mainsail East & Main



**Elena Coarse,
Director of Business Development, SCRIMMAGE**

As Director of Business Development, Elena offers considerable leadership experience within the training and development industry to engage and extend Scrimmage's customer base. Over her twelve years in the learning industry, she has spearheaded corporate training initiatives with hands-on instruction and guidance for Dale Carnegie Training, as well as other technical and soft skills organizations. Elena has an extensive background building relationships and streamlining training processes for SMBs to high value clients from the enterprise level.

Engaging the Modern Learner

With Tammy Cullen, Learning and Development Manager, Eli Lilly

Today, the workplace consists of five different (and very distinct) generations. In fact, many organizations have over a 50 year age gap between the youngest and oldest employee. Meanwhile, each generation in the workplace has their own perspective, their own rules, their own working style - and their own approach to technology. Yet, in order for an organization to be productive, it is imperative for all of the generations to leverage technology as a group for learning, knowledge sharing, efficiency, as well as their own talent development. However, finding the right technology for every generation and working style has been a significant challenge, no matter the industry, the department, or the company culture. This presentation will focus on understanding the generations and how to maximize technology across today's workplace, so ultimately everyone learns together and learns from each other.

Wednesday 28Sep2016 9:00 am - 10:15 am Mainsail West



**Tammy Cullen,
Learning and Development Manager. Eli Lilly**

Tammy has a PhD in Instructional Systems Technology from Indiana University and over 25 years of experience creating and conducting performance improvement programs. Currently she is a Manager of Learning & Development with Eli Lilly, with a team that supports the Product Research and Development. She began her career in public education as a mathematics teacher and Staff Development Coordinator.

Engaging the Modern Learner

with Elena Coarse, Director of Business Development, SCRIMMAGE

Wednesday 28Sep2016 9:00 am - 10:15 am Mainsail West



**Phillippe Dekeyser,
QA Director, EU Qualified Person, BMS**

Pharmacist, PhD in Pharmacy, Certification QP in Belgium

The Evolution of the R & D Qualified Person

What is a Qualified Person or QP? Have you always wanted to know what a QP is and what these people do? Well now is your chance to hear about the role of the certifying QP and what it takes to become a Qualified Person. This session will discuss these responsibilities and the evolution of the QP over the last decade. Come hear from a BMS IMP Qualified Person and learn what these individuals do to ensure quality of our investigational medicinal products.

Monday 26Sep2016 2:15 pm - 3:30 pm Mainsail Main



**Daniel Duncan,
Rowan Tree Studio**

Since 1998, Duncan has designed and developed over 600 custom learning programs for Johnson & Johnson, Apple, Eli Lilly, Genentech, Zimmer, and Visa. He is an Apple Certified Master Trainer and earned a Master of Science Degree from Purdue University in Learning Design and Educational Technology. He also taught high school biology and applied life sciences courses for five years.

The Many Voices of Instructional Content

Training programs tend to be "one-size fits all." But the needs of the audience vary greatly. There is power in tailoring the messaging of a course to meet these specific needs based on self-identification and logic. This presentation will introduce the eight essential voices and offer practical examples of how to develop impactful programs using logic and variables in e-learning courseware.

Monday 26Sep2016 10:15 am - 11:30 am Mainsail East



**Maryann Fox,
Training Specialist**

Maryann has extensive experience in the pharmaceutical and consumer healthcare industries as a Training Manager at McNeil Consumer Healthcare and as a Training Manager and Knowledge Management Analyst at GlaxoSmithKline. She has also worked as a consultant to the pharma and biotech industries. She has designed and implemented Training Systems and Learning Management Systems (LMS), developed Onboarding programs for new hires, and developed and delivered GMP new hire and GMP refresher training programs. Areas of expertise include Training Strategy, Learning Management System implementation, Instructional Design and Curriculum Design. She has a special interest in Root Cause Analysis attributed to Human Error, and Training Effectiveness.

Onboarding for GXP

In this interactive workshop, you will learn why it's important to engage new hires as soon as possible, and identify key elements for successful onboarding in GXP industries.

Monday 26Sep2016 10:15 am - 11:30 am Mainsail Main

Regulatory Trends and Updates for 2016

During this presentation, we'll discuss how you can identify GMP trends and review trends for 2016. We'll also discuss what you need to do about GMP trends, once you've identified them.

Wednesday 28Sep2016 9:00 am - 10:15 am Mainsail Main



**Chrissy Frey,
Associate Director, Compliance Learning, PTC**

Chrissy Frey graduated with her Executive MBA from the Jack Welch Management Institute (JWMI) and earned her Bachelor Science in Biology from Pennsylvania State University (PSU). In addition, Chrissy has a secondary teaching certificate from York College. Combining this education with over 20 years of pharmaceutical experience, ranging from large to start-up biological and pharmaceutical companies, she brings a plethora of experience, knowledge, and excitement to evaluating business and learning opportunities. She is a motivating and proven leader that successfully implements strategic goals and visions while aligning with business needs. Chrissy’s personal philosophy in life is that continuous improvement is mandatory for success and is a life-long process. Seeking new opportunities and challenges, as well as, growth and development learnings for her teams and self are just one of the many facets of her ideology

Training Effectiveness and the Brain

Looking to find an easier way to determine training effectiveness? Let's begin by examining the adult brain and how by making a few changes in our instructional design can make our trainings more effective.

Monday 26Sep2016 2:15 p. - 3:30 pm Mainsail West



**Cate Fry
Learning Manager, R&D Learning, Bristol Myers Squibb**

Engaging the Modern Learner

with Tammy Cullen, Learning and Development Manager. Eli Lilly

Tuesday 27Sep2016 3:45 pm - 5:00 pm Mainsail East



**Jack Garvey,
Founder and CEO, Compliance Architects**

The Challenges of Writing in FDA Regulated Industry

Despite being one of the most regulated industry sectors in the world, attention to and training on even basic writing practices within most FDA-regulated companies is almost non-existent. With extensive requirements for bulletproof communication of complex technical and scientific concepts, and documentation required for almost every operational activity, highly-technical personnel struggle to write to the appropriate audiences, and to choose the proper writing styles and techniques to effectively support great compliance outcomes. Even more striking is that many documents are never written with the anticipation and knowledge that an FDA Investigator will likely read them in the future and evaluate them for deficiency during an FDA inspection!

This short, one-hour overview program explores the problem of writing within FDA-regulated industry, including why most people writing compliance documents don't write well; the impact of poor writing to inspection (and by derivation) compliance outcomes; along with FDA 483 and Warning Letters showing writing deficiencies. In addition, the program examines a few tips and approaches for improving writing outcomes.

Monday 26Sep2016 12:45 pm - 2:00 pm Mainsail Main

Data Integrity

With John Lewis, Assoc. Dir. Operational Excellence, Merck & Co., Inc.

Tuesday 27Sep2016 10:15 am - 11:45 am Mainsail West



Kim Huynh-Ba
Executive Director & CEO
Pharmalytik

Kim Huynh-Ba is the Executive Director and CEO of Pharmalytik, which provide training and consulting services for pharmaceutical companies in US and internationally since 2003. She has over 25 years of expertise in areas of GMPs, Quality Systems, Regulatory and Compliance, Stability Sciences and Risk Management. Prior to Pharmalytik, she was the Director of Pharmacopeial Education Department of U.S. Pharmacopeia (USP), where she was responsible for their education programs worldwide. Kim has held several technical and management positions at Astra Zeneca (formerly ICI Americas), DuPont Merck, DuPont Pharmaceuticals, Bristol Myers Squibb and Wyeth Vaccines. She is an Adjunct Professor at Temple University-School of Pharmacy, Widener University and Illinois Institute of Technology (IIT) teaching pharmaceutical analysis, quality audit, GMP regulations and analytical chemistry graduate courses. She is also a short course instructor of ACS Professional Education and Sci-Mind programs. Kim has edited 2 book volumes and numerous publications. She is a member of the Editorial Board of AAPS Open Journal and the Pharmaceutical Chemistry Journal. She is also a national and international speaker of regulatory and compliance topics for the pharmaceutical industry. Kim has been an ACS member since 1987, and currently is an Alternate Councilor of ACS DE section. Kim is a member of the Executive Committee of Governing Board of Eastern Analytical Symposium (EAS) and was their 2013 President. She is a member of the USP Council of Experts, chairing the Chemical Medicine IV Expert Committee.

Training for the Pharma Labs: Would the Pokémon GO Model Work?
Personnel Qualification plays an important role in the Pharma laboratories. Every year, Pharma industry spends millions of dollars in training their employees to conduct activities in the GMP labs; however, warning letters and observations are continue to surround training areas. Different skill sets are necessary due to the challenges and complex of pharma industry, thus require solid training program. In addition to a scientific background, analyst must have different types of training are necessary from laboratory skills, documentation skills, writing skills, etc... Pokémon Go is a new game based on a cell phone has taken over our country by the storm. This game is to develop “Pokémon Trainer”, and it has gaining incredible momentum and interest from many age groups. So a discussion will be made to understand the concepts behind the game and see what we can adapt to the training process.

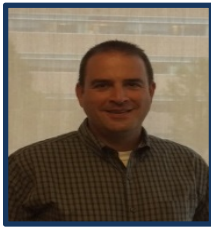
Monday 26Sep2016 2:15 pm - 3:30 pm Mainsail East



Brian Krenc, Director,
Learning and Development, Renaissance Pharma

Investigating Operator Error
A novel approach to identifying root causes in cases where operator error is the initial conclusion in order to identify system/process failures

Monday 26Sep2016 12:45 pm - 2:00 pm Mainsail East



**John Lewis,
Assoc. Dir. Operational Excellence, Merck & Co., Inc.**

John has over 25 years' experience with diversified talents in International, Federal, State and Local quality and compliance standards and regulations within the life science industries. He is a Sigma Black Belt and is currently working together with the Board of Directors, uniting individuals with a passion and concern for quality, compliance, education and training. John was the former CEO and Chairman of the Board of the GMPTEA and BOD member at large of American Red Cross, Jersey Coast Chapter.

Data Integrity
with Jack Garvey, Founder and CEO, Compliance Architects LLC

Tuesday 27Sep2016 10:15 am - 11:45 am Mainsail West



**Terry McGinn,
Vice-President, Skillpad**

Terry is a compliance leader who is creative and motivates individuals with an ability to manage, organize, prioritize, coordinate, and successfully accomplish all managerial assignments; particularly effective in securing the cooperation of others by providing a clear understanding of how to meet corporate objectives and achieve personal goals

Industry Best Practices for SOP Writing & Training
In this presentation, we'll take a look at how easily SOPs can be written and yet, how often they are misunderstood, in a GMP, GLP, and GCP environment. We'll discuss the different formats that are used and why.

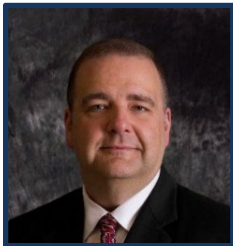
Monday 26Sep2016 10:15 am - 11:30 am Mainsail West
Wednesday 28Sep2016 10:30 am - 11:45 am Mainsail West



**Himanshu Naik,
QA Manager, BMS**

Device Regulations and their Impact!
FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. This presentation addresses the basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with which include Establishment Registration, Device Listing, 501k and PMA, IDE and QS regulation, Labeling and MDR

Tuesday 27Sep2016 10:15 am - 11:45 am Mainsail Main



**John Padfield,
Professor, Purdue University**

Jon is a Lean Six Sigma Master Black Belt with over 23 years' experience in industry leading medical device, automotive, and security products companies and 4 years' experience running his own process improvement consulting business. Jon's work experience includes 14 years of Lean Six Sigma project work, teaching and mentoring. Jon has also designed and delivered corporate training on quality and productivity improvements to over 50 companies across 4 continents. Jon's university teaching experience includes 7 years of part-time teaching in Purdue University's Weekend Masters Program where he taught graduate courses in Industrial Organization, Project Management, Statistics, Business Strategy, Quality & Productivity, and Engineering Economics. Jon brings with him strong communication skills including presentations, writing, group training and one-on-one mentoring. Jon has extensive experience working with employees at all levels from the manufacturing floor to executive management.

3D Printing

Monday 26Sep2016 3:45 pm - 4:45 pm Mainsail Main

SIGMA Tools Used in the Compliance World

Tuesday 27Sep2016 3:45 pm - 5:00 pm Mainsail West



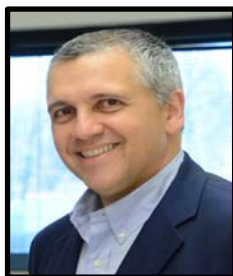
**Ken Petelinkar,
Associate Director, Compliance Systems, BMS**

Ken is a veteran learning and development professional with over 18 years' experience in the pharmaceutical industry leading high-performance teams. Ken's central focus is continuous improvement of skills and knowledge while balancing risk and compliance. Ken is a former GMPTEA Mid-Atlantic chapter president and active participant within the L&D, OD, Training, and Quality communities.

How Effective are You With Your Training?

We will look into the regulations on personnel qualification requirements and how we can actually determine if knowledge transfer has occurred. We will dissect the CFR regulations and seek to understand the expectations. We will overlay the Kirkpatrick model on these regulations to determine best practices for ensuring our people can perform their assigned functions. Finally we will review some benchmarking data across the training spectrum that can be used to identify how we are doing.

Monday 26Sep2016 3:45 pm - 4:45 Mainsail West



**Vincent Ranieri,
J&J**

Vincent A. Ranieri has been an employee of Johnson & Johnson for nearly 14 years. He began his JNJ career as an Assistant Scientist in 1999 with Janssen Pharmaceutica and is now the Manger, Laboratory Analyst Training & Certification Program, LATCP. He has over 25 years of medical, environmental and pharmaceutical analytical chemistry experience. Vince has over ten years of pharmaceutical sector experience being a leader in dissolution testing. He has earned a dissolution certification from United States Pharmacopoeia (USP) and has over 40 hours of outside dissolution training. From 2009 - 2012, Vince accepted a role as QA Training Manager in medical devices working for Integra LifeSciences putting together a compliant training system that passed challenges from U.S. FDA and several notified body assessments. A key strength is being the voice of quality and driving importance of GMPs. Vince holds a BS in chemistry from Le Moyne College in Syracuse, New York and has earned a Training Manager/Director certification from Langevin Learning Services.

Lab Analyst Training & Certification Program

Wednesday 28Sep2016 9:00 am - 10:15 pm Mainsail East



**Brad Shike,
Principal, Polyhedron Performance Solutions LLC**

Mr. Shike is a performance consultant at Polyhedron Performance Solutions LLC, a company that he formed in 2013. Prior to forming Polyhedron Performance Solutions, Mr. Shike had a 22 year career supporting pharmaceutical manufacturing operations at Merck & Co., Inc. where he worked in quality operations, pharmaceutical production supervision and training. He has particular expertise in designing, developing, and implementing technical curriculum and programs to support employee development that ensure regulatory compliance. His experience in training spans solid dosage manufacturing and packaging, sterile formulation / filling, and vaccine manufacturing. He utilizes Lean Six Sigma principles to optimize training administration and records management. Mr. Shike also effectively leads and develops project teams. Mr. Shike earned his BS in Engineering from the US Military Academy at West Point and left the Army as a Captain after assignments in Field Artillery and Psychological Operations. He earned his MA in Management from Webster University while in the Army and has also taken Master's level coursework in Instructional Design from Penn State University (Great Valley).

A System Model for the Learning Function

In this presentation I will introduce a system model showing nine critical elements, that when appropriately addressed, provides a road map to build and maintain an effective learning function. As we progress through each of the nine components of the model, I will provide recommendations that provide the basis for a strategic learning plan designed to effectively address the needs of organizations of all sizes. Utilizing this learning system model, each participant will have the opportunity, during the course of the presentation, to identify strengths and improvement opportunities they can apply in their own learning organization.

Wednesday 28Sep2016 10:30 am - 11:45 am Mainsail East



**Sheri Winter,
Dir. Client Development, Caveo Learning**

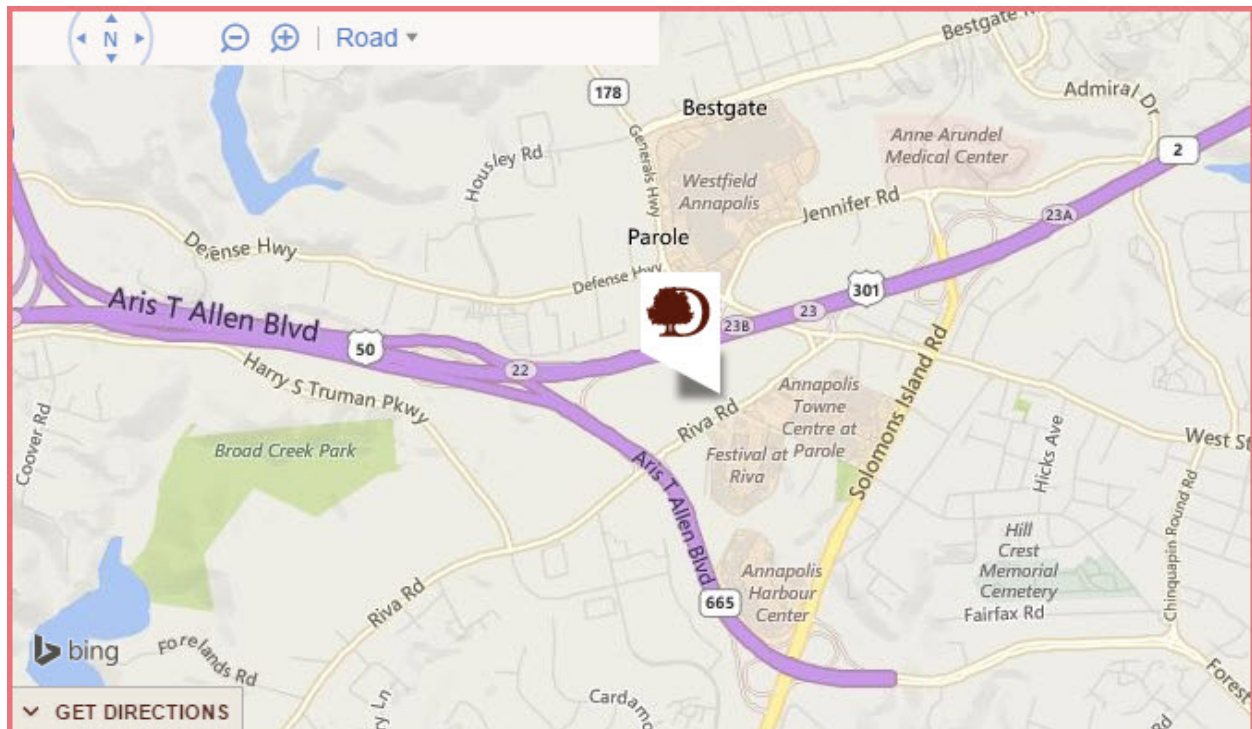
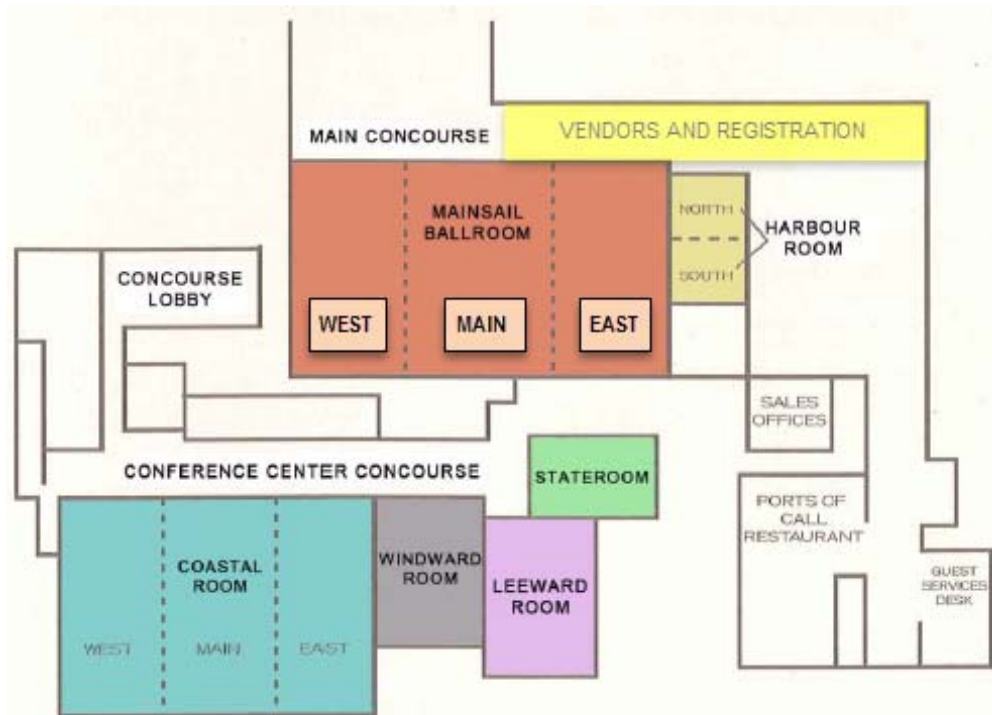
As Director of Client Development at Caveo Learning, Sheri is working directly with senior learning leaders and the business, helping them create learning strategies and solutions that deliver measurable impact to their organization's goals, with a focus on strategic learning consulting, learning & performance solutions, and learning technologies. Her experience as a thought leader, published author of many learning industry magazine articles, conference speaker, workshop/webinar leader and blogger has created a network of learning professionals and business leaders that are passionate about creating value for their organizations. Sheri has a BA in Communications and more than 30 years' experience in learning and media.

Maximizing the Business Value of Your Compliance Training

Every organization has a requirement to provide a certain level of compliance training to their workforce. Why not use this training opportunity to also improve the performance of that workforce? If you're investing the time, energy, effort and money anyway, you might as well make the experience active, engaging, and worthwhile for the learner and add actual value to the business. This interactive session will offer some examples of how you can take everyday compliance topics in GXP and use those training interventions to ensure that your workforce is not only compliant, but able to reduce your risk as an employer by being able to apply these principles in their jobs. You'll learn how to use technology to engage learners by applying what they have learned in a safe, virtual environment, assessing their own ability to make the right calls in compliance related decisions. You will also get a chance to take a compliance topic and create an engaging exercise that will offer an opportunity to improve workforce performance. Some samples of e-learning courses that use this performance-based approach will be shared. A final Q&A session will wrap it up.

Wednesday 28Sep2016 10:30 am - 11:45 am Mainsail Main

Map of Conference Floor Plan and Location



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