

The intention of this course is to go through the process of designing an experiment without the high intensity of mathematics/statistics. This will be an *introduction* to the DOE process. A statistically designed experiment is an excellent tool for helping identify the important factors/variables in any process. Not only can it help identify these factors/variables but it will help you understand how these factors influence each other when taken as a whole.

This short course of Design of Experiments is for people not acquainted with the DOE process, but who are interested in the process. No heavy statistical calculations are required, that is left for the statistician/engineer once the experimental runs are completed and data collected. However, mean, standard deviation, variance and analysis of variance with the F test will be reviewed. They will help you understand what is involved in a designed experiment process.

An experiment will be designed, conducted and analyzed in class.

A designed experiment is accomplished by the following steps:

- Determine who should be involved in design
- Brainstorming
- Design the experiment
- Conduct the experiment
- Collect data
- Analyze data
- Interpret the results
- Confirm experiment
- Report

**Bio: Vincent Vezza** has over thirty-five years in industry. He is retired from Ortho Clinical Diagnostics, a Johnson and Johnson Company. He now is an independent consultant. He has held positions as Statistician, Quality Engineer and Process Engineer at Eastman Kodak Company and Ortho Clinical Diagnostics a Johnson and Johnson Company. He holds a MS degree in applied and mathematical statistics and a BS degree in chemistry from Rochester Institute of Technology.

Contact Vince Vezza at [vincevezza@frontiernet.net](mailto:vincevezza@frontiernet.net) if you have further questions regarding the Class

**MICHELLE BONN**

Is your company manufacturing or planning to manufacture a medical device? Learn how FDA and ISO are blending manufacturing quality system requirements.

New international regulatory standards; ISO 13485:2016 and The upcoming Medical Device Single Audit Program (MDSAP)— are placing an even tighter grip on today's quality management processes. Learn how these new rules and revisions stretch throughout the QMS, especially for those managing large networks of suppliers and vendors. Document control, supply chain, product lifecycle, medical device risk assessments, device usability and post-market surveillance requirements will all be affected.

**Bio: Michelle Bonn**, President, Guideline Medical- an FDA regulatory and compliance consulting firm. Michelle's international business and medical manufacturing career has involved leading large-scale medical and industrial manufacturing projects across the US, Asia and Europe. She has led a variety of projects including; ISO-13485 certifications, medical device risk assessments, medical facility audits, FDA regulatory clearances, establishment registrations and Health Canada Medical Device License registrations. Her manufacturing expertise is focused on FDA Quality System Regulations, ISO standards and Six Sigma Quality methods.

She has worked in China, Hong Kong, Singapore, Iceland, Italy, Mexico, and the US. She is a certified, Six Sigma Black Belt and holds an MBA with a focus on strategic planning. Michelle has successfully completed RAPS medical-device regulatory certificate programs and is an active member of MedTech in Upstate New York.

A Method to Quantify the Influence of Fused Deposition Modeling Process Variables on Print Quality  
*Shu Chang, Christopher Lewis, Heng Li, Luiza Mol, Robert Parody and Drew Walters*

Fused deposition modeling (FDM) 3D printing constructs parts by delivering thermoplastic materials first line-by-line and then layer-by-layer. Several factors contribute to deviations of the printed part from the computer-aided design (CAD) 3D solid model. For example, as the extruded viscoelastic polymer exits the nozzle its diameter increases due to a phenomena known as die swell. Moreover, as the filament contacts the layer below to form a line, the cross-sectional area of the thread changes its circular shape to a trapezoid due to plastic flow. Finally, material specific volume changes during cooling and solidification contributes to deviations from the ideal part geometry. These phenomena are highly dependent on the printer, material and processing parameters used. A methodology to characterize shape quality of 3D printed parts will be presented where Geometric Element Test Targets (GETTs) consisting of an array of geometric features are printed and compared to the solid model geometry. The measurement system consists of a CAD target design, an FDM printed test target, an optical microscope and a standard operating procedure. A case study demonstrating the ability of this measurement technique to characterize the influence of various FDM processing parameters on print quality of biodegradable polymer blends based on polylactic acid (PLA) and polycaprolactone (PCL) will also be presented. Here a Taguchi experimental design is utilized where nozzle temperature, extrusion multiplier, slice height and print speed are systematically varied and 2D print quality is determined by comparing the area of digitally processed images to that defined by the CAD model.



**Bio: Shu Chang** is an Associate Professor at Clemson University in the Department of Graphic Communications. Prior to joining Clemson, Shu held the Melbert B. Cary Jr. Distinguished Professorship in Media Sciences at Rochester Institute of Technology. Shu worked in printing technology research and development at Xerox for over 20 years. Her work at Xerox spanned from printing technologies and materials science research to sustainability in printing and market explorations. Her expertise extends to process and materials systems, lean six sigma, modeling and simulation, and materials characterizations. Shu holds over 25 U.S. Patents and patent applications as well as over 40 publications. Shu obtained her Ph.D. in Materials Science from the University of Minnesota. Her research identifies techniques to bridge the system aspects of conventional digital printing to the rapidly growing field of additive manufacturing.



**Christopher L. Lewis** is an Assistant Professor at the Rochester Institute of Technology in the Manufacturing and Mechanical Engineering Technology Department. He holds a B.S. in Plastics Engineering Technology (Pennsylvania College of Technology), an M.S. in Polymer Engineering (University of Tennessee-Knoxville) and a PhD in Chemical Engineering (University of Rochester). Prior to joining RIT Chris worked for 10 years in the plastics industry engaged in materials and product development. His current research interests include shape memory and self-healing polymers, polymer composites, and additive manufacturing.

### Aligning People, Process and Strategy to Achieve Your Goals.

Organizations face unprecedented challenges in today's economy including: limited resources, constant pressure to lower costs while increasing quality, and rising customer expectations with more options to take their business elsewhere. In this environment, creating a culture in which people, process and strategies are aligned to a common purpose is critical to success.

With this reality in mind, leaders need to ask themselves three simple questions:

- Do we have a **strategy** for success with clear, specific, and measurable goals?
- Can our **people** implement our strategy and achieve their goals?
- Are our **processes** efficient, effective and aligned to our goals?

In this presentation, you will learn how to:

- Ensure goals are aligned at all levels in the organization
- Leverage the four key factors that drive people's performance and determine results
- Maximize processes to drive strategy execution and staff productivity
- Sustain alignment across the organization over time

Michael will share ideas and actions you can take, starting now, to create positive change for better business results.

**Bio: Michael Caceci** enjoys a diverse, successful career. He is owner of Excellerated Performance, LLC a consulting and professional development services firm based in Pittsford, New York. Mike brings extensive corporate and entrepreneurial experience to every client engagement. His areas of expertise include sales, management, marketing, business operations, professional training and development, strategic thinking and planning, lean six sigma, and driving organizational change.

Mike holds a BA in psychology and MBA in marketing management. As Trusted Advisors Network (TAN) Affiliate, he is certified to deliver professional development programs; and is part of an international association of independent consulting, human resource and quality professionals.

Mike is a certified Lean Six Sigma Black Belt; and has led multiple process improvement projects both at Xerox and for Excellerated Performance clients. He is also an Adjunct Professor at Saint John Fisher College School of Business.

Mike serves on the board of the Greater Rochester Quality Council. He is a past board member of the Small Business Council of Rochester, a member of Rochester Rotary, Greater Rochester Chamber of Commerce, Greece Chamber of Commerce, and National Human Resources Association - Rochester Chapter.

## THERESE COSTICH

### The Radical Paradigm Change for your Business Excellence Platform

Continuous improvement is the objective of all enterprises, but most larger companies remain mired in inertia. In fact, the bigger they are, the more they are likely to do the same things over and over, and the slower they are to shift with the changing tides of the larger economy. So it is fair to say that inertia is the enemy of agility. Organizations are only growing more reliant on data, and that data is flowing at a fire-hose pace. Companies can no longer respond in a timely fashion without a radical paradigm shift. To be a global leader, an organization must conquer inertia by harnessing today's massive computing power with the human mind's great ability to reduce massive data to actionable understanding. By embracing this change, enterprises will not only lower costs, improve efficiencies and boost revenues and profits in the near term, but they will also nurture continuous improvement to thrive far into the future. Business Excellence begins with Business Transformation and the change must be embraced from the C-suite through all levels of the organization.



**Bio: Therese Costich**, Vice President of Strategic Initiatives at Salient Management Company, has spent more than 25 years in the Lean Six Sigma and Continuous Improvement world, working with companies including General Electric, The Six Sigma Academy, Ford Motor, DuPont, Dominion Energies, Harris Corporation, Lenovo, The TCM Group, and Bausch & Lomb. With the focus of the global world becoming smaller and data becoming bigger in every industry, Therese's work with Salient helps hone their approach to continuous

improvement by bringing diverse data from multiple sources together at the speed of thought. Salient's model, coupled with Operation Excellence framework, measures how business activity creates value, quality, financial efficiency, and productivity; empowering employees at all levels with granular visibility and control of their resources, thereby reducing cost, increasing margin and profit, and improving customer satisfaction; all while supporting ongoing strategic and tactical process improvements to achieve corporate strategic objectives.

## The Future of Quality – What's Next?

Analyzing variables one at a time has become untenable in data rich environments. A battery of tests on a product might yield hundreds of measured values for each iteration. How can you effectively analyze this data?

Using a case study of how Harris Corp validated their test equipment as part of consolidating their manufacturing facilities into one building, you will see how easy it can be to use multivariate methods. The entire move was to take 2 weeks or less from last production part to first production part. How could the process team ensure that the more than 90 test benches performed the same in the new location as the old?

A combination of multivariate analysis methods and measurement systems analysis was used. Repeat tests were performed on 'gold' units at the original location. The same 'gold' units were then tested multiple times in the new location.

SIMCA© Software was used to quickly highlight the biggest differences in performance as a result of the move. SIMCA© can also be used to validate any changes to product or process to ensure there are no unintended consequences associated with a change.

This combination of multivariate methods and measurement systems analysis was awarded the Shainin Medal from ASQ in 2014.

Come and see how using multivariate methods, with the help of user friendly software, can lead you to the knowledge that is lurking in your abundance of data.

**Bio: Patricia Cyr** is a Lecturer in the Industrial and Systems Engineering department at RIT. She holds a BS in Chemical Engineering from the University of Pittsburgh and an MS in Applied and Mathematical Statistics from RIT. She was a Process Engineer for Corning and a Development Engineer for Mobil Chemical before becoming a consulting statistician for Kodak and Harris RF Communications. She received her Master Black Belt Certification in 2010.

Ms. Cyr was the ASQ Shainin Medal recipient in 2014 and has been an ASQ Certified Quality Engineer since 1993. She has taught statistics and quality courses to graduate and undergraduate students at RIT for over 25 years.

Restricted Substances – What requirements are applicable to my product?

Manufacturers, old and new, are dealing with many issues when trying to get products to market. Performance and safety requirements have been in existence for many years, but now the materials being used in your products, recyclability and end-of-life concerns are also important.

Manufacturers are being asked:

Do your products contain any materials which may harm the environment?

Do your electrical products meet RoHS (Restriction of Hazardous Substances) regulations?

Do your products meet the substance regulations of Europe (REACH) and/or California Proposition 65?

From design to production, everyone who is involved with the manufacturing process needs to ensure that all requirements are being met before the first product leaves the dock. Engineering needs to design products which conform to all applicable standards. Purchasing needs to procure materials which are compliant with requirements and also meet engineering specifications. Production needs to ensure that nothing 'bad' is added during the manufacturing process.

There are many reasons that manufacturers need to ensure products are in compliance with all applicable regulations. Non-compliance penalties can be expensive, but bad publicity may be even more costly.

This presentation will include information on the EU Restrictions of Hazardous Substance (RoHS) Directive and similar regulations currently enforced throughout the world; the EU's REACH (registration, evaluation, authorization of chemicals) regulation on material usage; California Proposition 65, which regards chemical exposure and water pollution.

**Bio: David Linder** has been involved with product regulatory compliance for over 25 years from both the agency and manufacturing perspectives. His diverse background has enabled him to gain a broader insight into the needs and methods for obtaining compliant products. From safety to EMC, material compliance to sustainability, Dave has helped manufacturer's deal with the ever-changing regulatory environment.

Currently working for SGS, as the Technical Manager for Restricted Substance Testing Services, Dave is the subject matter expert for REACH, RoHS, California Proposition 65 and other environmental compliance legislations throughout the world.

Before SGS, he was Manager of Product Compliance for divisions of TE Connectivity and Legrand NA, where he became the SME on all product compliance regulations across the global business unit. As the lead for all product safety, performance and environmental compliance, he worked specifically on UL, CSA, IEC, CE, REACH, RoHS, and Conflict Minerals standards, initiatives and certifications.

Dave began his compliance career with Intertek and CSA after graduating from the New Jersey Institute of Technology with a degree in Industrial Engineering. With this well-rounded view of product standards and regulations, he continues to work with manufacturers from all corners of the world, to provide compliant products.

What's next for the Quality practitioner who faces a world where our teams, leaders and stakeholders may be down the hall or a seven time zones away? You may know stakeholders by voice, only—never having met them if they work in distant locations. You cannot always get facial cues or body language to gauge how a team member or process owner is responding to specific elements of your project. Additionally, each person has a specific tolerance for change and various styles and ways to deal with conflict and disagreements. In this environment, the Quality practitioner deals daily with communication situations that are crucial and critical to the success of a process change. It would be a great place if we could take the time to analyze what type of conversation we need to have and how to structure it, before we even have it. But, increasingly that is not the

In this presentation, we will look at how to have these discussions, the role of emotional intelligence and the impact of change, to deal with colleagues, team mates, and superiors. We will test some 'critical' scenarios on each other and discuss the results. We will cover not only some strategies to deal with crucial discussions at pivotal times but also some thought-provokers to improve your communication with stakeholders and team members in your unique situation.

Take-aways include:

- Culture and communication style interaction
- Setting communication expectations during the Quality project
- Determining when a crucial, critical, impact-laden discussion is needed

**Bio: Margi Ochs** holds a BA degree from Georgetown University and an MBA from University of Rochester. She teaches Lean Six Sigma courses and assists students to apply and implement their studies through consultation, assessments and workshops to deepen their own knowledge and experience.

Margi joined the Center after teaching Marketing and Organizational Leadership courses at both the Simon School of Management at the University of Rochester and the Saunders School of Business at Rochester Institute of Technology. Margi trained as a Lean Six Sigma Master Black Belt at Xerox where she led over 60 projects in the areas of marketing, product development, strategic planning, customer service and manufacturing, totaling over \$350M in revenue generation and cost savings.

After completion of her in-program training, Margi carried her LSS expertise into a variety of positions, including Worldwide Vice President, Office Products Launch, Consumables Marketing and Strategy, and Competitive Consumables Market Development. She served as a Lean Six Sigma loaned executive, consulting with over 80 Xerox customers on LSS implementation in their organizations and lead external projects to solve business problems in areas as diverse as supply chain optimization, medical lean process improvement, and product design and launch optimization. She also has extensive experience mentoring other executives who were first-time project sponsors and working with cross functional teams dealing with formation and strategic integration of LSS into business and organizational planning.

## R/Shiny for Quality Organizations

**Abstract:** Quality in manufacturing/business has evolved since the early 20th century. In the 1970s, to keep up with the increasing high-quality competition coming from Japan and other areas, US manufacturers introduced the use of statistical analysis as well as other enterprise wide quality initiatives. Initially, statistical analysis needed to be done by hand, including learning to manipulate matrices and the in-depth mathematics involved. As computing evolved, statistical packages were created to remove some of this burden. With the advent of Industry 4.0 and the explosion of data, systems are becoming even “smarter” and the use of high level computing is becoming even more prevalent. Statistical analysis has and will evolve along with this. In this presentation, we will talk about the computing packages R and Shiny. We will discuss not necessarily how to use the packages, but what they can do for a quality organization. Some of these things include simplifying and interpreting statistical analyses, visualizing and summarizing quality processes, such as CAPA and auditing and the automation of procedures for governing bodies such as the FDA or ISO.

**Bio: Rob Parody** is an associate professor in applied statistics at Rochester Institute of Technology and the President of Responsum Analytics. He is an experienced statistician with a six sigma blackbelt leading a dual life: educator and statistical consultant by day, custom statistical software developer by night. He has developed dashboards and statistical software for creating output and interpreting results for experimental design, gage R&R and model prediction, to name a few. He has extensive experience in fields such as manufacturing, biodefense, pharmaceuticals, medical devices, pre-clinical, non-clinical and clinical studies.

## Communicating to Improve Quality in the Complexity of Today's Workplace

The role of the quality professional is changing and must become more of a teacher, mentor, and coach. With 5 generations currently inhabiting the workplace the role of communication is more important than ever before. This interactive session will outline problems currently facing the quality professional and offer ways in which to bridge the generational gaps as well as identify ways to improve organizational and interdepartmental communication. The goal being to have participants leave with action plans they can utilize today.



**Bio:** **Beth Sears**, PhD., Speaker, Author, Communication Expert and the North American expert on interpersonal and organization communication, has been called the Transformation Titan. She has spent over 30 years integrating best practices with real life experience to help organizations become more productive and profitable. Using her unique approach, Beth has helped leaders to clarify their vision and create language that inspires and engages their workforce, resulting in collaborative, focused teams.

An inspiring international speaker, Beth is sought after by organizations and associations for events, and creative leadership seminars. She has been invited back to speak at the International Conference on Knowledge, Culture and Change in Organizations at Oxford University and then again at the University of Hawaii at Manoa. The facilitation of offsite retreats, improving workplace communication through understanding, empowering through coaching and leadership development have been numbered among her work. She enjoys integrating her education with her real-world experience, to improve the lives of others, and the organizations in which they work. A recent client stated, "Beth helped "us get over a "hurdle that has plagued our company for many years ... The skills that Beth has are remarkable to get to the root cause and to get everyone to participate."

Beth holds a Ph.D. in Communication and is a graduate of the prestigious Million Dollar Consulting® College. Beth has been adjunct faculty for Cornell Industrial Labor Relations School for 18 years and taught graduate courses in the School of Business at Nazareth College, and the Communication Department at the University at Buffalo. She has been quoted in the Wall Street Journal, PR News Employee Communication Guidebook, and ANZI Insights a professional development series from The Australian and New Zealand Institute of Coaching. She has authored several hundred professionally published articles and her monthly newsletter is a fantastic resource for thousands of business owners.

## **The 5 Practices of Exemplary Leadership Model**

The backbone of The Leadership Challenge book states that leadership is an observable set of similar patterns of behavior (skills and abilities) that can be taught and learned *by everyone*. Three decades of research provide strong and enduring support for the model. When leaders are at their personal best, they demonstrate five core practices:

- They Model the Way
- Inspire a Shared Vision
- Challenge the Process
- Enable Others to Act
- Encourage the Heart.

*Credibility* is the foundation of every leader-follower relationship. To be viewed as a credible, leader, you need to consistently:

Do What You Say You Will Do (DWYSYWD).



**Bio: Steve Whittaker** is a Quality, EHS and Environmental Sustainability Professional. Stephen has worked in the graphic communications/printing industry for his entire professional career. He recently completed a long term career as the Vice President of Quality Management and Environmental Sustainability Initiatives for Monroe Litho, Inc. of Rochester, New York.

With a tenure of near twenty nine years with this firm, he lead in the preparation of over two dozen successful third party quality system audits by major national Fortune 100 Corporations [Bausch & Lomb, Xerox Corporation, Eastman Kodak, Ortho McNeil Pharmaceutical and others] that resulted in appropriate certifications. Within the American Society for Quality, he is a Certified Manager of Quality/Organizational Excellence, a Certified Quality Auditor and a Senior Member. He is listed with the National Registry of Environmental Professionals as a Certified Environmental and Safety Compliance Officer.

In the environmental sustainability area, he organized a series of third party audits that resulted in Forest Stewardship Council Chain of Custody Certification and Sustainable Forestry Initiative Chain of Custody Certification. In 2011, the company printed the FSC logo at client request on over thirty percent of its work. He organized the protocol that enabled Monroe Litho to have become the first commercial printer in the US [outside of the beta test group] to have become SGP [Sustainable Green Printing Partnership] Certified.

He was featured in a Channel XXI Public Television interview in the Fall of 2011 that can be accessed at <http://www.youtube.com/watch?v=bfAYsvHOAHE>.

Stephen is in his twenty second year as an Adjunct Professor in the School of Media Sciences, College of Imaging Arts and Sciences at the Rochester Institute of Technology where he teaches graduate level courses. As a graduate of this School, in 2010 he was the recipient of the “Distinguished Alumni Award” and in 2014 was the inaugural recipient of the Edline M. Chun Award for achievement and service as an Adjunct Faculty member.

## “Conversations that Build Trust”

Over the past year, trust within the USA has been in free fall. Trust in all sectors including Business, Government, Media, and NGOs has degraded at unprecedented rates. This talk will describe the problem and causes. The focus will be on what things can be done in organizations to improve the culture of trust. The future of quality relies on regaining of trust within all organizations.

Join Bob Whipple “The Trust Ambassador” for an experiential and entertaining program that will highlight the following topics:

- How trust in the USA was impacted in 2017
  - Share data from Edelman Trust Barometer
  - Show impact of trust loss in USA
- How to build a culture of higher trust
  - The importance of following the values
  - Balanced Accountability
  - The First Law of Trust
  - Reinforcing Candor
- The nexus of trust and ethics
  - Share ETHIE Award Process
  - Show relationship between trust and ethics
- Improving Accountability Conversations – a five-part model
  - Comprehensive and Balanced
  - Contribution
  - Care
  - Collective Responsibility
  - Clarify Expectations



Participants will leave with a set of specific skills they can apply in their organization to begin a culture of higher trust. A link to some free demo videos on building trust will be given out at the session.

**Bio:** **Bob Whipple** is CEO of Leadergrow Incorporated, an organization dedicated to development of leaders. He speaks on leadership topics and the development of trust in numerous venues internationally. He also has taught graduate leadership and business classes at several universities. As a leadership coach and business consultant, he works with individual clients as well as large organizations such as government agencies, corporations, and The Greater Rochester Chamber of Commerce. Mr. Whipple is a student of the quality leadership process and has developed unique approaches to achieving excellent results through full engagement of people. He is author of four books on trust:

The Trust Factor: Advanced Leadership for Professionals (2003),  
Understanding E-Body Language: Building Trust Online (2006)  
Leading with Trust is Like Sailing Downwind (2009)  
Trust in Transition: Navigating Organizational Change (2014)

Favorite quote: “The highest calling for any leader is to grow other leaders.”