

ASQ Greater Fort Worth - Section 1416 Meeting

Thursday, September 14, 2023

Continuing at Diamond Oaks
Shifting to SECOND THURSDAYS thru December
-- Registration Requested --

We must charge a \$6.00 fee for even those not wanting a meal.
Diamond Oaks has begun charging room fee in addition to the meal.

Registration at end of page

Posted 9/07/23



Sponsored by:

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Program Topic: “Root Cause Analysis: A Holistic Approach”

Ask yourself:

1. How many nonconformities or customer complaints keep reoccurring?
2. How many root cause investigations only dealt with the problem’s symptoms?

During this presentation, we will delve into the fundamental aspects of Root Cause Analysis from a practical and holistic perspective. Our exploration will encompass a range of principles, methodologies, and concepts while also considering relevant regulations, industry practices, and common audit findings to provide clear and supportive insights for essential points. This presentation covers the basics, theories, and real-world use of root cause analysis tools.

By the end, attendees will gain the following knowledge:

- Acquaintance with the essential concepts and principles of Root Cause Analysis.
- Understanding the various Root Cause Analysis tools, investigations, and their potential impact on the business.
- Ability to apply Root Cause Analysis principles and concepts to your organization.
- Appreciation of the significance of Root Cause Analysis in GMP operations, QMS, and overall business success.

Speaker: **Jorge Sugranes**, Senior Director of Audits for Americas, PSC Biotech

- Jorge has over 38 years of hands-on experience in the pharmaceutical and medical devices industry. He is a Certified Manufacturing Engineer with expertise in quality assurance, regulatory compliance, and manufacturing operations. His experience ranges from sterile medical devices to parenteral pharmaceutical products.
- Mr. Sugranes has gained extensive experience in technical, managerial, and leadership roles throughout his career. He has worked in positions such as, Director of QARA Strategic Manufacturing, Associate Director of Manufacturing Science & Technology, Director of Validation & Risk Management, Plant QA Manager, Senior Manager of QA Regulatory Compliance, Project Manager, Validation Manager, Validation Engineer, Scientist, and more.
- He has been employed full-time by various companies such as Abbott Labs, Johnson & Johnson, Novartis, Sandoz, Alcon, CareFusion (BD), Teleflex, and consulting firms.
- Education: BS United States Military Academy; MS Colorado State University
- Master Black Belt (J&J Medical); past ASQ certifications include CQA, CQE and CRE
- Current role: leading a global Reporting and Analytics function that transforms data into value-added and sustainable data solutions.

Tutorial 1 (General): “Random Observations of a Quality Manager... to a Management, Engineering & Production Audience”

Presentation is modified summary of a presentation given to the functional diversified audience attending the “Pipelines Conference” in San Antonio in August. Content will include:

- project integration across functions
- anticipated problems coordination will encounter
- factors to meet project success
- lack of documentation – tacit knowledge of retiring personnel
- required involvement – responsibilities / accountability

Speaker: **Gary Savanyu, PE**, Quality Manager, Trinity River Authority

Tutorial 2 (Specialty): “Dorian Shainin Problem Solving!”

This is the first of a three-part series on Dorian Shainin Statistical Problem Solving methods

Sep 14 – Red X problem-solving is a method to find the main root cause yet the opposite of traditional Six Sigma belt methods. It takes more than five whys, fish bones, and Pareto analysis to pinpoint the causes of our most solution resistant problems.

Oct 12 – Red X problem-solving examples

Nov 09 – Red X Resilient engineering enables companies to quickly transform designs and processes into defined digital data streams. It is laser focused on the high risk areas of a design or process by addressing the finite number of functions that must go right rather than the infinite number that can go wrong.

Dorian Shainin (1914 – 2000) was an American quality consultant, engineer, author, and college professor most notable for his contributions in the fields of industrial problem solving, product reliability, and quality engineering, particularly the creation and development of the "Red X" concept.

Shainin, founder of the technical-problem-solving company Shainin LLC, is responsible for the development of over 20 statistical engineering techniques that have become the core of the "Shainin System" for quality and reliability improvement.

Throughout his life, Dorian Shainin worked to improve the quality and reliability of an array of products, including paper, printing, textiles, rubber, nuclear energy, airplanes, automobiles, cassette decks, space-ships, light bulbs and disposable diapers, with clients representing over 200 different industries, ranging from the U.S. Department of Defense, Rolls-Royce Ltd. and Exxon to Polaroid, Hewlett-Packard, AT&T and Ford Motor. In total, Shainin advised over 800 companies, 43 of which were among the Fortune 100.

ASQ Link: [The Shainin System™ - Shainin Red X Method | ASQ](#)

Speaker: **Jenni Martin**, Operations Engineer Principal, Lockheed Martin Aero

- Experience – 27 years with Lockheed Martin Aeronautics – Fort Worth, Texas
 - Production Operations Engineer Principal and LM Associate Fellow
 - Quality Engineer Senior Staff – F-35 Production
 - Manufacturing Engineer Staff – Advanced Development Programs
 - Manufacturing Engineer – Research & Development
 - Determining Cause as Red X Master, Six Sigma and Lean, Corrective Actions and Improvements, Quality Engineering Science, Manufacturing Processes
 - BorgWarner Automotive TorqTransfer Systems – Longview, Texas
- Education: BSME, MS Mechanical Engineering
- Certifications: Shainin Red X Master, LM21 Black Belt, Lean Manufacturing Master ASQ CQE, PE License, LM Program Manager Level 1

Recognition: PD Meeting Perfect Attendance:

Roxanne Pillar	Jesus Ortiz	Paul Cummings
Jim Conkle	Ann Au	John Breckline

Prepaid Meal Purchase via Web:

We have full capability to accept pre-paid meals and/or plan a vegetarian meal via the web using the ASQ “Memberplanet” reservation system, which costs \$1.75 per person in fees. Upon returning to DOCC we are also being charged a room use fee and must cover the cost of it by the attendees. With 50 attending, the distributed cost is about \$6.00 per person.

For Diamond Oaks planning, and to manage costs, we **must have registrations for all attendees**. Reservations for meals must be completed **by NOON on Tuesday** to order adequate food. The standard cost of the meal is \$30.00. However, reservations by deadline above will be discounted to \$25.00 which includes the \$6.00 seat fee.

If unable to join the meeting, and the meal reservation becomes a “no-show”, the Section plans to process a refund over the weekend. We do not want to penalize you for unknown business needs.

Reservation Link: [Ft Worth ASQ Recurring PD Meeting](#) – it looks a bit different than we had for the last year **and** you can process multiple person meals in one transaction. Look for “**Buy Tickets**” on the upper right side of the page.

Choose: [PD Meeting ASQ Dinner](#)

- Buffet Meal – meat, a vegetable, salad, bread, etc.
 - Vegetarian / Vegan Option – often a pasta dish
 - Gluten Free Option
 - Just Program Access – room fee – No Meal (**\$6.00**)
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All meals options \$25.00 include room fee

If problems, contact jbreckline@att.net

Typical Meeting Schedule:

5:30 – 6:00 Check-in – Networking

6:00 – Tutorial/s (30 min)

6:30 – Dinner – advance reservations requested – limited walk-in availability

Not required to have dinner to attend meeting but a ‘seat fee’ applies

7:15 – Recognition and Short What’s Happening Meeting

7:30 – Program Speaker (45 min)

8:30 – Head on Home...

Location:

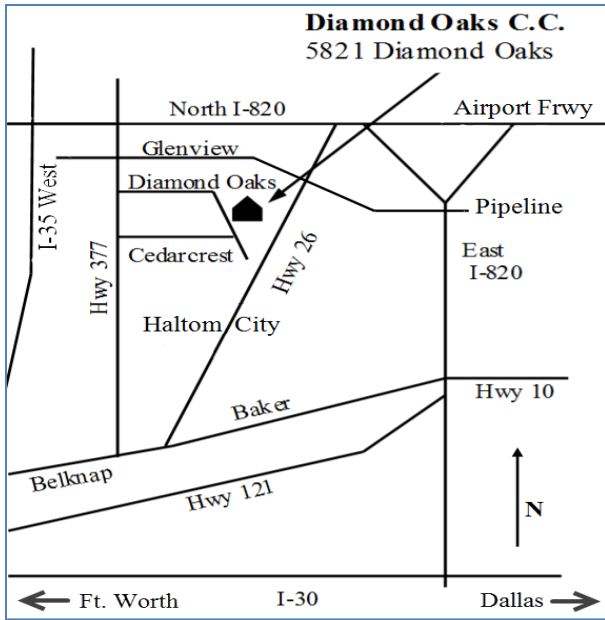
**5821 Diamond Oaks Drive North,
Fort Worth, TX 76117-2862**

[MAP HOTLINK](#)

TRAFFIC ALTERNATIVES:

For the ‘northerners’, use 114 to 377 south

From east or downtown, take 10 to 377 north



Not to scale