

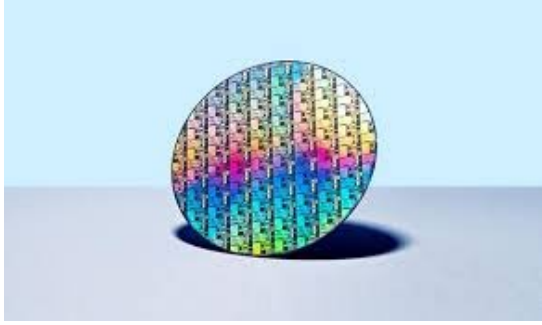
Value-Add Auditing—A Paradigm Shift to Drive Value

How I learned to stop worrying and love the audit

James Shore – Chief Quality Officer
Quality Lean Solutions



A little about me



Diversity of business



Last quarter:

UV Bonding manufacturer audit

Warehouse and distribution audit

Welding procedure review

Medical Device Summative Usability Study

Precision Machining/Contract Manufacturer audit

IVDR testing equipment independent design reviewer

Implantable orthopedics audits

Monitoring equipment QMS updates

Organ transplant, recovery, and processing inspections

Teaching and Implementing Risk Management

Updating QMS for EU MDR and ROW

Auditing sterilization facilities

Proctoring exam for Welding Inspectors certification

FDA QSR to QMSR requirements webinar

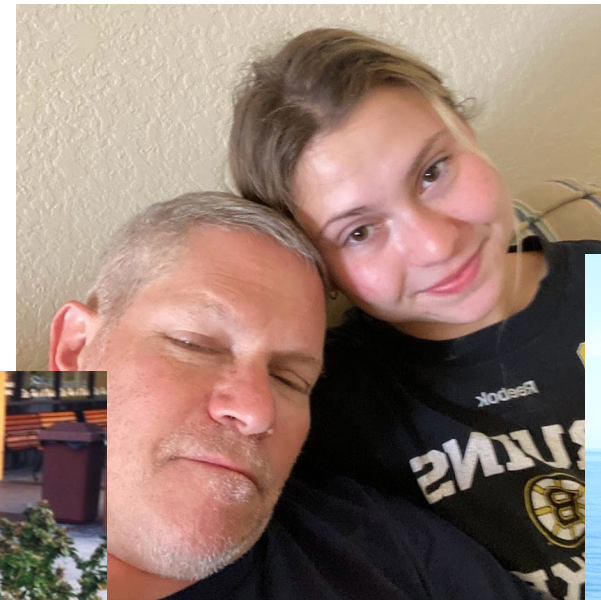
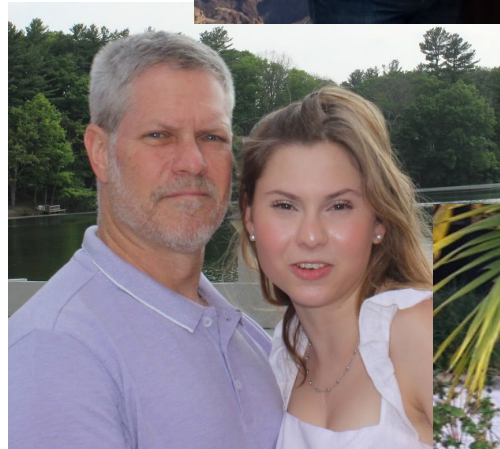
Teaching classes on Supplier Management

When I'm not working



Spain, Portugal, Taiwan, India

What is your why?



Annual MRI and tests
Angioplasty
Stents
transcatheter aortic valve replacement (TAVR)

You have an audit!

- Panic
- Anger
- Denial
- Frantic



Why?



- Is it from what has been seen in Warning Letters?
- Is it from I have enough on my plate and now this?
- Is it the knowledge that they know you have issues but haven't had time to finish them?
- Is it from the time in middle school when the teacher pulled a pop quiz and you didn't study?
- **Is it because usually the auditor only looks for the bad?**

How I learned to stop worrying and love the audit

- Audits CAN (and should):
 - Add value
 - Identify risks
 - Identify inefficiencies and waste that cost money \$\$\$
 - Identify best practices
 - Provide positive feedback
 - Provide benchmarking feedback



What is the purpose of the audit?

IS:

- Verify compliance with the audit scope
- Help look for areas for improvement
- Provide feedback and benchmarking information
- Provide examples of potential solutions

IS NOT:

- Look for nonconformances to make the Quality person look bad
- Trying to see if you can get one past the auditor



Value of auditing - Feedback

- Helps identify areas that are not easily seen by those involved in the process everyday
- Ensures the processes meet the Standard, Regulations, and Requirements
- Provides feedback to the internal audit process and auditors as well as the auditees
- Prepare employees for when external people enter your company for an audit

Examples of value

- Identify issues before an ISO or Notified Body Audit
- Point out inefficiencies that COST money
 - Redundancy inspections
- Avoid business AND safety risks
 - Trip hazards, not wearing PPE
- Eliminate non-value-added activities or extra work that the customer doesn't want or pay for it
 - Kitting and Final QA Inspection process
- Stop issues that are passed along in the process that result in rework costs and work stoppages
 - Testing to find bad parts vs. pre-inspection go/no go fixture



Examples of value

- Feedback on how they are doing against other companies and **benchmarking activities**
- Industry-reported issues that they may not be aware of that are applicable to their product
 - [National Highway Traffic Safety Administration](#)
 - [Medical Device Reportable Events](#)
- **Identifying outstanding employees and processes**



Examples of value auditing

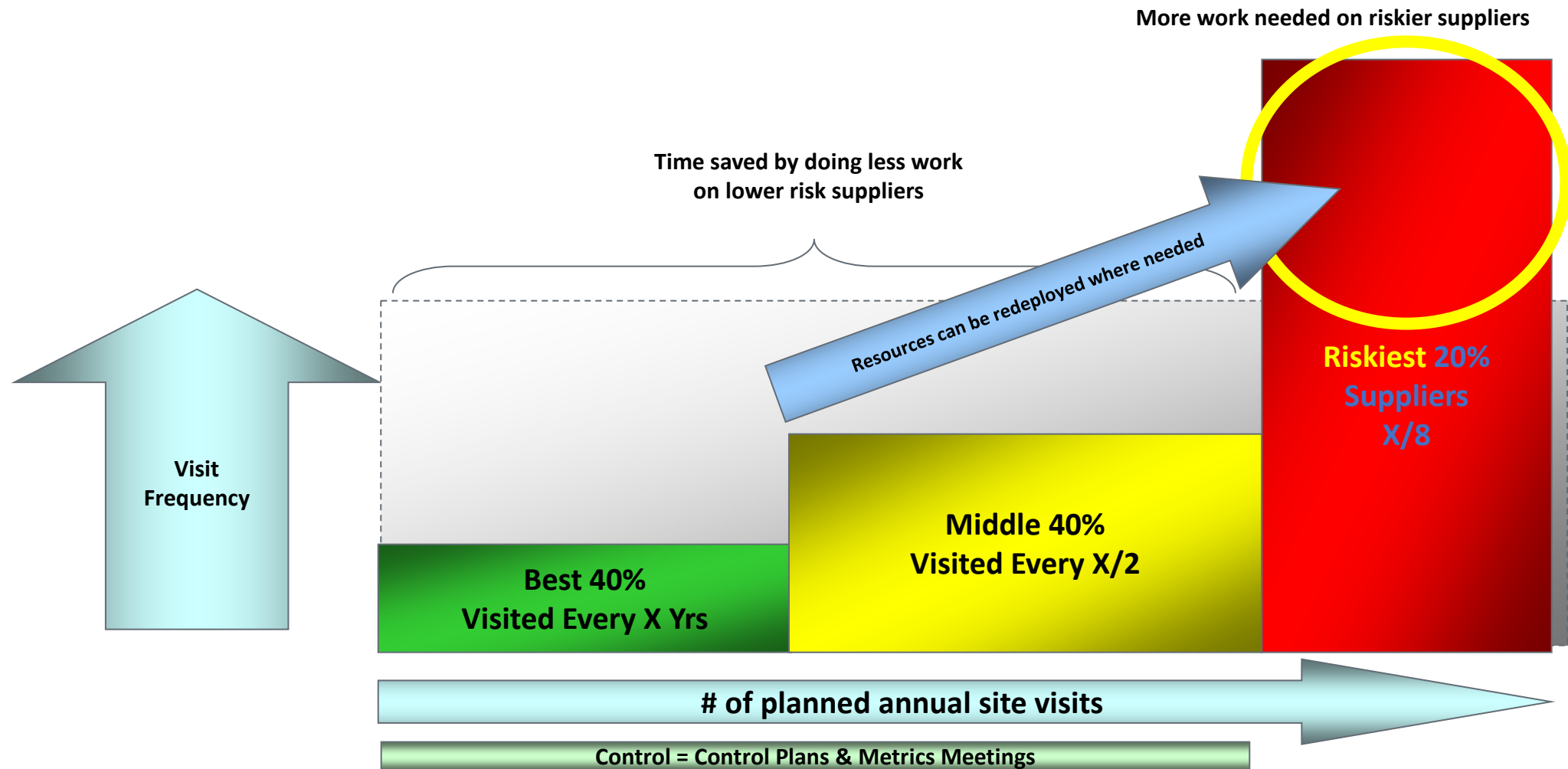
- Supplier Audits

- Does everyone have to be audited?
- Does everyone have to be audited on-site?
- Why do I want to do these audits?

- Answers

- No! Use Risk tools to identify who really needs the audit
- No! It could be a hybrid of remote and self assessments
- To protect your supply chain, understand the challenges of your suppliers and maintain a good business relationship

Pareto approach – risk based decision



Case Study – Risk-Based Audit Decisions

- Company manages clinical assets for hospitals and facilities across the US
- Capacity is 60 audits/year
- Use risk factors to create the annual audit list
 - External audit issues
 - Internal audit issues
 - Audited in the past five years
 - Meeting internal customer performance metrics
- Provide data analysis prior to the audit
- Highly performing sites are recognized during Quality Reviews held every Quarter



Risk-based Approval and Review Process

| Initial Approval | Level 1(Critical) | Level 3 (moderate) | Level 3 (low) | Level 4(Negligible) |
|---|--|------------------------------------|------------------------------------|---------------------|
| ISO Certification | Yes | Yes | Recommended | N/A |
| Supplier Assessment Questionnaire | Yes | Yes | Recommended | N/A |
| On-site audit | Yes | Recommended | Optional | N/A |
| Quality Agreement | Yes | Change Notification | Optional | N/A |
| Review period | Six months | Annual | Two years | N/A |
| Document updates | Update questionnaire and ISO Certs Review Quality Agreement | Update questionnaire and ISO Certs | Update questionnaire and ISO Certs | N/A |
| Audit (Can change based on performance) | On-site/remote | Desktop | Desktop | N/A |
| Performance Criteria For Quality | 99% | 95% | 95% | N/A |
| Performance Criteria for Delivery | 99% | 95% | 90% | N/A |

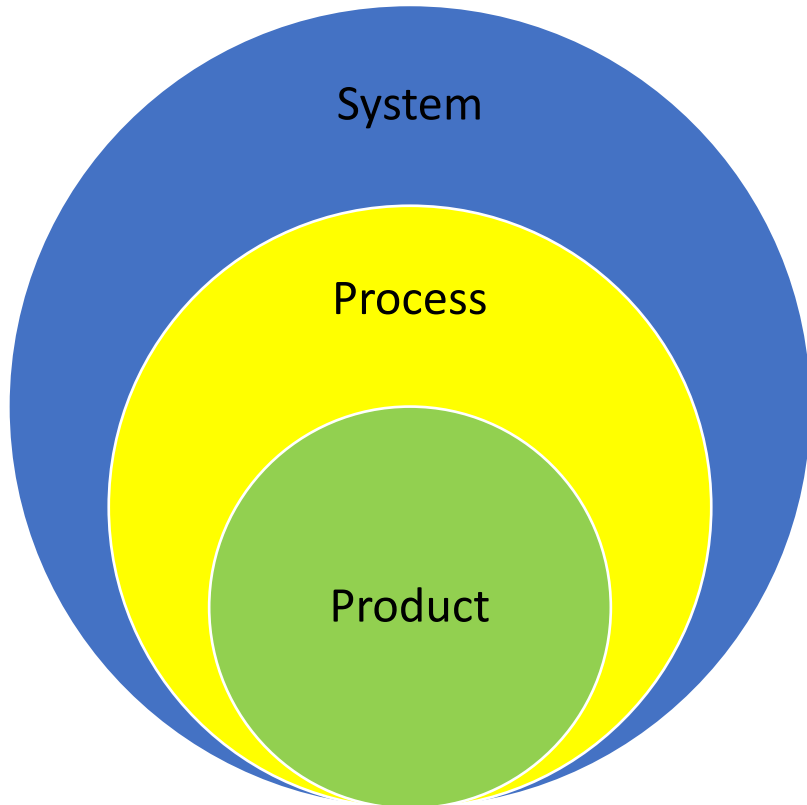
Manufacturer of Class I Surgical system (US)/Class II (EU)

When I have to audit, what should I do?

- Do your homework first!
 - Performance data
 - Financial Reporting (D&B, 10-K)
 - Industry analysis and challenges i.e. Titanium
- Based on the supplier, what type of Audit should I do?
 - System, Process, product
 - Focus on your products and related processes
 - What elements of the QMS are applicable? Do I have to look at everything?
- Logistics
 - On site or remote, or hybrid
- Time duration
 - How much time do I need to cover the important elements?
 - The resource capacity of your team and the supplier

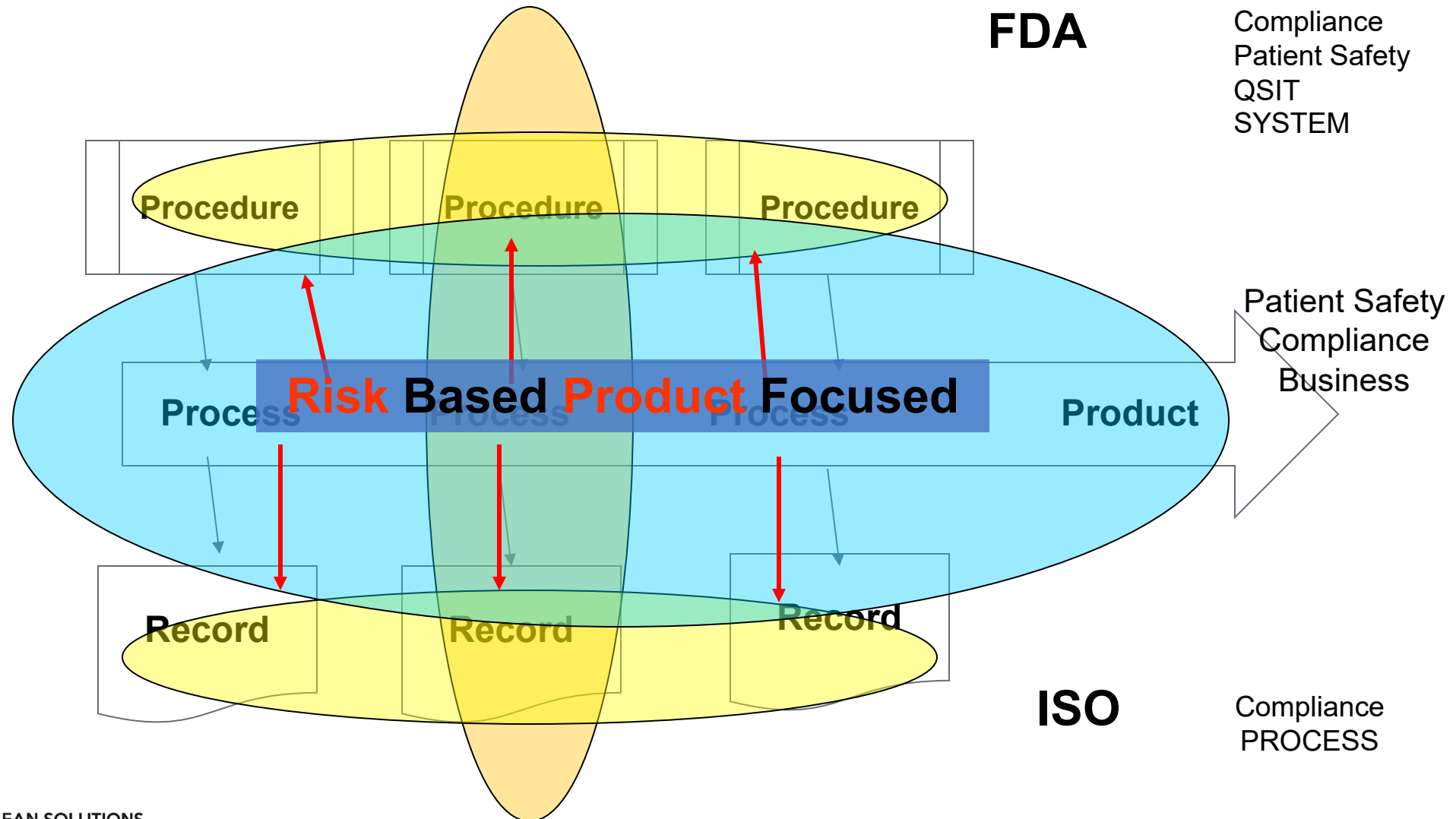


Types of focused audit approaches



- System audit - Is the quality system adequate?
- Process audit - Is the process operating properly?
- Product audit - Does the product meet requirements?

Risk Based - Product-focused Audit – Best of all approaches



Benefits of Risk Based - Product-focused audits

- The supporting elements and records are verified during the audit
 - Calibration
 - Nonconforming material
 - Identification and traceability
- Process Controls
 - Focus on the product, safety, and efficacy
 - Robustness of the process to identify issues
 - The RIGHT testing – eliminate non-value vs. testing that should be done AND reviewed
- Output
 - Better understanding of the process and product for all involved
 - Insight into the supplier's capabilities and maturity
 - Product specifications and risk management plans may need to be updated
 - Control Plans – change notification

Audit etiquette

- Setup pre-audit call
 - Reduce the stress and anxiety – appropriate humor
- You may be the only person they meet from the company
- “Read the room”
 - Your mannerisms, behavior, and body language are being monitored –you may have to modify them
- Manners. Maketh. Man.”
 - Please and thank you
 - Listen, Listen, Listen – ACTIVE Listening
 - Apologize if you make a mistake
 - Learn about the company, country, culture
 - Ask clarifying questions



Constructive Feedback is value



- Strengths – positive observations about the process AND people
- Observations – things that could turn into an issue
- Opportunities for Improvement – tweaks that can make a quick impact
- Nonconformances – what needs to be fixed AND how severe is it
 - Suggestions on what might be helpful to fix it (another set of eyes)

Train auditors to do value-added audits

- Invest in skills in other areas of the business
 - Finance, Operations, Lean, Safety
 - Better understanding of the impact and interaction of each function
- Keep their skills sharp
 - Certifications
 - Conferences
 - Professional engagements
 - Volunteer in related organizations i.e. ASQ, AAMI, AME
 - Benchmarking – organizations that share best practices
 - Presentation and communication skills

How do I find these types of auditors?

- People in similar industries or backgrounds and work responsibilities
 - Aerospace, Automotive, Semiconductor
- Hands-on practitioners – Technicians
- Attend Professional conferences
- Hire Veterans
 - Highly trainable
 - Team approach
 - Discipline
 - Problem Solvers
 - Relevant EXPERIENCE
 - Transferrable Skills



Summary

Auditors do want to add value – give them a try!

Use risk to help identify the audits to drive value

Use Product focused Risk-based assessments

“Thank you for your Service” -hiring Veterans is the best way to show it!



We work with clients looking for **customized solutions** that can be **simply implemented, scale, and are sustainable.**

We love working with our clients but our goal is to empower you and your teams with the knowledge, tools and processes needed for success.

Our Services

Developing and implementing Quality Management Systems

Implement Lean Manufacturing techniques to reduce costs

Conducting training for Quality Compliance AND Improvement

Implementing Robust Supplier Quality Systems & Supply Chain

Conducting Supplier and Internal Audits And Support External audits

EU Medical Device Regulation Compliance and auditing

Get in touch to see how we can create your customized solution.

James Shore, Chief Quality Officer www.qualityleansolutions.com mobile 508.726.0574

Thank you

- Please reach out to me if you have any questions!
- Mention “ASQ Granite State” and receive a 10% on your first project.

