Proactive Supplier Management

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Abstract

The changes to ISO 13485:2016 have placed additional emphasis on Supplier Controls. As more companies outsource more of their processes or become virtual, the expectation are controls are implemented. What are the big problems found during the ISO audits? What are the best practices?

During this presentation, we will review the ISO Requirements and some of the best practices that are being used in industry.

Question to answer

Are there compliance issues with Supplier Controls?

- Do Supplier Controls extend into other regulatory or compliance requirements?
- What do we need to know?
- What are best practices to be compliant?

FY2017 Top 10 P&PC 483 Observations Domestic and Foreign

CFR Number	# of Domestic Observations	Percentage
21 CFR 820.50	115	13%
21 CFR 820.75(a)	112	13%
21 CFR 820.72(a)	63	7%
21 CFR 820.70(a)	56	6%
21 CFR 820.80(d)	49	6%
21 CFR 820.80(b)	42	5%
21 CFR 820.80(a)	39	4%
21 CFR 820.70(i)	31	4%
21 CFR 820.70(c)	29	3%
21 CFR 820.50(a)(10)	27	3%

CFR Number	# of Foreign Observations	Percentage
21 CFR 820.75(a)	52	18%
21 CFR 820.70(a)	32	11%
21 CFR 820.50	24	8%
21 CFR 820.80(d)	18	6%
21 CFR 820.250(b)	14	5%
21 CFR 820.70(i)	14	5%
21 CFR 820.80(b)	13	4%
21 CFR 820.70(c)	11	4%
21 CFR 820.72(a)	11	4%
21 CFR 820.75(b)	9	3%

Source: **FY2017 Annual FDA Medical Device Quality System Data**

Regulatory and compliance impact

- Medical Device Single Audit Program (MDSAP)
  - Major Sections of the audit model
  - Considered a critical process
- Medical Device Regulations
  - Economic Operators and Distributors
- CE Mark
  - Unannounced audits at suppliers and subcontractors
- Country specific requirements
  - Suppliers and subcontractors identified in the Design and Manufacturing Technical Documentation
- EU Medical Device Regulation
  - Supplier Controls, Distribution Suppliers

Expectations of Notifying Bodies/Regulatory Authorities

Understand:

- The changes to ISO 13485:2016 specific to supplier controls and changes needed to your Quality System
- The requirements regarding the necessary controls on purchased, services and **outside processes**
- The requirements needed to effectively select and manage suppliers based on risk proportionate to the product risk
- The tools necessary to properly monitor suppliers and evaluate ongoing quality **based on risk**

Controls proportionate to risk

Definitions and requirements (ISO 13485:2016)

purchased product - product provided by a party outside the organization's quality management system

When the organization **chooses to outsource any process** that **affects product conformity to requirements**, it **shall monitor** and **ensure control** over such processes. The **organization shall retain responsibility of conformity** to this International Standard and to customer and applicable regulatory **requirements** for outsourced processes.

The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements….**The controls shall include written quality agreements**.

So is there any good news?

- Most changes to ISO 13485:2016 are harmonized to 21 CFR 820
  - FDA plans of migrating to the ISO requirements
- Captures the current practices of most companies
- More importance with other requirements
  - Makes justification for compliance easier
- Three major process streams:

Requirements
Gap Analysis
Best Practices

Criteria for **evaluation and selection** of suppliers

- **Supplier ability to meet requirements.**
- **Supplier performance**
- **Proportional** to the **risk associated** with the device.

Monitoring and **re-evaluation** of suppliers

- Product **performance shall** be monitored
- Results **shall** be part of the re-evaluation

Communication and **controls**

- **Adequate** specific purchasing requirements
- PO **shall** include "**change notification**"
- **Traceability** of relevant information in the form of documents and records.

Selection | Performance | Risk | Change Management

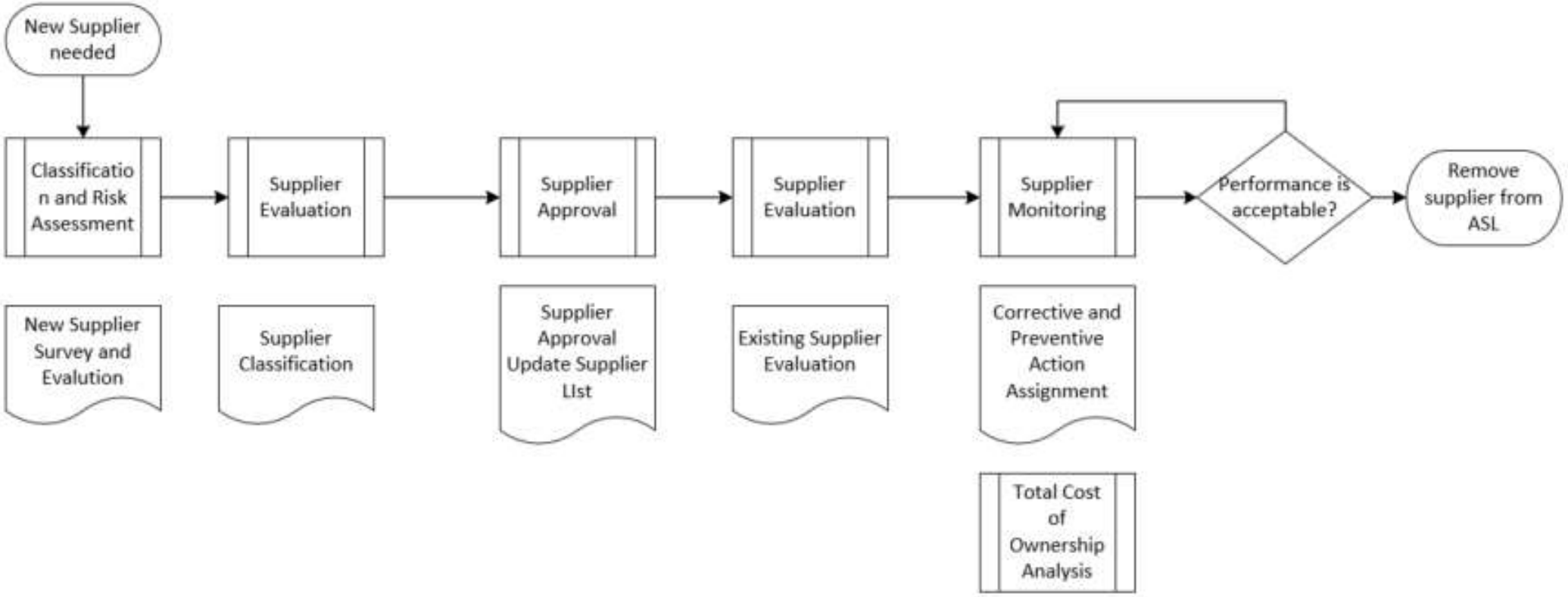
Reference:

- ISO 13485, Para 7.4.1
- 21 CFR 820.50(a)(b)
- MDSAP Checklist

Gap Analysis – Purchasing Controls

- Does the Approved Supplier List have the list of outside processes?
  - Manufacturing, QMS, Consulting
  - Distributors
  - Sponsors (Australia)
- Does your company use risk levels and performance in selecting suppliers?
- Does your company monitor performance of your suppliers at regular intervals?
  - If so, what are the limits and what action is taken if those limits are exceeded?
  - How is this documented?

Create Process Map



Easier to follow which results in compliance – people are visual leaners

Risk based thinking for Supplier Controls

Category	Risk level	Commodities	Controls
1	Critical or high	Finished medical devices Contract manufacturers Outsourcing of software used in manufacturing Outside processes	Initial on site assessment Quarterly/annual assessments Dun & Bradstreet reporting Process control plans Incoming inspection plans Monthly reporting
2	Medium	Precision components Printed circuit board assemblies Distributors	Initial on site assessment Annual assessments based on performance Dun & Bradstreet reporting Process control plans Incoming inspection plans Quarterly reporting
3	Low	Noncritical components Off-the-shelf items, noncritical Sponsors	Initial on site assessment may be waived depending on risk assessment On-site assessments every two to three years (if necessary) based on performance Incoming inspection plans Supplier survey provided by the supplier Annual reporting
4	Negligible	Janitorial services for nonmanufacturing areas Office supplies Consultants	Paper survey provided by the supplier Monitoring based on areas that are serviced No reporting required

Criteria can be changed based on the supplier evaluation and specific requirements

Approved Supplier List

Number	Name	Location	Commodity	Critical	Risk Level	Outside Process
Unique Number	Full Name	If more than one, each one should have a separate number	Machining PCB Hardware Distributor	Yes or No	Use simple list of levels or categories	If yes, what do they do? Plating Sterilization Consulting Sponsor

Watch outs:

- Minimum items
- If the master list is from a software system, make sure the validation is documented!
- Outsourced processes, sponsors and Consultants need to be on list

Supplier Monitoring

- Break up the list into four equal parts, review those suppliers on a quarterly basis
- Criteria can be simple
  - Quality and Delivery
- KEY: define the metric and calculation
  - Quality =Lots accepted/lots received
  - Delivery=Lots received (3 days early/no days late)/lots received
- Key: have limits
  - Warning Limits – review and investigate
  - Action Limits – full corrective action
- Watch outs –
  - software validation if quality decisions are made based on this report

Acceptance Requirements| Change Management

Information **shall** describe or reference the product to be purchased

- Product **specs**
- **Requirements** for acceptance
- **Requirements** for supplier personnel qualification
- QMS **requirements**

PO **shall** be reviewed prior to sending to the supplier

Change notification **shall** be included (as applicable)

Reference:

- ISO 13485, Para 7.4.2
- 21 CFR 820.50(a)(b)
- MDSAP Checklist

Gap Analysis – Purchasing Info

- Do you have clear quality requirements including acceptance methods documented? Do you share them with your suppliers?
- Do you have Supplier Quality Agreements for your critical or high risk suppliers?
  - Do your agreements include notification of change approval prior to making those changes?
  - Do you have at least Change Notification Agreements to notify you of any changes to the product or service?
- If your product has CE mark approval, do your SQA documents include the unannounced audit requirements (critical suppliers)?

Purchasing best practices

- Send the latest drawing and inspection requirements with every PO via email.
  - Avoids the wrong information being used
  - Provides the inspection criteria for compliance
- Send the Terms and Conditions with every PO via email
  - Make sure the change notification and unannounced audit requirement is part of the document
- Send the Quality Inspection Plan
  - Focus on the critical attributes
  - This does not mean they are not responsible for compliance

Risk based thinking for Quality Agreements

Change Notification Agreement

- Most times this covers 70% of the suppliers for change control

Supplier Quality Agreements (SQA)

- Which suppliers require SQA is based on product risk levels.
- The agreements should cover the scope of work that the supplier is providing and the regulations that are required.
  - Make the agreement flexible for the specific situation.
  - Don’t add incoming inspection requirements for the Software Development supplier.
- Unannounced Audits (for CE Marked product only)

Verification| Risk | Change Management

Shall stablish and implement inspection or other activities

- Ensure the product **meets** the purchasing requirements
- The extent of the **verification shall be proportional** to the supplier evaluation and the **risk** of the purchased item.

If the company is notified of any changes

- **Shall** determine **if the changes** affect product realization process
- Or the finished medical device

Reference:

- ISO 13485, Para 7.4.3
- 21 CFR 820.50(a)(b)
- MDSAP Checklist

Source Inspection

- If the acceptance is going to be at the suppliers facility
- The intended verification and method **shall** be documented on the PO
- Records shall be maintained

Gap Analysis – Verification of Purchased Product

- Do you have a method to ***identify which items require inspection?*** Are they clearly identified in a risk matrix?
- For those inspection plans, ***is the inspection level based on the risk*** identified in the Risk Management File, such as the Design FMEA or Hazard Analysis?
- Do you have procedures in place to ***assess supplier changes*** and how are they handled through your inspection process?

Analysis of Control methods

Controls	Cost	Resources
3rd party inspection requirement	high	3rd party inspectors
Source Inspection	high	Traveling inspectors
100% Lot inspection	high	In-house inspection and required metrology equipment
Sampling Lot inspection	medium	In-house inspection and required metrology equipment
Reduced sampling inspection	medium	In-house inspection and required metrology equipment
Supplier Provided Inspection data review/acceptance	medium	In-house inspection and less metrology equipment
Skip lot sampling inspection	low	In-house inspection and less metrology equipment (less frequent)
Tailgate sampling inspection	low	In-house inspection and less metrology equipment (less frequent)
Dock to Stock/periodic inspection	low	In-house inspection and less metrology equipment (less frequent)
No inspection/Certification program	ideal	In-house inspectors/traveling inspectors Little to no required metrology equipment
Review of Supplier Process Control Plans	ideal	Traveling Engineers and Inspectors based on performance (not schedule)

"Proactive Supplier Management in the Medical Device Industry," Quality Press, 2016.

Verification Activities

Part number	Revision	Attribute	Sample size	Accept/ Reject	Inspection tool and number
Drawing number	Current revision	Specific item to be measured	AQL Quantity per shipment	Quantity	Write in the tool or asset number

Clause 8.2.6

- Sample size is based on risk and performance
- Record the tool asset/ID when recording inspection results
- Record when a Supplier makes a change or an Engineering Change is made to verify they change will not impact the product
  - Use the “18 inch rule” during verification

Total Risk Factor ™

Risk Factors

- Severity of product
- Supplier's Quality System Detection
- Financial Stress Factor (viability)
- Order Capacity (% of your business)
- Lead-time

Weighted Factors – not everything is a priority

Source: "Proactive Supplier Management in the Medical Device Industry," Quality Press, 2016.

Risk Factor examples

Detection	Criteria	Suggested range of detection method	Ranking
Almost impossible	Quality system (QS) will not and/or cannot detect a potential cause/mechanism and subsequent failure mode.	None; no QS in place.	10
Low	QS has a poor chance of detecting a potential cause/mechanism and subsequent failure mode.	Indirect/infrequent checks only.	8
Moderate	QS may detect a potential cause/mechanism and subsequent failure mode.	Visual checks and measurements/gauging components. Periodic charting and tracking.	6
High	QS has a good chance to detect potential cause/mechanism and subsequent failure mode.	Measurements/gauging or testing/sampling of components during production to prevent potential failures. Continuous charting and tracking.	4
Almost certain	QS almost certain to detect potential cause/mechanism and subsequent failure mode.	Continuous monitoring predicts potential failures prior to occurrence.	2

Effect	Criteria: Severity of effect	Ranking
Hazardous	Very high severity ranking when a potential failure mode affects safe product operation. Noncompliance with government regulations. Patient death.	10
High	Product inoperable, with loss of primary function. Customer very dissatisfied.	8
Moderate	Product operable, but nonessential system inoperable. Customer experiences discomfort or dissatisfaction.	6
Low	Fit and finish does not conform. Defect noticed by most customers.	4
Minor to none	Fit and finish does not conform. Defect noticed by discriminating (<25%) customers, or no effect	2

Financial stress risk class	Financial stress score
1	1316–1875
2	1288–1315
3	1255–1287
4	1216–1254
5	1001–1215

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Total Risk Factor Matrix ™ - weighted

Supplier	Severity (dFMEA)			Supplier QS detection			Financial strength			Lead time			Order capacity			TRF
	S	WV	R1	D	WV	R2	F	WV	R3	LT	WV	R4	OC	WV	R5	
A																
B																
C																

Risk = Value* WV
TRF = R1+R2+R3+R4+R5

WV = weighted value
R = Risk

TRF Weighted example

Total Risk Factor (TRF) Assessment Criteria Form

	Weighted Approach														
Supplier	Severity (Design FMEA)			Supplier QS Detection			Financial Strength			Lead Time			Order Capacity			TRF
	S	Weight Value	Risk	D	Weight Value	Risk	F	Weight Value	Risk	LT	Weight Value	Risk	OC	Weight Value	Risk	Results
A	8	1.5	12	6	0.75	4.5	2	1	2	4	0.5	2	1	0.25	0.25	**20.75**
B	8	1.5	12	2	0.75	1.5	3	1	3	2	0.5	1	1	0.25	0.25	**17.75**
C	8	1.5	12	4	0.75	3	5	1	5	3	0.5	1.5	1	0.25	0.25	**21.75**

Total Risk Factor	Recommended Action
TRF ≥ 25	Either avoid supplier or use the most extreme level of control. **Examples:** Person in the plant monitoring day-to-day activities or releasing product, 100% Receiving Inspection (RI), 100% inline inspection/testing during your assembly, continuous supplier monitoring, excessive inventory buffer, back up supplier, probation period, continuous monitoring of supplier's financial status
20 ≤TRF> 25	High to moderate risk for selection/level of control associated with supplier. **Examples:** Use of tightened to normal RI, ongoing supplier monitoring, moderate inventory buffer, could consider single source supplier, frequent monitoring of supplier's financial status
TRF < 20	Moderate to low risk for selection/control of suppler. **Examples:** Use of normal to reduced RI, periodic supplier monitoring, use as single source supplier, light to no inventory buffer

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TRF Example – Audit determination task

High = 10 Medium = 5 Low = 1	10	8	1	10	5	8	5	
Short Description	**Supplier Product Impact H= Repac, Relabel, Manufac. Creates CoA M= Distributor L= Broker/Sales Office**	**Supplied H=Tier One M= Tier Two L= Tier Three**	**Quality Agreement H=No M= In progress L= Yes**	**Audit History H=Critical Obs or Tier 1 no site audit M=3 + Major Obs L=0 Major Obs**	**Site Feedback H= Critical Issue or >1 M= 1 Issue L= No issues**	**Supplier Status H= New M=Approved/Accepted L=Qualified**	**(Site Feedback) Complaints/ SCARS H= 2+ or Any Unresolved M= 1 L= 0**	**Total**
Scottsdale, AZ	5	10	10	10	1	5	1	290
Buffalo, NY	10	1	10	1	1	5	1	178
Fort Worth, TX	5	1	10	1	1	5	1	128
Visalia, CA	5	1	10	1	1	5	1	128
Batavia, IL	5	1	10	1	1	5	1	128
Scarborough, ME	5	1	10	1	1	5	1	128
Randolph, MA	5	1	10	1	1	5	1	128
York Beach, ME	5	1	10	1	1	5	1	128
Cataumet, MA	5	1	10	1	1	5	1	128
St. Louis, MO	5	1	10	1	1	5	1	128

Scope:
600 suppliers with resources to cover only 400
TRF™ assessment = 250 audits, solid justification

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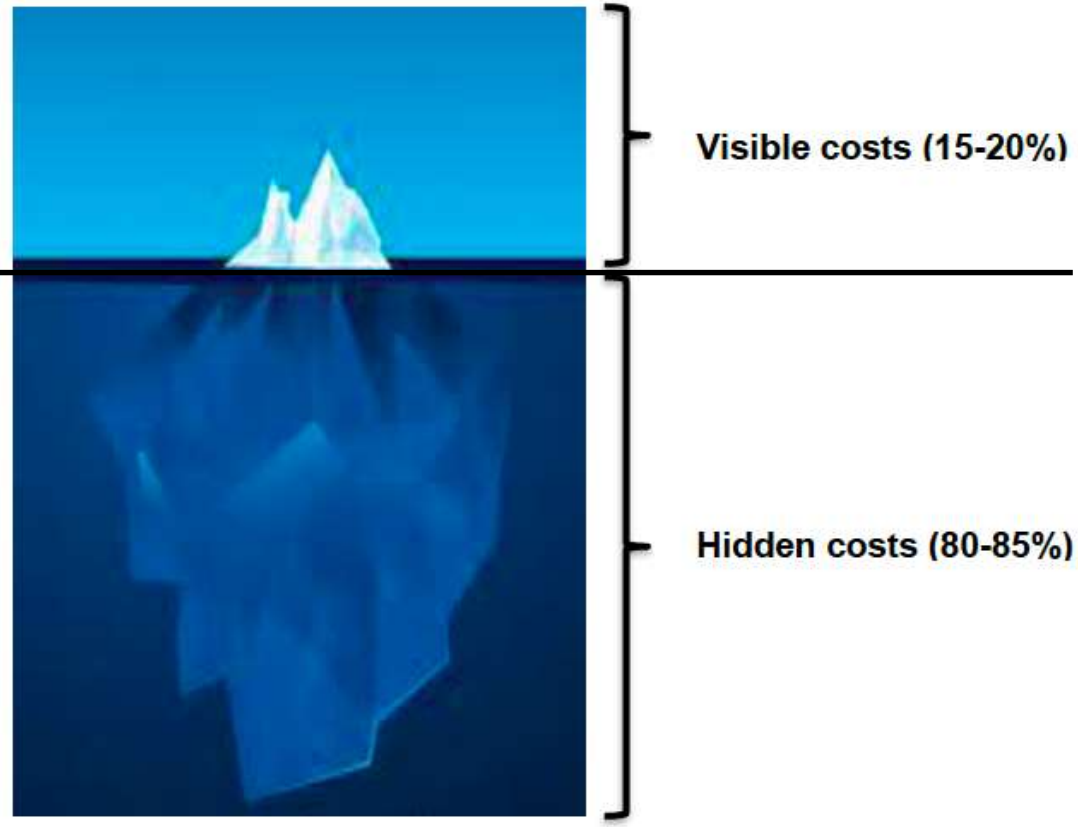
Benefits of Consolidation/Risk Reduction

- Overall reduces risks
- Reduction of suppliers will reduce your overall costs
- Improved relationships
- Focus on issues quicker and reduce the impact on production
- Stronger relationships can be built
- Larger buying power
- Shipping and Freight costs

Total Cost of Ownership (TCO)

Part cost or purchase price variance (PPV)

Shipping costs
Poor performance
Rework
Technical resources
Inspection
Extra inventory



Wait, no one said there would be math today…

$TCO = A_1 * A_2 * A_3 * A_4 \ldots$

Where A_x is the key attribute and all the values are consistent with the weighting factors

A_1 *–cost of Quality*

A_2 *- Cost for delivery performance*

A_3 *– Cost of inventory*

A_4 *– Cost of Freight/Shipping*

TCO Model

Attribute	How to calculate it	How to assign a weighting factor
A_1—Cost of quality	Look at the supplier's overall reject rate as a percentage of all parts or lots received. Use the percent defective as a multiplier to identify the suppliers that are creating more expenses for rejections.	If the supplier has 100% quality, then the factor would be one. If it's 95%, then the factor would be 1.05.
A_2—Cost of delivery performance	Look at the supplier's overall on-time delivery rate as a percentage of all parts or lots received. Use the percent late as a multiplier to identify the suppliers that are creating more expenses for late deliveries.	Similar to quality, if the supplier has had 100% on-time delivery, then the factor would be one. If it has had poor delivery performance, such as 85%, then the factor would be 1.15.
A_3—Cost of inventory	If inventory turns are already calculated, then use those numbers. If not, then look at the percentage of shipments that can be delivered directly to the manufacturing area (JIT). Look at this like aging of products you have that you're not using but still have in your inventory (if shipments can't be determined, use cost of inventory).	Higher inventory turns are better, so this weighting is the inverse of the two previous calculations: 1–3 turns, factor = 2 4–6 turns, factor = 1.5 7–11 turns, factor = 1 >12 turns, factor = 0.5 The same weighting factor should be applied to % of shipments or cost of inventory. The less % than can be used directly to manufacturing or the higher the cost of inventory is part of the "hidden factory costs."
A_4—Cost of freight/shipping	Add freight and shipping costs and divide the total cost by the total number of units shipped. This will give you the transportation cost per unit.	Use a Pareto chart to look at the results. Scale of 1–3, 1 being no cost associated and 3 being the most cost. 1 = less than 10% total cost 1.5 = 10%–30% total cost 2 = 30%–60% total cost 3 = greater than 60% of total cost

TCO in action

Measurements	Supplier A	Supplier B	Supplier C
Pricing	The Best!	Great pricing	Not as good as Supplier B
Quality Performance	95%	95%	99%
Delivery Performance	100%	90%	99%
How is the product delivered?	Large overseas shipping container, requires 100% sorting through incoming inspection	Your company pays for shipment costs so that the deliveries can be on time	Weekly shipment via UPS by the supplier
How much inventory do you have on hand?	Three months	Two months	Two weeks

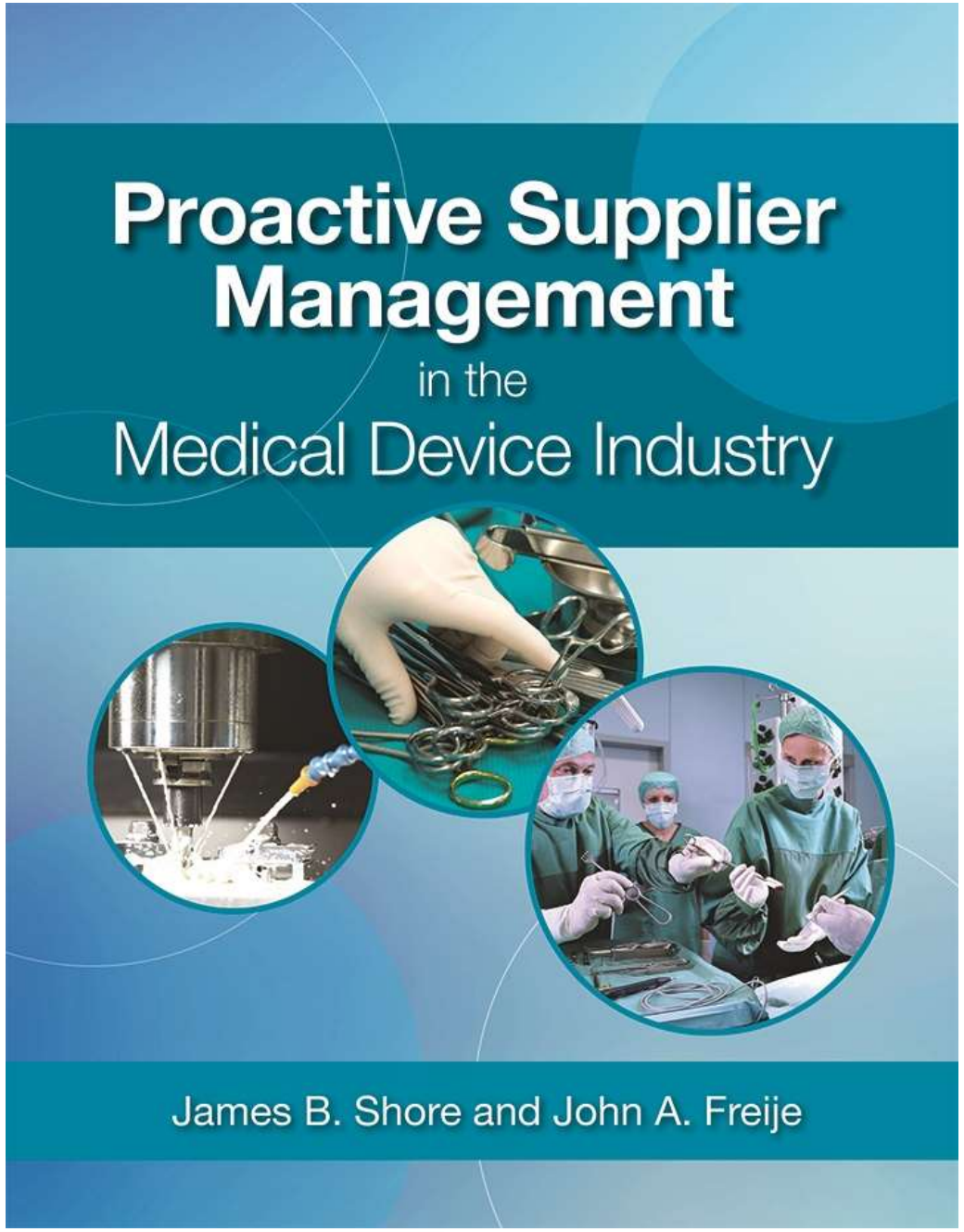
TCO = Quality*Delivery*Inventory*Freight

		quality	delivery	inventory	freight
Supplier	TCO	A_1	A_2	A_3	A_4
A	4.20	1.05	1.00	2.00	2.00
B	2.60	1.05	1.10	1.50	1.50
C	1.28	1.01	1.01	1.00	1.25

Supplier C is 1/3 less expensive than Supplier A

Summary

Are there compliance issues with Supplier Controls?	YES but avoidable!
Do Supplier Controls extend into other regulatory or compliance requirements?	• Yes - MDSAP, MDR and CE
What do we need to know?	• Understand the requirement • Keep it simple – sustainable - solution
What are best practices to be compliant?	• Risk based decision making tools



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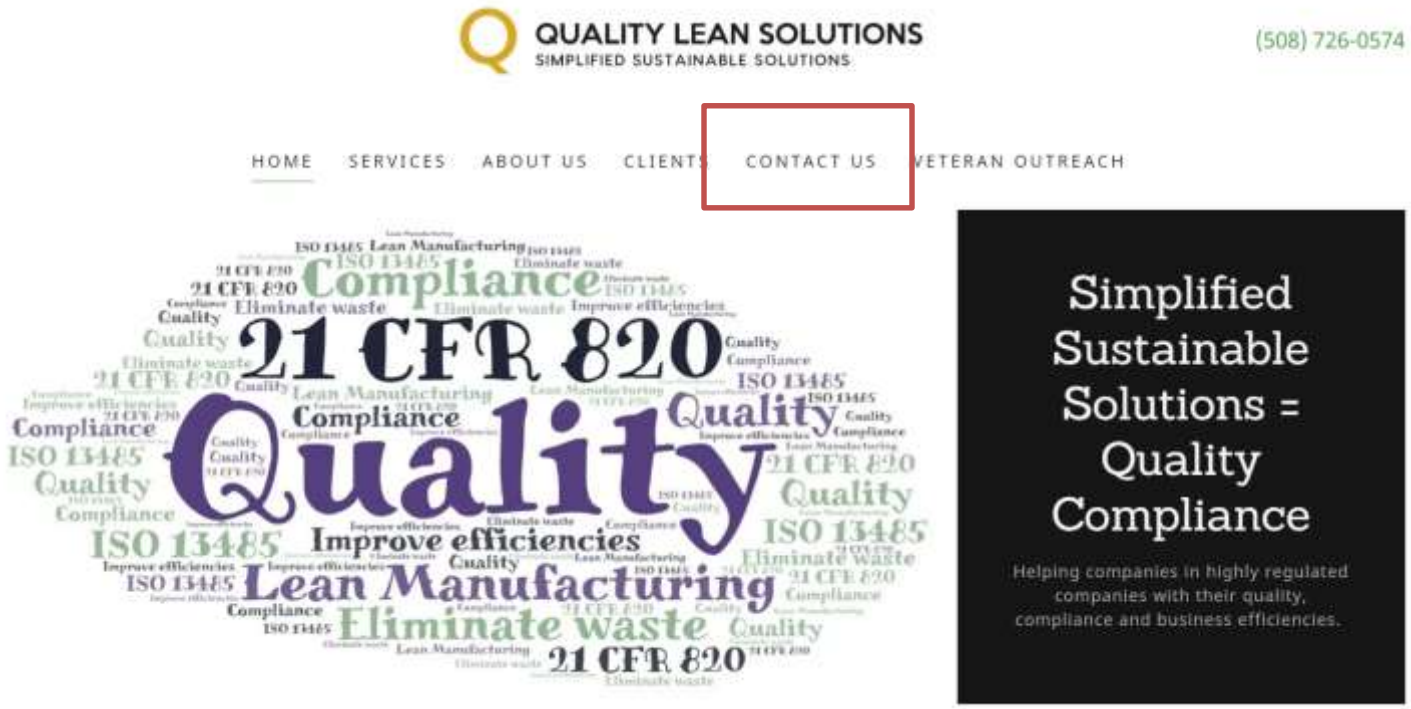

- What do you like about the site?
- What are three things that should be changed, updated or removed?

FREE

Supplier Quality Agreement template
Total Risk Factor ™
Cost of Ownership worksheet

Thank you!!

Jim Shore

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