Turning the FDA and IMDRF Model into SOPs

from initial supplier selection to contract end

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FDAnews Medical Device Quality Conference
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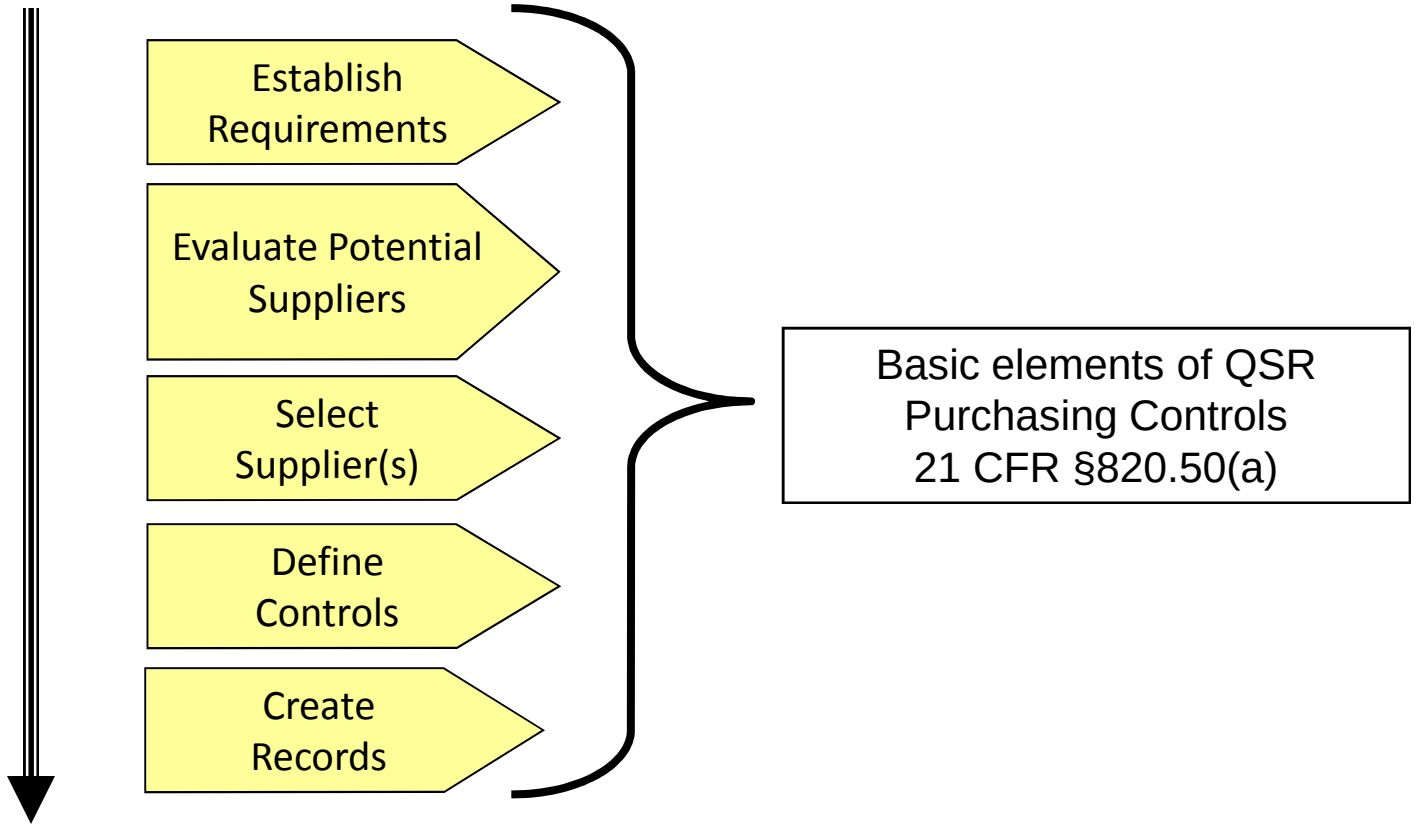
Agenda

six phase model

dealing with virtual companies

creating your program overview

Purchasing Controls §820.50(a)

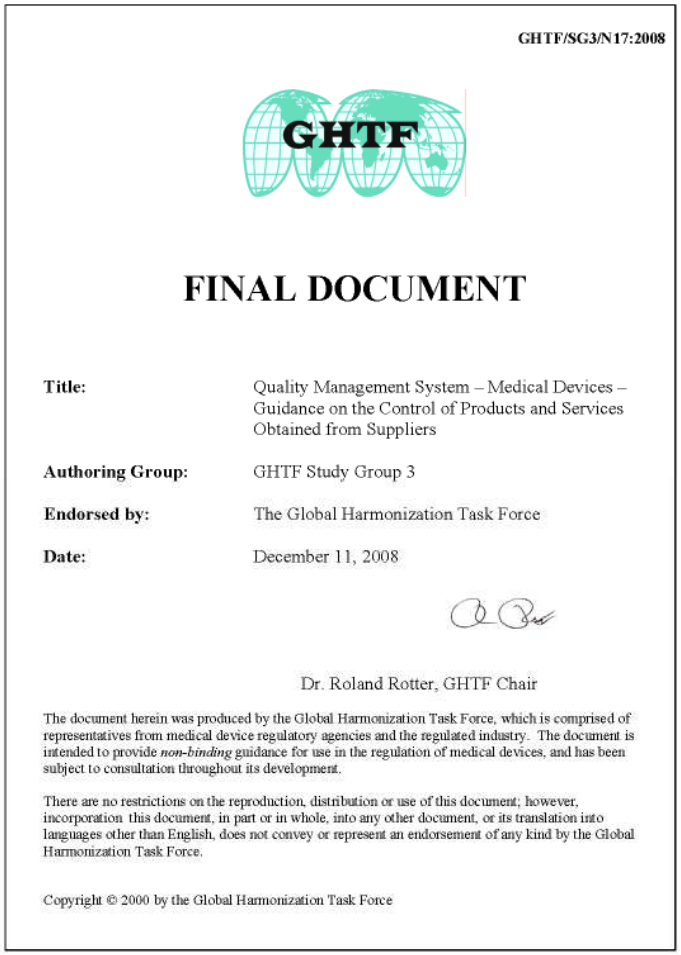


an average company in the US has

651 suppliers

Source:
International Journal of Purchasing and Materials Management
Institute for Supply Management

GHTF-IMDRF Model



GHTF/SG3/N17:2008

GHTF

FINAL DOCUMENT

Title:	Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
Authoring Group:	GHTF Study Group 3
Endorsed by:	The Global Harmonization Task Force
Date:	December 11, 2008

Dr. Roland Rotter, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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"A supplier is anyone that is independent from the manufacturer's quality management system."

- SG3-N17 Guidance on the Control of Products & Services from Suppliers

all GHTF guidelines can be found on IMDRF website at http://www.imdrf.org/documents/documents.asp

GHTF SG3-N17 Guidance

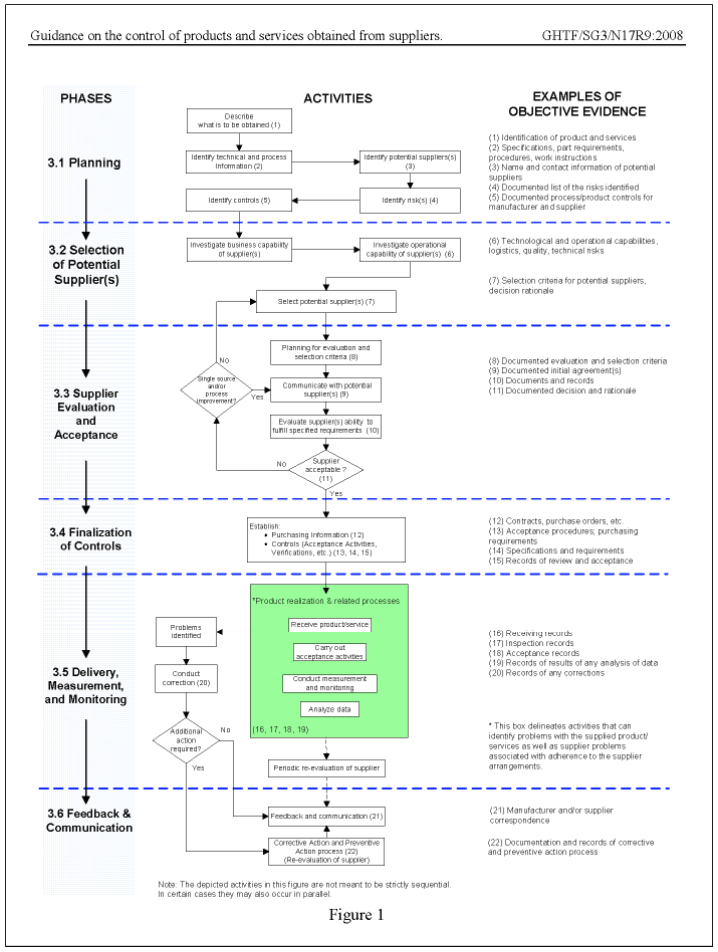
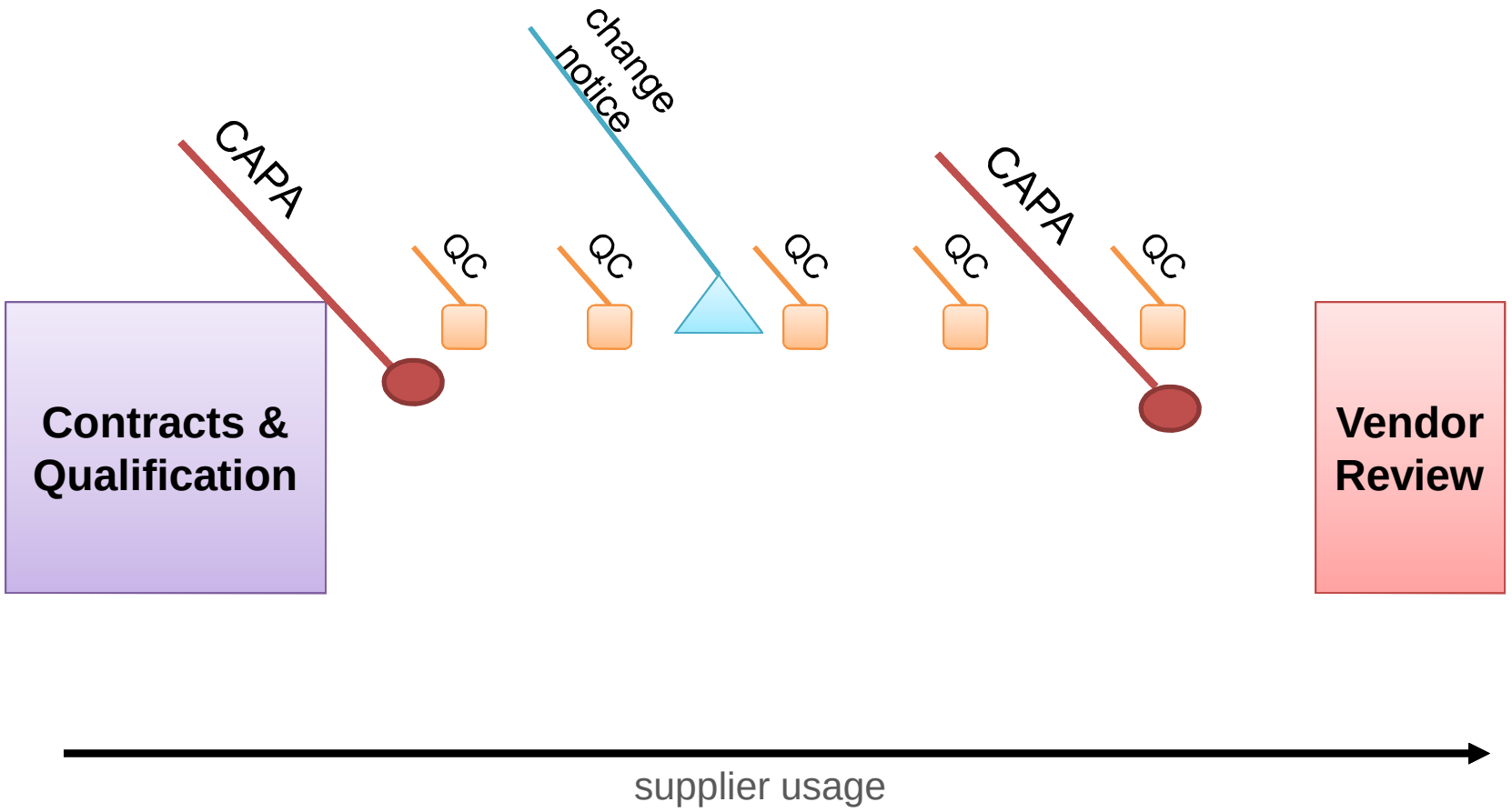


Figure 1

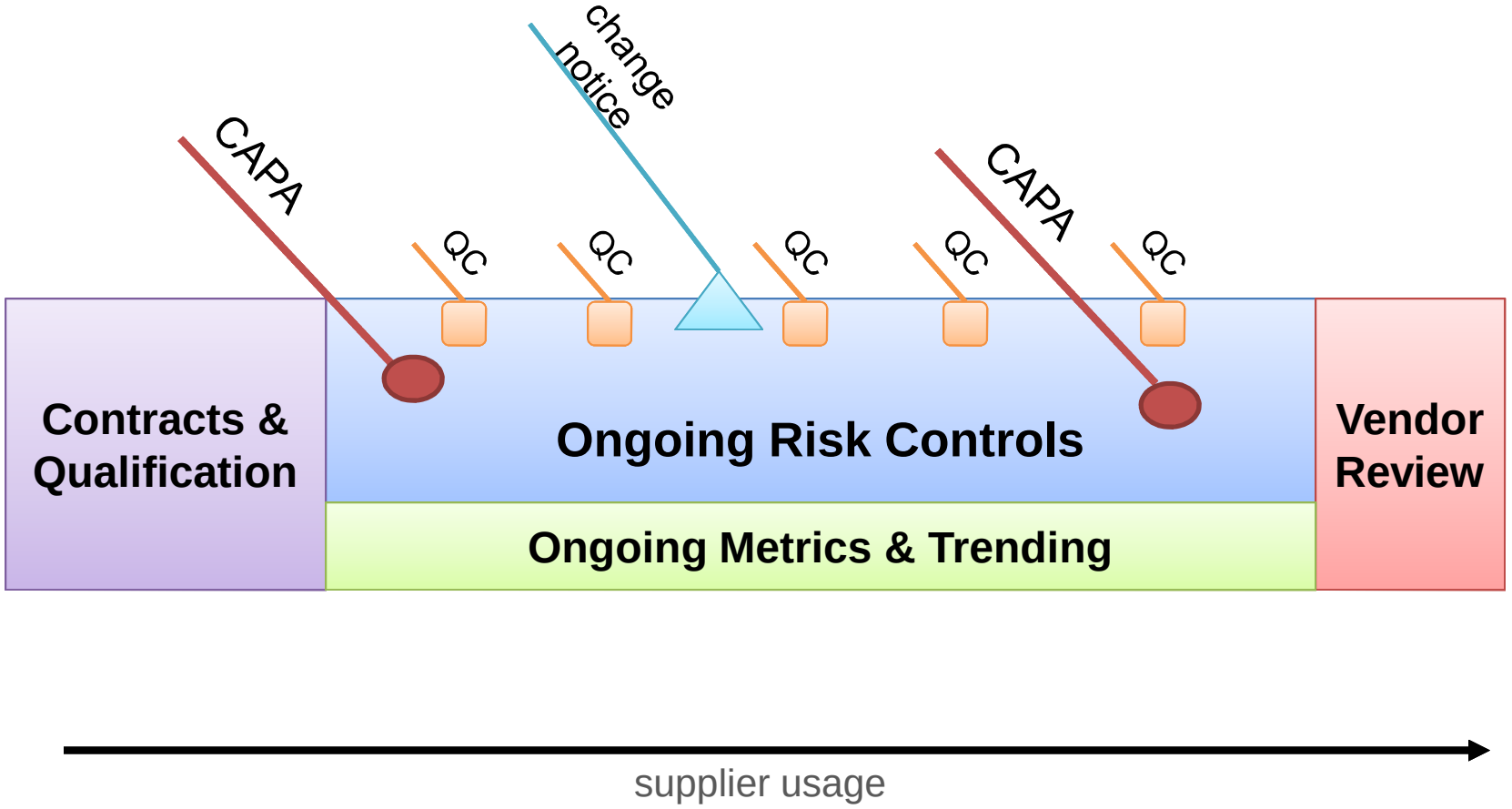
Guidance on Control of Products and Services Obtained from Suppliers (2008)

- Six overall phases
- 22 distinct activities
- Each phase ≈ one SOP
- Each SOP -> record(s) as proof

Oversight - Traditional



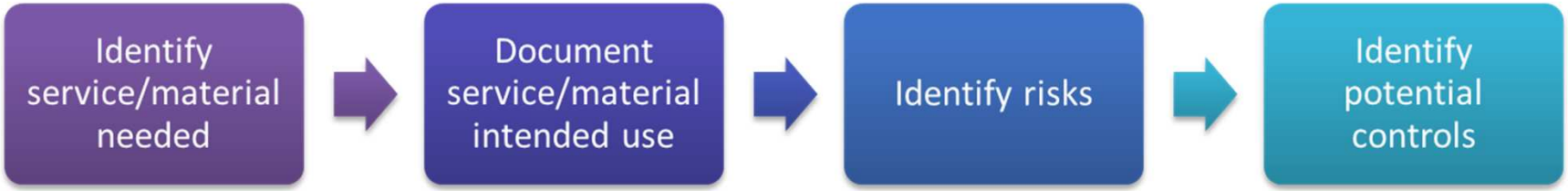
Oversight – 21st Century



*adapted from Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine (Logos Press, 2010)

Overall Process

Step 1: Planning



Determine Sourcing Needs

Stem from device development

- parts/ingredients/components
- work activities (manufacturing, warehousing, distribution, data center hosting, etc.)

Re-use risk assessments if available

- previous work with ingredient or supplier
- from clinical production

Do not forget to document UDI requirements

Rapidly Assess Risk

Non-conforming materials **directly** result in ...

... product failure

... patient injury

...your noncompliance

Non-conforming services **directly** result in ...

... product failure

... patient injury

...your noncompliance

Rapid Risk Example

We've decided we want to outsource production of our new device to a contract manufacturer (CMO) in Brazil. The CMO will send the finished product to us for final distribution. The CMO does **NOT** have a good laboratory practices-certified lab in which to test finished product for release.

Assuming no other controls are in place, will the lack of a GLP QC lab in Brazil likely...

a)Result in a loss of patient safety?

b)Result in a lessening of product efficacy?

c)Result in our non-compliance with a statute or regulation?

d)Result in our non-compliance with a harmonized guideline?

Identify Potential Controls

- Stratified acceptance of supplies/services
- Status reports (monitoring reports)
- On-site liaisons
- Supplier integration into product spec development for new products
- Service level agreements
- Independent advisor as SME
- Regular mock FDA audits
- Quarterly reports
- Increased raw materials testing/imports (at supplier)
- Increased incoming supplier product sampling/testing (at sponsor)
- Data formats
- Data integrity controls to ensure data is not changed or created without authorization
- Record retention
- Periodic conference calls
- Dedicated communication channels
- Limit off-shoring of workforce or sub-suppliers
- Periodic budget reviews
- Specific monitoring audits

etc., etc….

Control Example

Think back to our Brazilian CMO and their lack of a finished product QC lab that is GLP-compliant.

Which **one** of the following controls has the greatest likelihood of minimizing risk to our patient safety, our product efficacy, and our compliance?

a) Increased raw materials testing at the CMO?
b) Formal change control involvement between us and the CMO?
c) Increased incoming finished product testing at our site before we release the product?
d) A yearly onsite quality system audit at the CMO?

Number of Controls

Confidence Level

Threat/Risk Level	Low (90%)	Medium (95%)	High (>99%)
Unlikely	Do not actively manage		1
Low	1+	2+	3+
Medium	3+	4+	5+
High	5+	6+	7+

Costs →

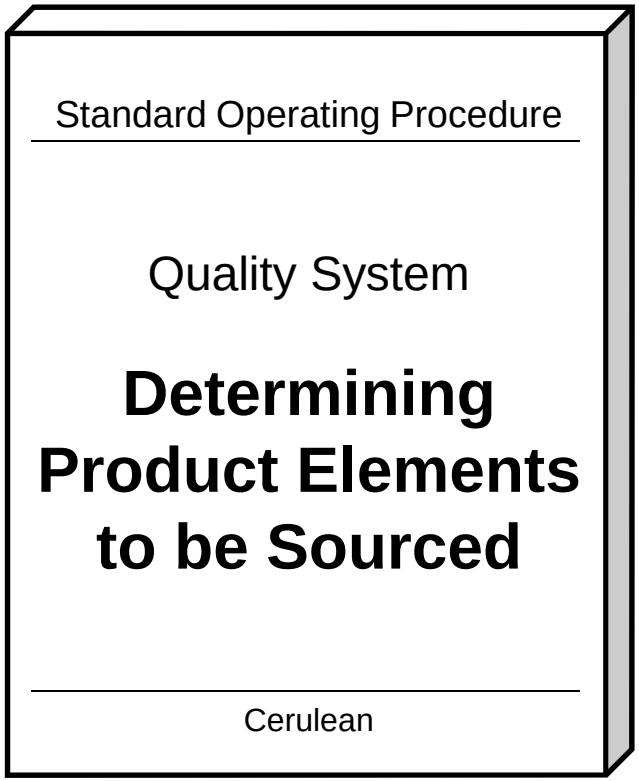
SOP: Sourcing Determination

Workflow

1. use DHF to identify components or work activities to be sourced
2. re-use DHF risk assessments, otherwise conduct

Record(s) generated

- list of elements to be sourced
- list of risks to be controlled
- list of controls (contract, qualification, etc.)



Step 2: Selection

Basic criteria → Advanced criteria → International criteria → Supply chain mapping

Evaluate Capability

Basic Criteria

- What is the supplier's financial viability?
- Has the supplier worked with customers in your industry before?
- Does the supplier have any personnel-related restrictions?

Advanced Criteria

- What is the amount of work you expect to provide the supplier versus their overall capacity?
- Does the supplier need to make capital investments to support your business?
- What level of disaster recovery or business continuity can the supplier provide?

International Criteria

- Will you rely upon supplier's translation of critical information? How will you verify their translation?
- Is the supplier registered with FDA?
- Has the supplier worked with customers in your country before?
- In what monetary denomination does the supplier expect to be paid?
- How will you communicate regularly (email, teleconferences, etc.) with the supplier if you do not speak their language?
- How will you coordinate across time zones?
- Do you have mutually compatible IT systems?

International Criteria

- In a country with ongoing FDA import alerts?

  www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/

- In a country with export restrictions?

  www.bis.doc.gov/policiesandregulations/regionalconsiderations.htm

- In a country with significant market instability?
- In a country with IP loss worries?
- In a region with conflict minerals?

SOP: Selecting Suppliers

Workflow

1. evaluate business capabilities
2. assess international impact
3. consolidate into 2+ potentials

Record(s) generated

- list of suppliers considered
- checklist of basic criteria
- known supply chain (to Tier 2)

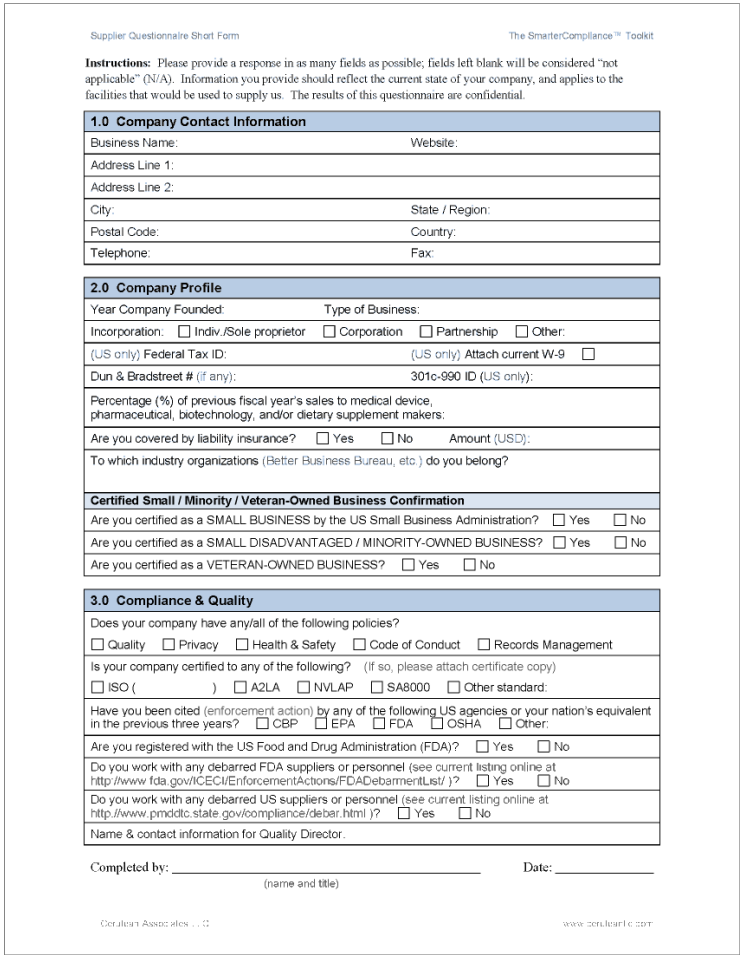
Step 3: Qualification

Basic → Remote → Onsite → Personnel

Supplier Qualification

Basic due diligence

- 1-page supplier questionnaire
- intent is to gather **(confirm)** basic business information
- can also serve as rapid **red flag** review
- supplement with internet reviews



Supplier Questionnaire Short Form — The SmarterCompliance™ Toolkit

Instructions: Please provide a response in as many fields as possible; fields left blank will be considered "not applicable" (N/A). Information you provide should reflect the current state of your company, and applies to the facilities that would be used to supply us. The results of this questionnaire are confidential.

1.0 Company Contact Information	
Business Name:	Website:
Address Line 1:	
Address Line 2:	
City:	State / Region:
Postal Code:	Country:
Telephone:	Fax:

2.0 Company Profile	
Year Company Founded:	Type of Business:
Incorporation: ☐ Indiv./Sole proprietor ☐ Corporation ☐ Partnership ☐ Other:	
(US only) Federal Tax ID:	(US only) Attach current W-9 ☐
Dun & Bradstreet # (if any):	301c-990 ID (US only):
Percentage (%) of previous fiscal year's sales to medical device, pharmaceutical, biotechnology, and/or dietary supplement makers:	
Are you covered by liability insurance? ☐ Yes ☐ No	Amount (USD):
To which industry organizations (Better Business Bureau, etc.) do you belong?	
Certified Small / Minority / Veteran-Owned Business Confirmation	
Are you certified as a SMALL BUSINESS by the US Small Business Administration? ☐ Yes ☐ No	
Are you certified as a SMALL DISADVANTAGED / MINORITY-OWNED BUSINESS? ☐ Yes ☐ No	
Are you certified as a VETERAN-OWNED BUSINESS? ☐ Yes ☐ No	

3.0 Compliance & Quality
Does your company have any/all of the following policies? ☐ Quality ☐ Privacy ☐ Health & Safety ☐ Code of Conduct ☐ Records Management
Is your company certified to any of the following? (If so, please attach certificate copy) ☐ ISO ( ) ☐ A2LA ☐ NVLAP ☐ SA8000 ☐ Other standard:
Have you been cited (enforcement action) by any of the following US agencies or your nation's equivalent in the previous three years? ☐ CBP ☐ EPA ☐ FDA ☐ OSHA ☐ Other:
Are you registered with the US Food and Drug Administration (FDA)? ☐ Yes ☐ No
Do you work with any debarred FDA suppliers or personnel (see current listing online at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/)? ☐ Yes ☐ No
Do you work with any debarred US suppliers or personnel (see current listing online at http://www.pmddtc.state.gov/compliance/debar.html)? ☐ Yes ☐ No
Name & contact information for Quality Director.

Completed by: _____ Date: _____
(name and title)

Cerulean Associates . . .

www.ceruleanllc.com

Supplier Qualification

Remote audit

- conduct critical personnel interviews
- prepare for any onsite audit
- request and review:
  - at least 5-10 SOPs or policies
  - recent (within past 3 years) third-party audit summaries
  - most recent quality systems management review (QSMR)
  - 12 CAPAs (1 per month) associated with key words/phrases important for your product or outsourced service
  - (if relevant) UDI barcode printing and inspecting capabilities
  - etc.

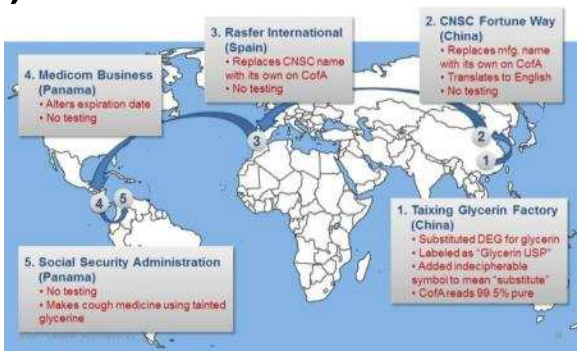
Supplier Qualification

High-level map of your supply chain thru supplier

- know who your supplier's suppliers are
- if won't tell you, then find out region (China, etc.)

Critical suppliers only

- critical components, ingredients, and outsourced services
- distribution trail
- imagine recall and traceability



Supplier Qualification

Onsite due diligence

- cost: $ 6,000 – 14,000 (USD) each
  + plus $1,000 – 2,000 for travel + $230/day hotel/taxi/meals
- time: 20-30 days each (including up to 4 days on site)

Prioritize on critical suppliers

- document timeline and progress to complete all
- document follow-ups and closures on any open items
- consider hiring outside experts when cost-effective OR need supplemental assurance (e.g., Part 11 and data integrity, etc.)

Supplier Qualification

1. Check FDA debarment list
   www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/
2. Check HHS debarment list
   http://oig.hhs.gov/exclusions/exclusions_list.asp
3. (international only) Check US State Department exclusion list
   www.pmddtc.state.gov/compliance/debar.html
4. Google key exec name and phrases:
   - “warning letter”
   - “consent decree” or “corporate integrity agreement”
   - “bankruptcy”
   - “investigation”
   - “fraud”
   - “scam”
   - “debar” (not debarment)

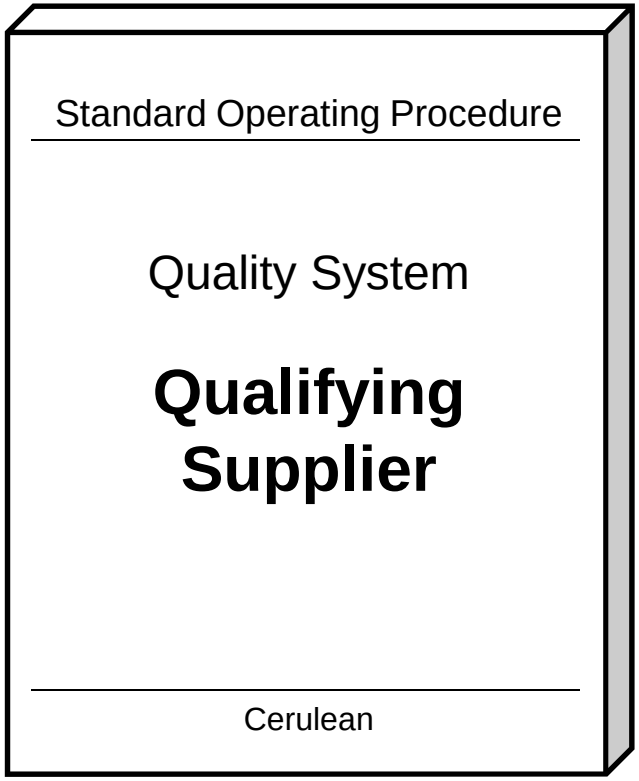
SOP: Qualifying a Supplier

Workflow

1. initial remote due diligence
2. remote audit
3. onsite audit
4. key personnel review

Record(s) generated

- basic questionnaire
- remote audit checklist
- onsite audit checklist
- key personnel review checklist
- supplier qualification report



Step 4: Controls & Contracts

Finalize specific controls → Negotiate contract/quality agreement → Determine division of controls

Controls at the Supplier

First line of defense

- incoming raw materials inspections
- raw materials warehousing/staging/inventory
- production controls – SOPs, PAT, personnel, etc.
- finished product quality control
- data integrity controls

Supplemental considerations

- change control involvement (vs. notification)
- CAPA involvement (vs. notification)

Controls at the Sponsor (you)

Last line of defense

- batch record reviews
- incoming vs. outgoing inspection
- storage/inventory controls
- final shipment inspections – product, labels, etc.
- your data integrity controls

Ongoing monitoring controls

- reviewing trip reports
- tracking budgetary expenditures

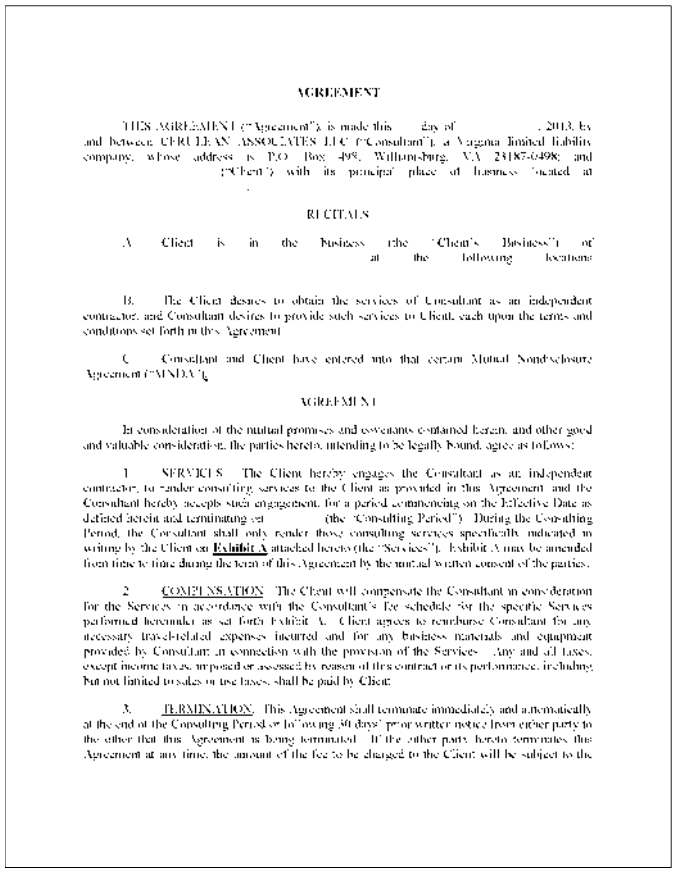
Legal Agreements

FDA expects to see “mutually negotiated”

Practical realities:

- not going to do any mutual negotiation for off-the-shelf items (P.O. T&C’s, credit card terms, etc.)
- unlikely to take any supplier to court that you buy less than $15,000 - $25,000 from
- “quality agreements” need to be negotiated and signed by officers of a company (no legal standing otherwise)
- unenforceable agreements (between affiliates, subsidiaries, etc.) run the risk of being exercises in paperwork only

Contractual Points



AGREEMENT

THIS AGREEMENT ("Agreement") is made this day of , 2013, by and between CERULEAN ASSOCIATES LLC ("Consultant"), a Virginia limited liability company, whose address is P.O. Box 499, Williamsburg, VA 23187-0498; and ("Client"), with its principal place of business located at .

RECITALS

A. Client is in the business (the "Client's Business") of at the following locations:

B. The Client desires to obtain the services of Consultant as an independent contractor, and Consultant desires to provide such services to Client, each upon the terms and conditions set forth in this Agreement.

C. Consultant and Client have entered into that certain Mutual Non-Disclosure Agreement ("MNDA").

AGREEMENT

In consideration of the mutual promises and covenants contained herein, and other good and valuable consideration, the parties hereto, intending to be legally bound, agree as follows:

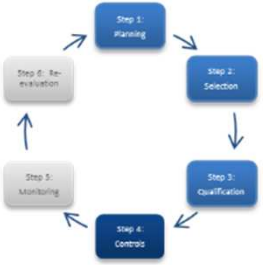
1. SERVICES. The Client hereby engages the Consultant as an independent contractor, to render consulting services to the Client as provided in this Agreement, and the Consultant hereby accepts such engagement, for a period commencing on the Effective Date as defined herein and terminating on (the "Consulting Period"). During the Consulting Period, the Consultant shall only render those consulting services specifically indicated in writing by the Client on **Exhibit A** attached hereto (the "Services"). Exhibit A may be amended from time to time during the term of this Agreement by the mutual written consent of the parties.

2. COMPENSATION. The Client will compensate the Consultant in consideration for the Services in accordance with the Consultant's fee schedule for the specific Services performed hereunder as set forth Exhibit A. Client agrees to reimburse Consultant for any necessary travel-related expenses incurred and for any business materials and equipment provided by Consultant in connection with the provision of the Services. Any and all taxes, except income taxes, imposed or assessed by reason of this contract or its performance, including, but not limited to sales or use taxes, shall be paid by Client.

3. TERMINATION. This Agreement shall terminate immediately and automatically at the end of the Consulting Period, or following 30 days' prior written notice from either party to the other that this Agreement is being terminated. If the other party hereto terminates this Agreement at any time, the amount of the fee to be charged to the Client will be subject to the

- Workflow responsibility matrix (copy control points from CFRs and guidances)
- Identify who's accountable for retaining records, their integrity – and for how long (and transfer controls!)
  - *Note:* FDA, EMA and Health Canada very interested in transfer and other data integrity controls….
- Ensure your ability to audit with an independent auditor
- Obtain an annual statement of compliance

SOP: Finalizing Supplier Controls



Workflow

1. determine controls (from risk assessment) to have at supplier
2. determine controls you'll have
3. negotiate legal agreements

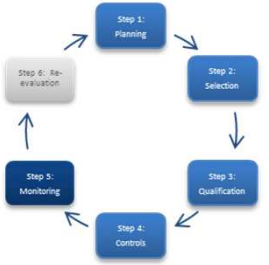
Record(s) generated

- legal agreements
  - addendum listing of controls
  - addendum listing of records ownerships/retention
  - addendum listing responsibilities
- purchase orders, etc.

Step 5: Monitoring

Supply realization → Problem resolution → Ongoing communications → Regular trending & reporting

Control Reference



- Trend (and document) metrics to assess supplier consistency & reliability
- Examples:
  - changes you were involved in ahead of time vs. post-change
  - non-conformances/CAPAs
  - critical personnel turnover
  - delivery deadlines/slippage
  - percentage of returns/rejects
  - shipment times/delays
  - certificates of sterility
  - certificates of conformance
  - completeness of bill of materials

SOP: Monitoring and Maintaining Supplier Compliance

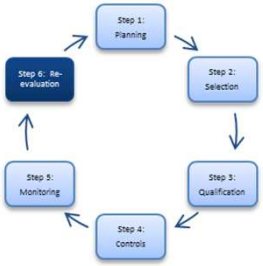
Workflow

1. define & collect metrics
   - don't forget incoming material receipts, etc. (C of A, C of C, C of S)
   - also includes CAPAs, etc.
2. regularly review (QSMR, annual product review, etc.)

Record(s) generated

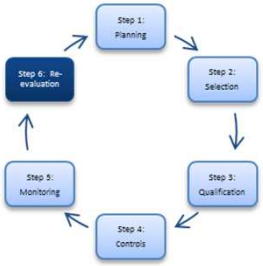
- collected metrics (see shipping & receiving SOP outputs, etc.)
- supplier correspondence
- supplier-related CAPAs and change controls
- communication matrix

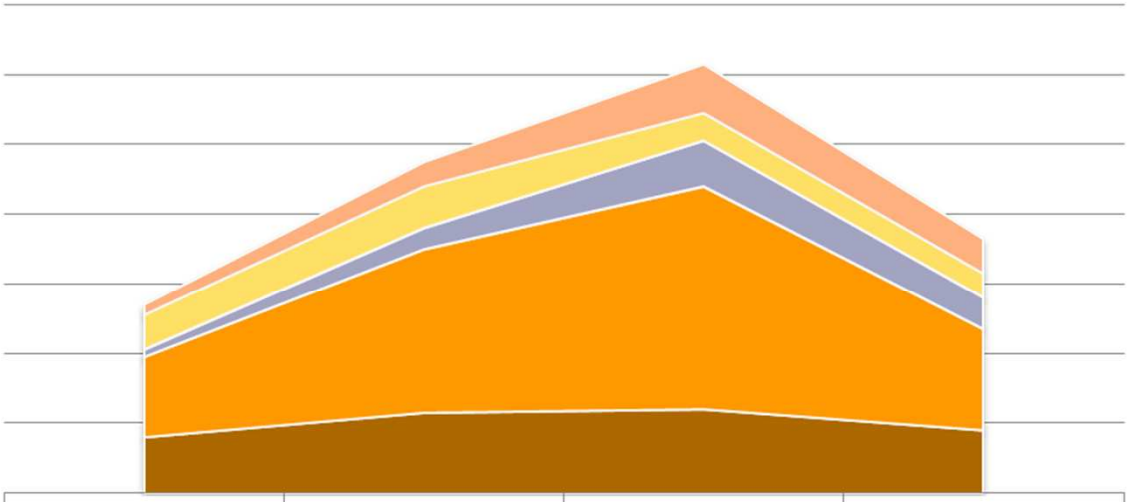
Step 6: Re-Evaluation



Annual Product Review → Annual QSMR → End of Contract Re-Evaluation

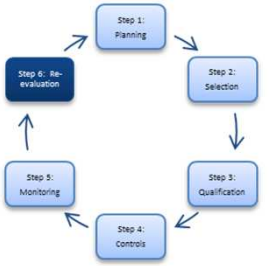
Product Review or QSMR





	Q1	Q2	Q3	Q4
Raw Materials NCs	3	7	14	10
Batch/Lot Failures	10	12	8	7
Consumer Complaints	2	6	13	9
Production Runs	23	47	64	29
Mfg Personnel	16	23	24	18

Contract Renewal



Supplier Re-Evaluation Worksheet

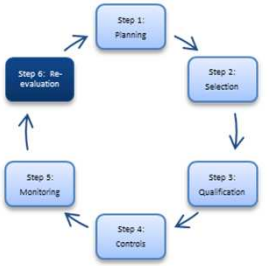
Supplier Name _____

Check the applicable boxes based on the Approved Supplier List
☐ Material ☐ Equipment ☐ Services

MATERIAL SUPPLIER		
Question	Y/N	If No, explain the reason. Discuss this supplier at the next Management Review meeting.
This supplier's material arrives on time.		
This supplier's material arrives correctly.		
This supplier's material arrives with all the required documentation (CoC, CoA, *etc.*)		
We have not issued a Nonconforming Vendor Material Report to this supplier in the previous 12 months.		
This supplier is easy to work with.		

EQUIPMENT SUPPLIER		
Question	Y/N	If No, explain the reason. Discuss this supplier at the next Management Review meeting.
This supplier provided after sale support when we needed it.		
Spare (or replacement) parts are readily available from this supplier.		
This supplier's equipment meets reliability and maintainability expectations.		
We have not issued a Nonconforming Vendor Material Report to this supplier in the previous 12 months.		
This supplier is easy to work with.		

SOP: Re-Evaluating Suppliers

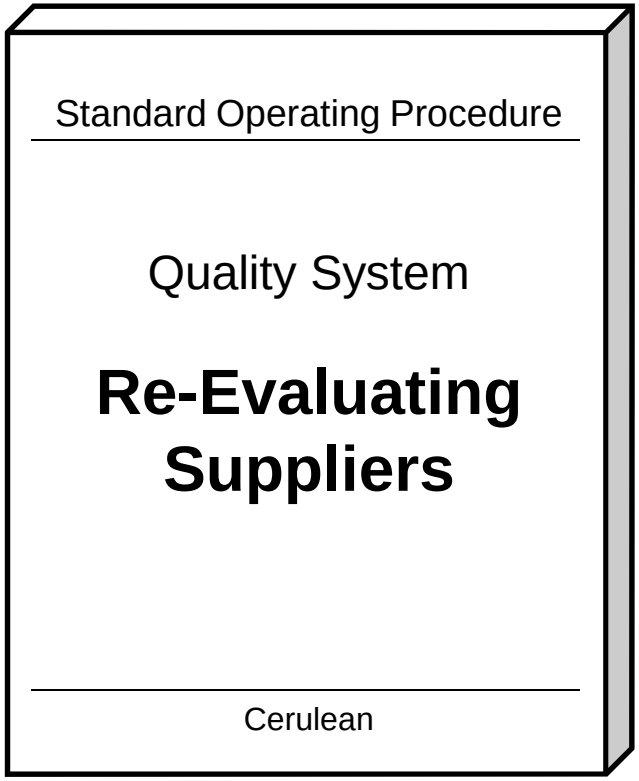


Workflow

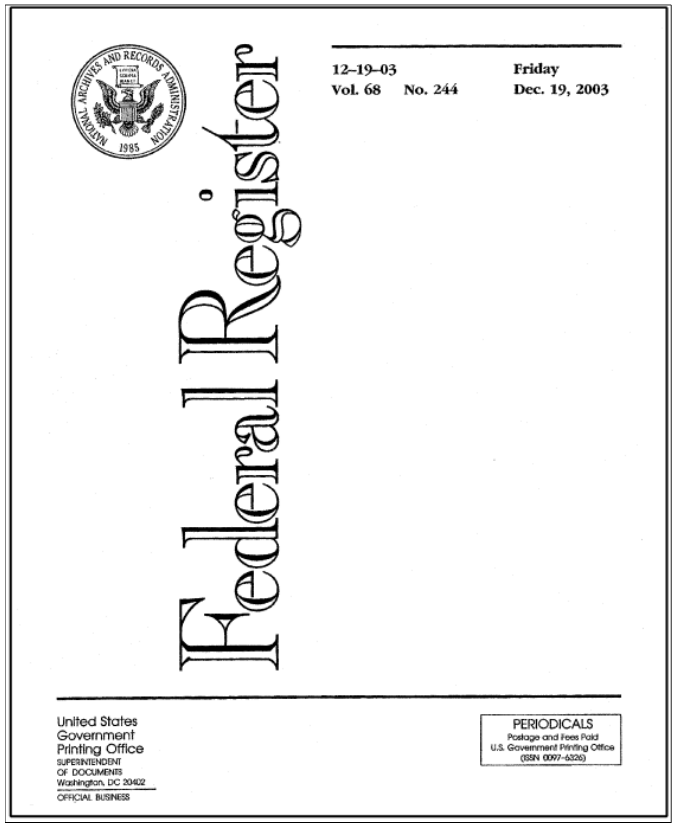
1. schedule re-evaluation 1 year **prior** to contract end
2. re-send basic questionnaire
   - may want to do yearly for critical
3. conduct formal re-evaluation

Record(s) generated

- updated questionnaire
- re-evaluation worksheet



FDA's Additional SOP List



Federal Register, Vol. 76, No. 188
(September 2011)

- SOP on receipt, testing and approval of product components, containers and closures
- SOP on reviewing, examining and verification of labeling and packaging materials
- SOP on warehousing
- SOP on final product distribution

http://www.gpo.gov/fdsys/pkg/FR-2011-09-28/pdf/2011-24991.pdf

Key Points so far…

- Process must handle at least 651 suppliers
- GHTF/IMDRF guidance can be encapsulated into 6 SOPs
- FDA adds 4 SOPs on warehousing, testing, distribution
- Each SOP has to produce records of compliance

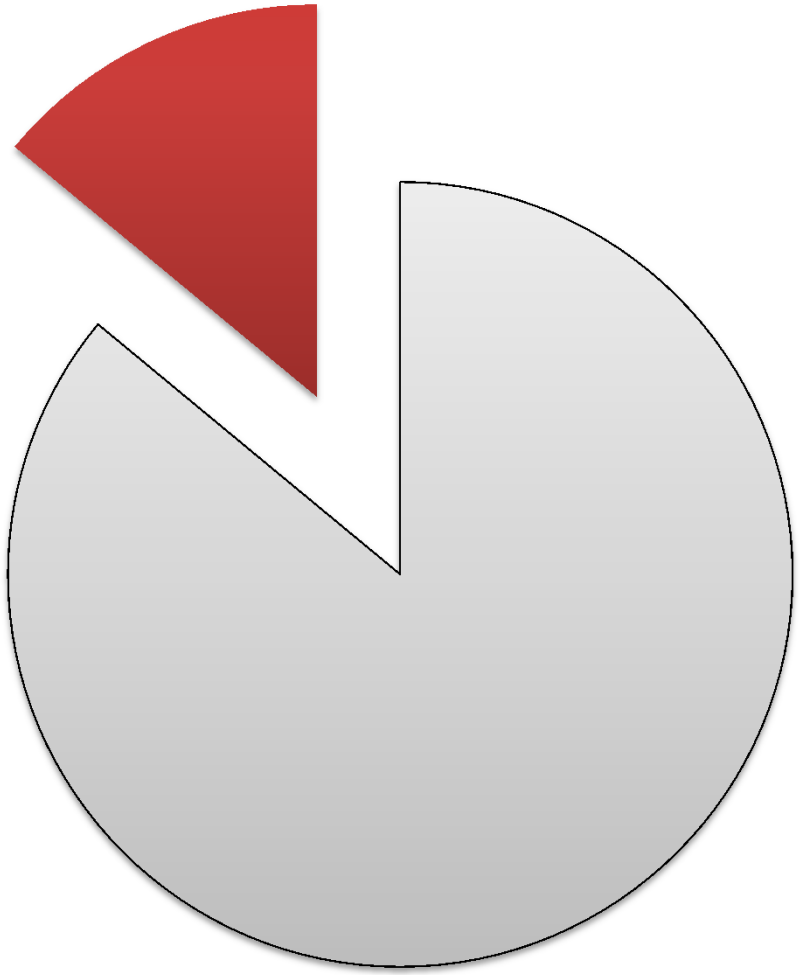
Interactive Exercise

Dealing with Virtual Companies

"Oh, we'd **never** do business with a virtual company."

- medical device CEO to his consultant … *from a virtual consulting firm*, February 2010

More than 11% of the entire global workforce...



source:
Australian Virtual Business Network

...work for a **virtual company**

Translation:

1 out of 10 of your suppliers

is virtual

“So how can I tell which of my suppliers are virtual?”

Question to Consider

Which of these likely indicates a virtual supplier?
A company that…

a) Uses a PO Box for its mailing address?
b) Doesn't list all of its senior management or managing partners on its website?
c) Hosts its website in the UK but has a US mailing address?
d) Is not publicly traded?
e) Does not list a mailing address on its website?
f) Recently changed its name and mailing address?
g) Doesn't have any SOPs for you to review?

"It is **impossible** for you to produce a medicine if you expect to conduct an **onsite audit** of every one of your suppliers."

- Kim Trautman, FDA, CDRH, August 2010

Example FDA Questions

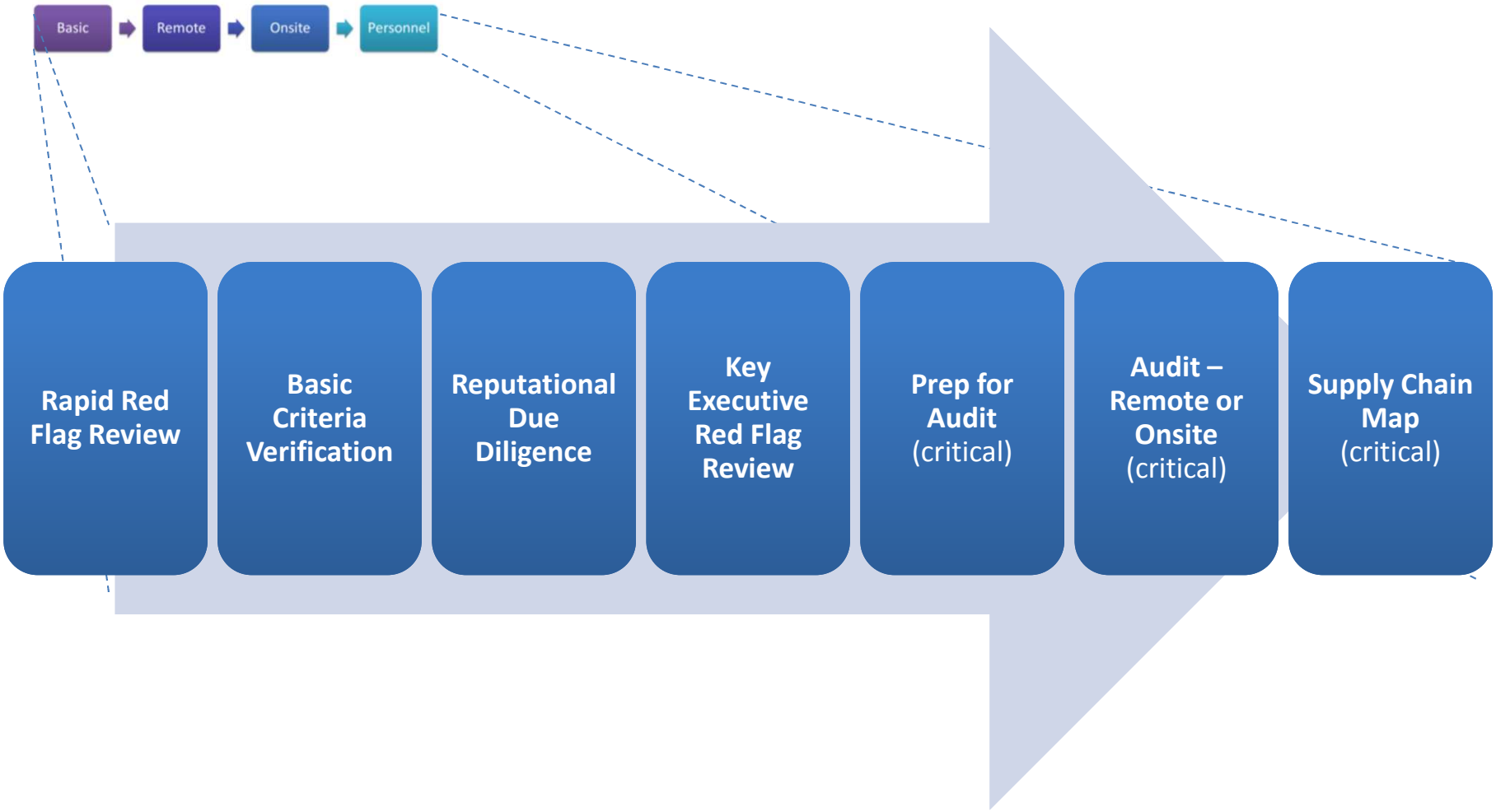
- does the contract with the supplier define the specific responsibilities of each party?
- are the types of oversight to be exercised by the sponsor described in the contract?
- what documentation does the sponsor have to show that the supplier was the actual manufacturer (or that the sponsor was aware of the actual material maker)?
- does the sponsor obtain periodic independent testing of supplied materials and/or finished drug?
- for APIs, does the sponsor know its own supply chain (at least through tier 2 suppliers)?
- **how does the company consistently oversee and monitor those suppliers whom it does not audit?**
- **how does the company qualify suppliers it cannot physically audit?**

Supplier Qualification

Remote audit

- conduct critical personnel interviews
- ~~prepare for any onsite audit~~
- request and review:
  - at least 5-10 SOPs or policies
  - recent (within past 3 years) third-party audit summaries
  - most recent quality systems management review (QSMR)
  - 12 CAPAs (1 per month) associated with key words/phrases important for your product or outsourced service
  - (if applicable) UDI capabilities and controls
  - etc.

7-Step 21st Century Qualification



Rapid Red Flag Review

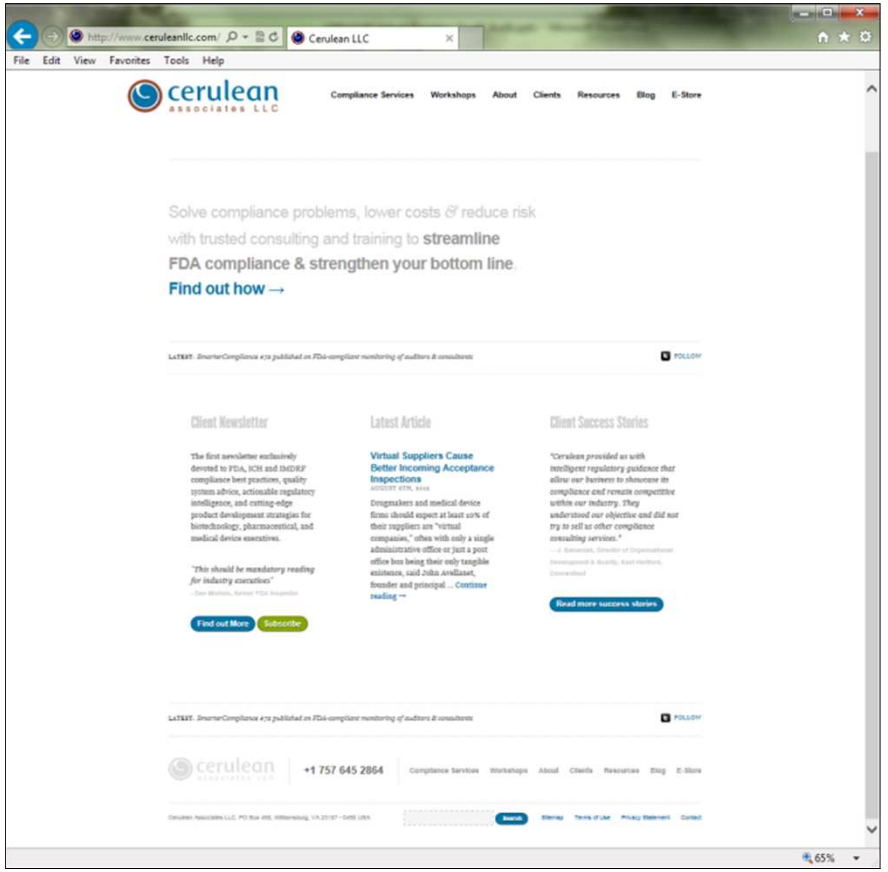
Review Firm's Website

- Info is consistent (look for misspelled common regulatory acronyms – HIPAA, FDASIA, FDAAA, etc.)
- Relatively current
- Email address matches website URL
- Physical address should fit expectations (google earth)
- Privacy policy, terms of use, etc.
- Online payment security:
  - is a "verified business" through an online payment processor (PayPal, etc.)
  - sends you to encrypted section to input payment info (https)

Example

- ✓ Info consistent
- ✓ Up-to-date
- ✓ Email matches URL
- ✓ Physical address
- ✓ Privacy policy
- ✓ Online payment security
- ✓ Debarment-free

Put in vendor dossier



Basic Criteria Verification

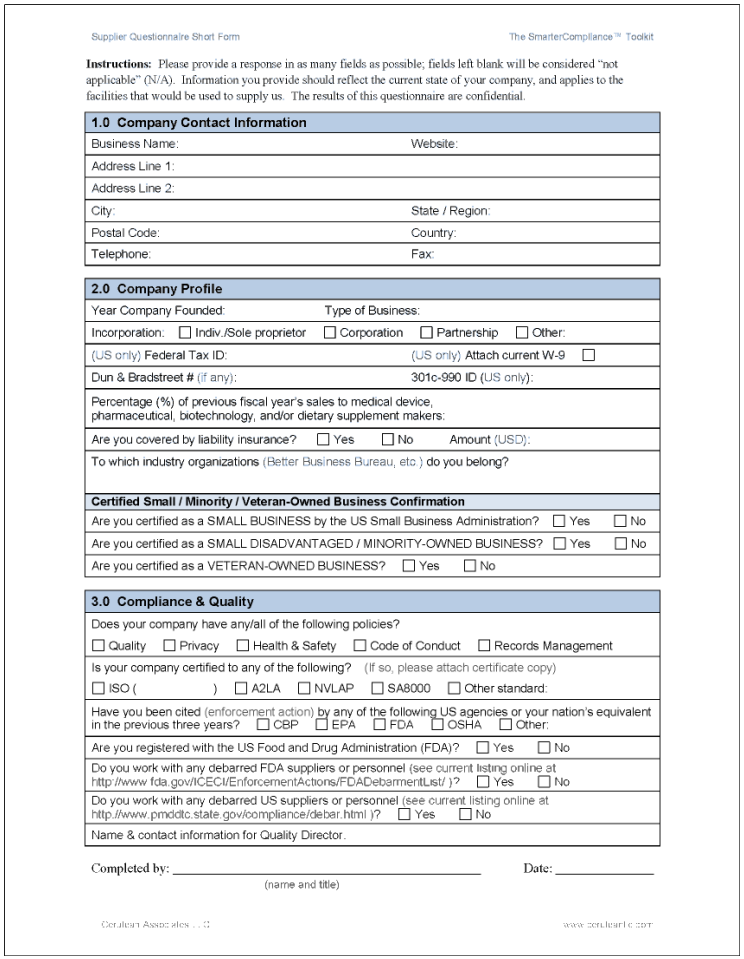
- Incorporated with liability insurance
- Financial track history (D&B, etc.)
- Experienced with what you want to purchase or contract for
- Experienced dealing with regulated customers (generally – don't be all "niche-y")
- Experienced dealing with customers in your overall region (Europe v. southwestern England)
- Registered with FDA (see regulatory requirement)
- Has someone fluent in your language (or vice versa)

Basic Criteria Verification

- One page
- Easy to return:
  - SASE
  - website form submission
  - fax
  - email PDF

Put in vendor dossier

Do not forget "super-secret squirrel" technique to get 100% + compliance!



Supplier Questionnaire Short Form — The SmarterCompliance™ Toolkit

Instructions: Please provide a response in as many fields as possible; fields left blank will be considered "not applicable" (N/A). Information you provide should reflect the current state of your company, and applies to the facilities that would be used to supply us. The results of this questionnaire are confidential.

1.0 Company Contact Information	
Business Name:	Website:
Address Line 1:	
Address Line 2:	
City:	State / Region:
Postal Code:	Country:
Telephone:	Fax:

2.0 Company Profile				
Year Company Founded:	Type of Business:			
Incorporation: ☐ Indiv./Sole proprietor	☐ Corporation	☐ Partnership	☐ Other:	
(US only) Federal Tax ID:		(US only) Attach current W-9 ☐		
Dun & Bradstreet # (if any):		301c-990 ID (US only):		
Percentage (%) of previous fiscal year's sales to medical device, pharmaceutical, biotechnology, and/or dietary supplement makers:				
Are you covered by liability insurance? ☐ Yes ☐ No	Amount (USD):			
To which industry organizations (Better Business Bureau, etc.) do you belong?				

Certified Small / Minority / Veteran-Owned Business Confirmation		
Are you certified as a SMALL BUSINESS by the US Small Business Administration?	☐ Yes	☐ No
Are you certified as a SMALL DISADVANTAGED / MINORITY-OWNED BUSINESS?	☐ Yes	☐ No
Are you certified as a VETERAN-OWNED BUSINESS?	☐ Yes	☐ No

3.0 Compliance & Quality
Does your company have any/all of the following policies? ☐ Quality ☐ Privacy ☐ Health & Safety ☐ Code of Conduct ☐ Records Management
Is your company certified to any of the following? (If so, please attach certificate copy) ☐ ISO ( ) ☐ A2LA ☐ NVLAP ☐ SA8000 ☐ Other standard:
Have you been cited (enforcement action) by any of the following US agencies or your nation's equivalent in the previous three years? ☐ CBP ☐ EPA ☐ FDA ☐ OSHA ☐ Other:
Are you registered with the US Food and Drug Administration (FDA)? ☐ Yes ☐ No
Do you work with any debarred FDA suppliers or personnel (see current listing online at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/)? ☐ Yes ☐ No
Do you work with any debarred US suppliers or personnel (see current listing online at http://www.pmddtc.state.gov/compliance/debar.html)? ☐ Yes ☐ No
Name & contact information for Quality Director.

Completed by: _____ Date: _____
(name and title)

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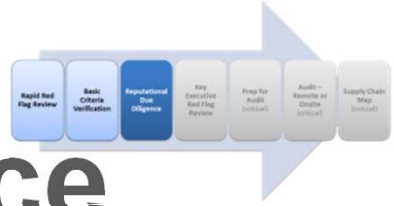
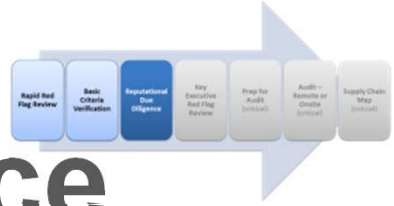


Reputational Due Diligence

Industry Reputation

- Industry accreditations and certifications
  - ISO
  - BBB
  - ITIL or TickIT+
- Industry association memberships (codes of ethics)
- Industry awards
- Independent 3rd-party assessment reports (availability)
- Industry periodical publications (vs. whitepapers)



Reputational Due Diligence

Regulatory Compliance History

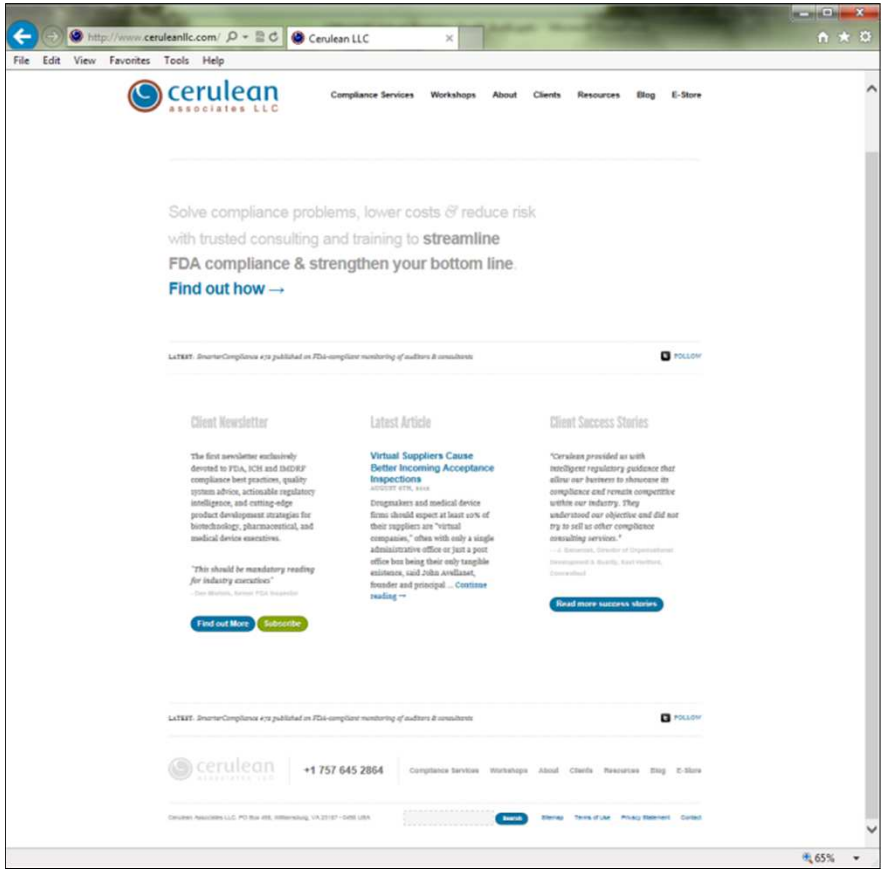
Google "[*company name*]+____" and look within past 3 years:

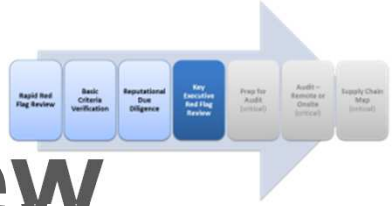
- Regulatory enforcement actions
  - Untitled letter (example: google "cerulean + untitled letter")
  - Warning letter (example: google "cerulean + warning letter")
  - Consent decree/corporate integrity agreement
- Product liability litigation
- Recalls
- Other litigation trouble

Example

- ✓ BBB accredited
- ✓ List association membership
- ✓ List awards
- o 3rd party audit report
- ✓ List recent publications

Put in vendor dossier





Executive Red Flag Review

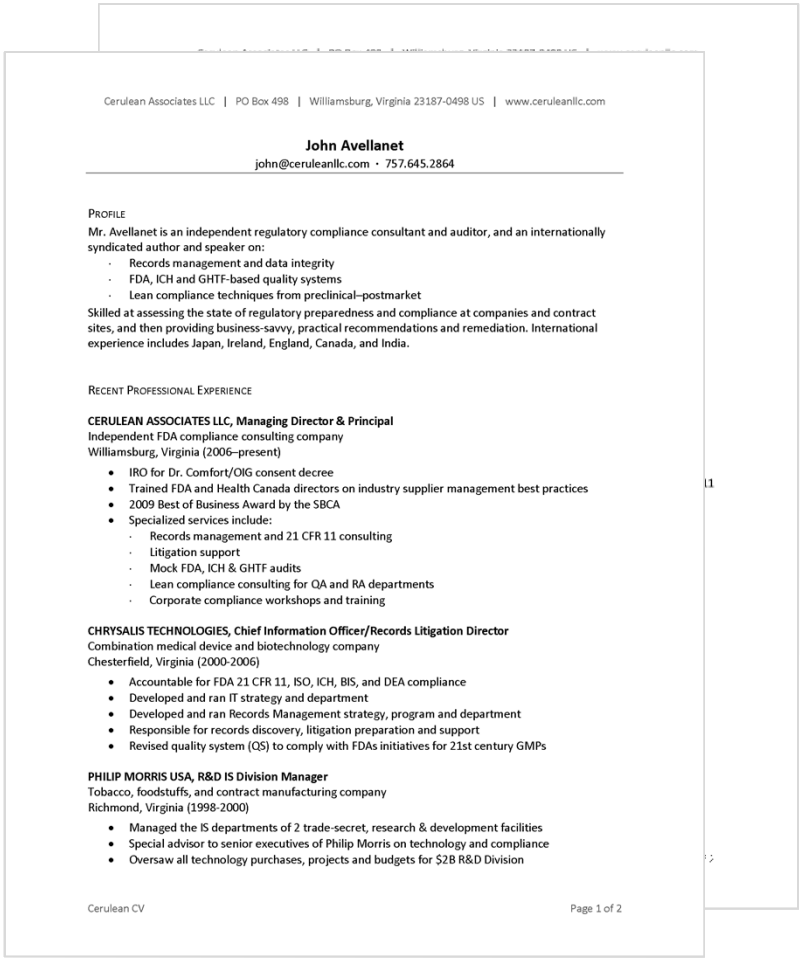
- Google your point-of-contact at supplier, and their CEO, CCO, CFO for no-no's associated with each name:
  - "_____+fraud"
  - "_____+consent decree"
  - "_____+prison"
  - "_____+bankruptcy"
  - "_____+investigation"
  - "_____+debar" (not "debarment")

- Review CV/resume of consultants & auditors
- Look for any public speaking or guest lecture/teaching activities
- Look for any published media interviews (skim through)

Example

- ✓ Google search clear
- ✓ Current CV available
- ✓ List of media interviews available online
- ✓ List recent public speaking available online

Put in vendor dossier



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John Avellanet
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PROFILE

Mr. Avellanet is an independent regulatory compliance consultant and auditor, and an internationally syndicated author and speaker on:

- Records management and data integrity
- FDA, ICH and GHTF-based quality systems
- Lean compliance techniques from preclinical–postmarket

Skilled at assessing the state of regulatory preparedness and compliance at companies and contract sites, and then providing business-savvy, practical recommendations and remediation. International experience includes Japan, Ireland, England, Canada, and India.

RECENT PROFESSIONAL EXPERIENCE

CERULEAN ASSOCIATES LLC, Managing Director & Principal
Independent FDA compliance consulting company
Williamsburg, Virginia (2006–present)

- IRO for Dr. Comfort/OIG consent decree
- Trained FDA and Health Canada directors on industry supplier management best practices
- 2009 Best of Business Award by the SBCA
- Specialized services include:
  - Records management and 21 CFR 11 consulting
  - Litigation support
  - Mock FDA, ICH & GHTF audits
  - Lean compliance consulting for QA and RA departments
  - Corporate compliance workshops and training

CHRYSALIS TECHNOLOGIES, Chief Information Officer/Records Litigation Director
Combination medical device and biotechnology company
Chesterfield, Virginia (2000-2006)

- Accountable for FDA 21 CFR 11, ISO, ICH, BIS, and DEA compliance
- Developed and ran IT strategy and department
- Developed and ran Records Management strategy, program and department
- Responsible for records discovery, litigation preparation and support
- Revised quality system (QS) to comply with FDAs initiatives for 21st century GMPs

PHILIP MORRIS USA, R&D IS Division Manager
Tobacco, foodstuffs, and contract manufacturing company
Richmond, Virginia (1998-2000)

- Managed the IS departments of 2 trade-secret, research & development facilities
- Special advisor to senior executives of Philip Morris on technology and compliance
- Oversaw all technology purchases, projects and budgets for $2B R&D Division

Cerulean CV Page 1 of 2

Key Points so far…

- Process must handle at least 651 suppliers
- GHTF/IMDRF guidance can be encapsulated into 6 SOPs
- FDA adds 4 SOPs on warehousing, testing, distribution
- Each SOP has to produce records of compliance
- Virtual suppliers need additional remote due diligence
- Re-use virtual supplier approach for consultants

Creating Your Program Overview

Intent

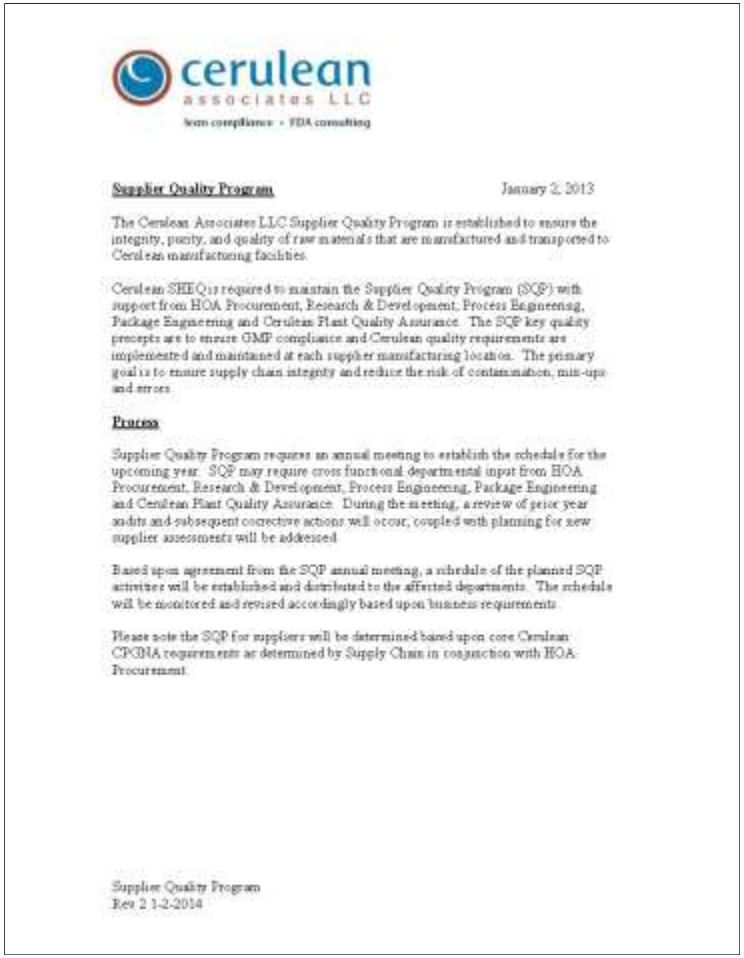
Provide high-level, simple overview

- training purposes (for “big picture”)
- outside auditors (especially ISO certification)
- FDA investigators (show “close the loop” controls”)
- management (awareness, cross-functional nature)

Keep It Simple Silly (KISS)

Two Approaches

- SOP: Sourcing
- SOP: Supplier Selection
- SOP: Supplier Qualification
- SOP: Finalizing Controls
- SOP: Supplier Monitoring
- SOP: Re-Evaluation



cerulean associates LLC

Supplier Quality Program January 2, 2013

The Cerulean Associates LLC Supplier Quality Program is established to ensure the integrity, purity, and quality of raw materials that are manufactured and transported to Cerulean manufacturing facilities.

Cerulean SHEQ is required to maintain the Supplier Quality Program (SQP) with support from HOA Procurement, Research & Development, Process Engineering, Package Engineering and Cerulean Plant Quality Assurance. The SQP key quality precepts are to ensure GMP compliance and Cerulean quality requirements are implemented and maintained at each supplier manufacturing location. The primary goal is to ensure supply chain integrity and reduce the risk of contamination, mix-ups and errors.

Process

Supplier Quality Program requires an annual meeting to establish the schedule for the upcoming year. SQP may require cross functional departmental input from HOA Procurement, Research & Development, Process Engineering, Package Engineering and Cerulean Plant Quality Assurance. During the meeting, a review of prior year audits and subsequent corrective actions will occur, coupled with planning for new supplier assessments will be addressed.

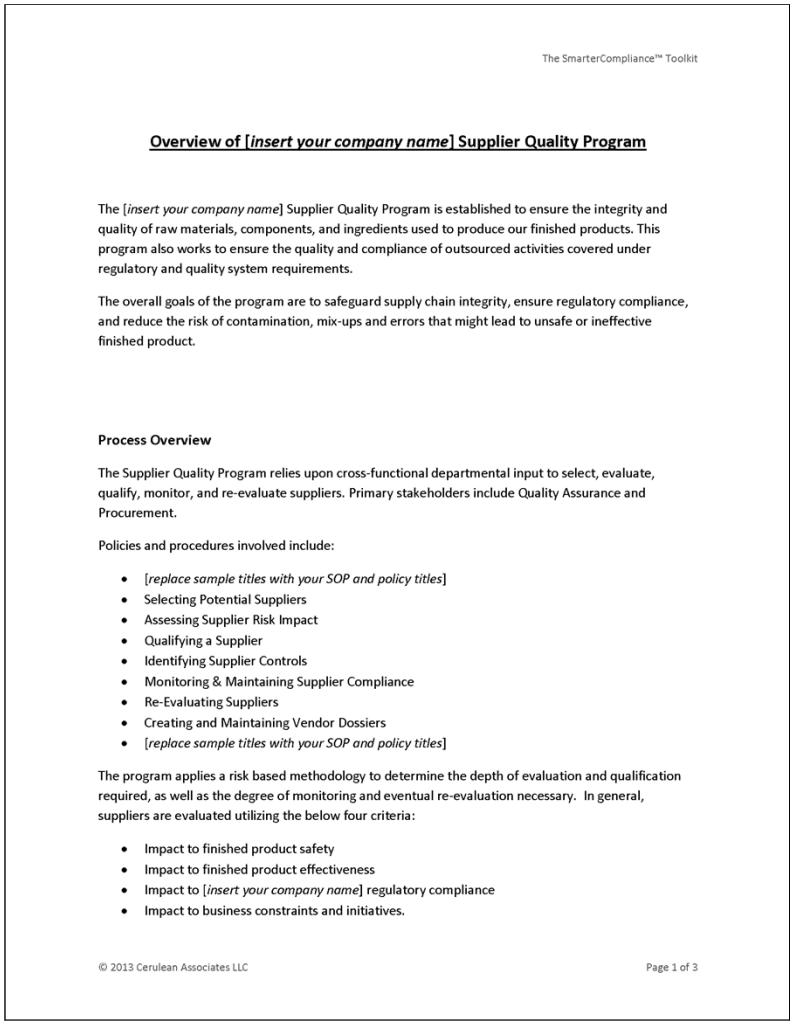
Based upon agreement from the SQP annual meeting, a schedule of the planned SQP activities will be established and distributed to the affected departments. The schedule will be monitored and revised accordingly based upon business requirements.

Please note the SQP for suppliers will be determined based upon core Cerulean CPGMA requirements as determined by Supply Chain in conjunction with HOA Procurement.

Supplier Quality Program
Rev 2 1-2-2014

Contents

- 2-4 pages max
- sections:
  - procedural overview
  - controls overview
  - oversight documentation
  - implementation status
- easily skimmable
  - tables
  - bullet lists
  - lots of white space



The SmarterCompliance™ Toolkit

Overview of [*insert your company name*] Supplier Quality Program

The [*insert your company name*] Supplier Quality Program is established to ensure the integrity and quality of raw materials, components, and ingredients used to produce our finished products. This program also works to ensure the quality and compliance of outsourced activities covered under regulatory and quality system requirements.

The overall goals of the program are to safeguard supply chain integrity, ensure regulatory compliance, and reduce the risk of contamination, mix-ups and errors that might lead to unsafe or ineffective finished product.

Process Overview

The Supplier Quality Program relies upon cross-functional departmental input to select, evaluate, qualify, monitor, and re-evaluate suppliers. Primary stakeholders include Quality Assurance and Procurement.

Policies and procedures involved include:

- [*replace sample titles with your SOP and policy titles*]
- Selecting Potential Suppliers
- Assessing Supplier Risk Impact
- Qualifying a Supplier
- Identifying Supplier Controls
- Monitoring & Maintaining Supplier Compliance
- Re-Evaluating Suppliers
- Creating and Maintaining Vendor Dossiers
- [*replace sample titles with your SOP and policy titles*]

The program applies a risk based methodology to determine the depth of evaluation and qualification required, as well as the degree of monitoring and eventual re-evaluation necessary. In general, suppliers are evaluated utilizing the below four criteria:

- Impact to finished product safety
- Impact to finished product effectiveness
- Impact to [*insert your company name*] regulatory compliance
- Impact to business constraints and initiatives.

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Page 1 of 3

Key Points

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- FDA adds 4 SOPs on warehousing, testing, distribution
- Each SOP has to produce records of compliance
- Virtual suppliers need additional remote due diligence
- Re-use virtual supplier approach for consultants
- Create an overview for auditors, management, and training

BREAK TIME

Please take 10 minutes

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