Recordkeeping

proving your compliance of your supplier oversight

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Agenda

FDA inspection tactics
your supplier dossier
dealing with record integrity at suppliers

Top 10 FDA QSR Citations (2013)

QSR Citation	Short Description	Frequency (%age of 483s)
21 CFR 820.100(a)	Lack of or inadequate SOPs	378 (34%)
21 CFR 820.198(a)	Lack of or inadequate complaint handling SOPs	245 (22%)
21 CFR 820.100(b)	Poor documentation and **recordkeeping**	133 (12%)
21 CFR 820.75(a)	Lack of or inadequate process validation	127 (12%)
21 CFR 820.50	Lack of or inadequate purchasing controls	110 (10%)
21 CFR 820.90(a)	Inadequate nonconforming product SOPs	98 (9%)
21 CFR 820.30(i)	Lack of or inadequate SOPs for design changes	93 (8%)
21 CFR 820.181	Poor **recordkeeping** for DMR	77 (7%)
21 CFR 820.22	Lack of or inadequate internal quality audit SOPs	73 (7%)
21 CFR 820.184	Poor **recordkeeping** for DHR	72 (7%)

Source:
FDA Inspection Observations FY2013
http://www.fda.gov/iceci/EnforcementActions/ucm250720.htm

Top 10 FDA QSR Citations (2014)

QSR Citation	Short Description	Frequency (%age of 483s)
21 CFR 820.100(a)	Lack of or inadequate SOPs	360 (37%)
21 CFR 820.198(a)	Lack of or inadequate complaint handling SOPs	251 (26%)
21 CFR 820.50	Lack of or inadequate purchasing controls	129 (14%)
21 CFR 820.75(a)	Lack of or inadequate process validation	122 (13%)
21 CFR 820.100(b)	Inadequate **recordkeeping** and documentation	101 (11%)
21 CFR 820.30(i)	Lack of or inadequate SOPs for design changes	100 (10%)
21 CFR 820.22	Lack of or inadequate internal quality audit SOPs	90 (09%)
21 CFR 820.198(c)	Poor **recordkeeping** for complaints	68 (07%)
21 CFR 820.25(b)	Inadequate training SOPs and **recordkeeping**	61 (06%)
21 CFR 820.40	Inadequate design control SOPs and **records**	61 (06%)

Source:
FDA Inspection Observations FY2013
http://www.fda.gov/iceci/EnforcementActions/ucm250720.htm

Top 10 FDA QSR Citations (2015)

QSR Citation	Short Description	Frequency (%age of 483s)
21 CFR 820.100(a)	Lack of or inadequate SOPs	377 (37%)
21 CFR 820.198(a)	Lack of or inadequate complaint handling SOPs	294 (29%)
21 CFR 820.50	**Lack of or inadequate purchasing controls**	**139 (14%)**
21 CFR 820.75(a)	Lack of or inadequate process validation, controls	134 (13%)
21 CFR 820.90(a)	Lack of, inadequate nonconforming product SOPs	114 (11%)
21 CFR 820.100(b)	Inadequate **recordkeeping** and documentation	97 (09%)
21 CFR 820.22	Lack of or inadequate internal quality audit SOPs	95 (09%)
21 CFR 820.30(i)	Lack of or inadequate SOPs for design changes	89 (09%)
21 CFR 820.181	Poor **recordkeeping** for DMR	77 (07%)
21 CFR 820.25(b)	Inadequate training SOPs and **recordkeeping**	72 (06%)

Source:
FDA Inspection Observations FY2015

FDA Warning Letter Excerpt

“ **Failure to define the type and extent of control to be exercised over suppliers**, as required by **21 CFR 820.50(a)(2)**. Specifically, your Purchasing Process and Supplier Evaluation Process Map (7.4.1) is **ambiguous on how you will monitor your suppliers**. Your process map lists the "input" for monitoring trends of performance as identifying performance parameters for suppliers. These **parameters are not defined**. Additionally, your firm **has no quality data records to show that suppliers are being monitored**.”

Warning Letter to Meridian Medical Systems, July 2013

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm359625.htm

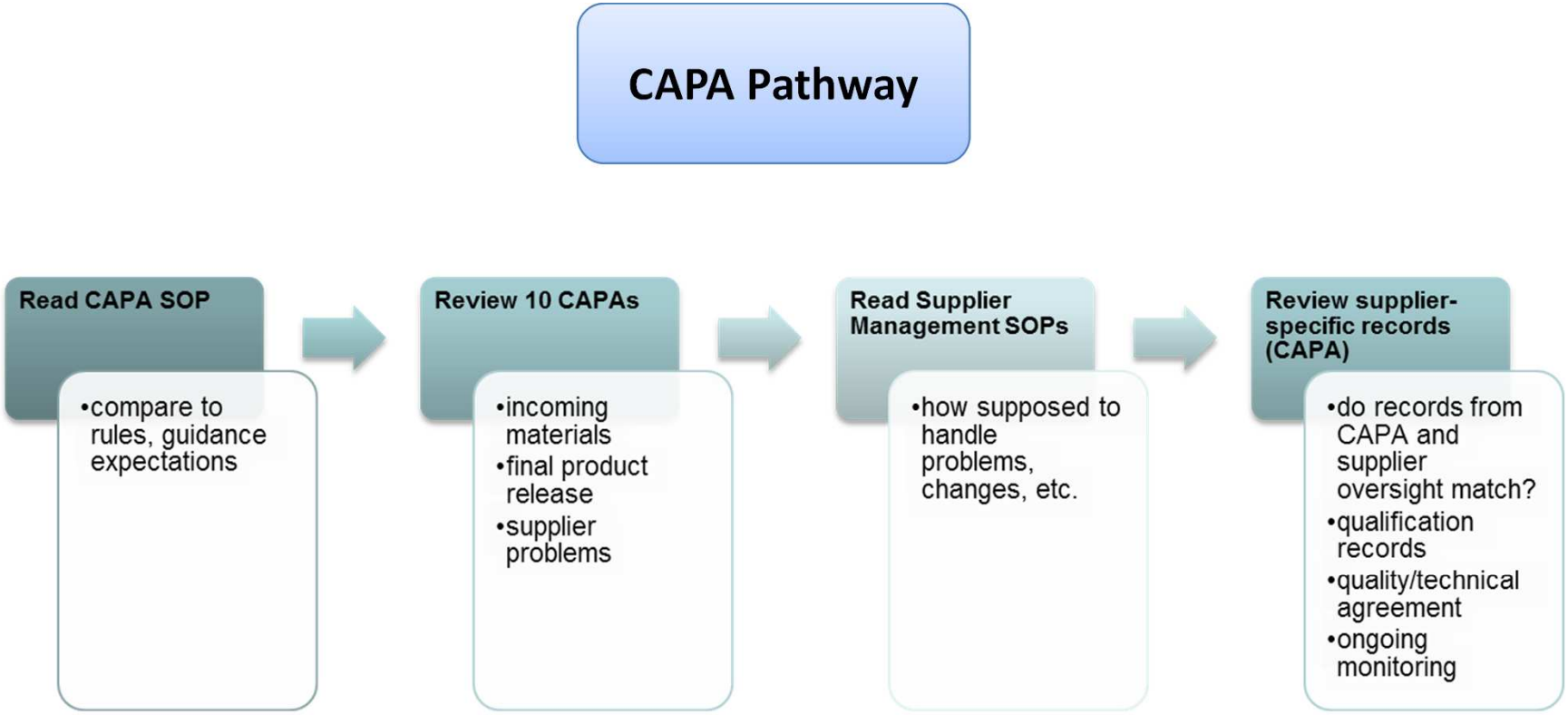
FDA-483 Excerpt

“ Procedures to ensure that **all purchased or otherwise received product and services conform to specified requirements** have not been adequately established. *Evaluation of Subcontractors* procedure Rev. No. 1 dated 8/20/2014 is **inadequate in that it does not require documentation that applicable suppliers such as p.c. board suppliers have adequate process validation of special or automated processes**....”

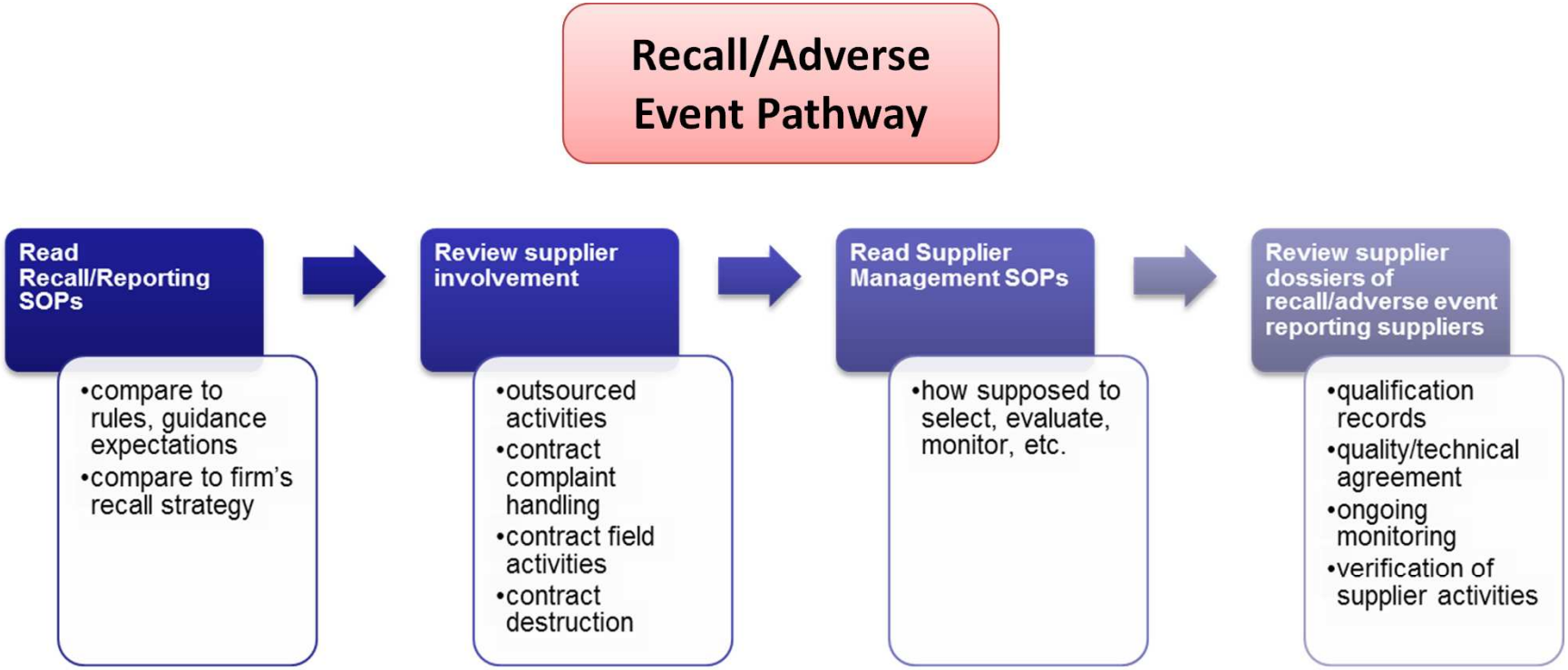
FDA-483 to Avotec, Inc, July 2015

“So how does FDA get to all this – just by asking about our Purchasing Controls?”

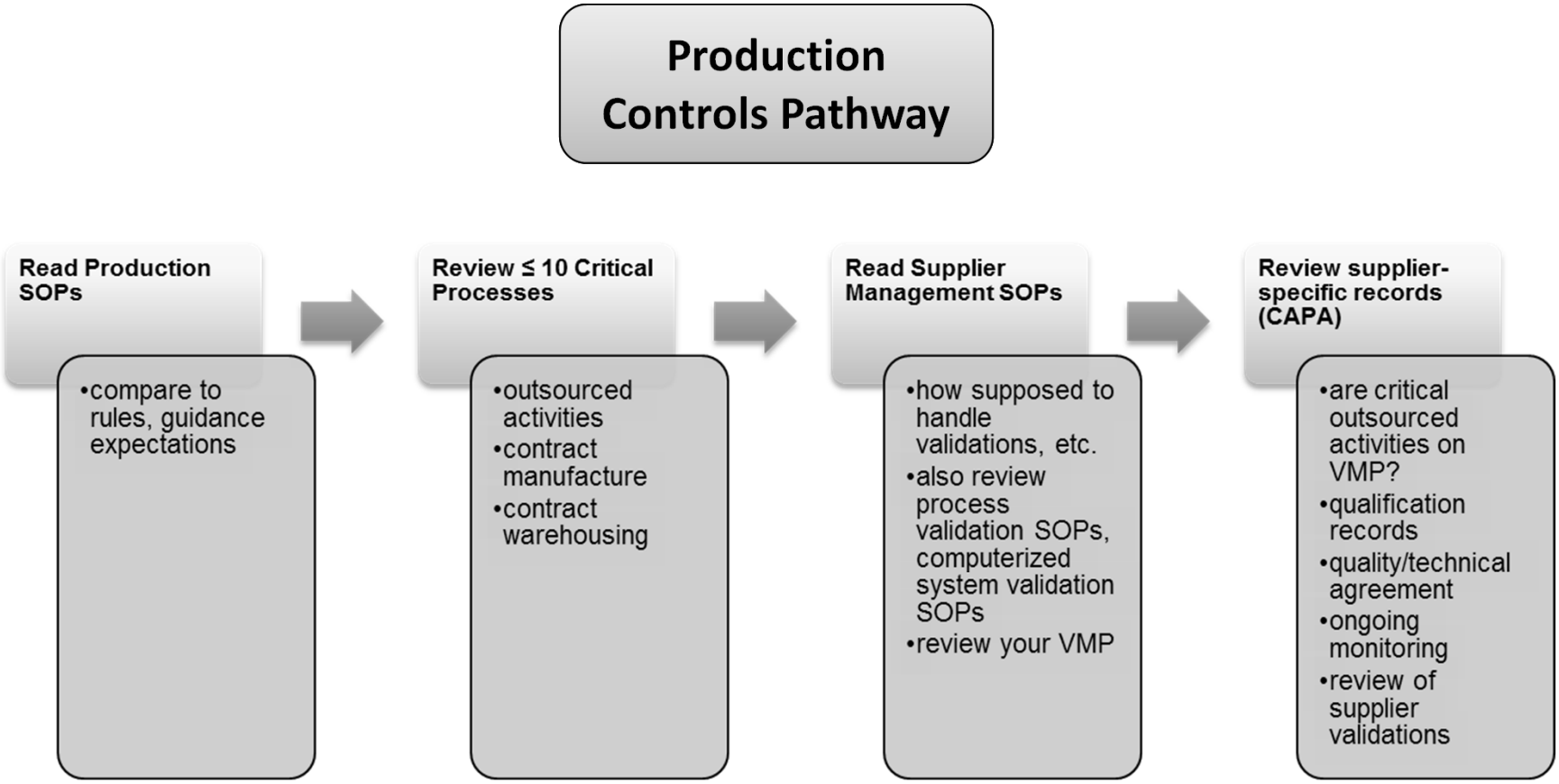
Other Inspection Paths



Other Inspection Paths



Other Inspection Paths



FDA Inspection FAQs

- Does the firm have written, approved, and specified requirements – including quality requirements – for purchased or otherwise received products and outsourced activities?
- Does the firm have procedures for conducting supplier evaluations?
- Does the firm's written procedures on selecting suppliers include (or reference) requirements that suppliers and outsourced service providers must meet?
- If suppliers provide specialized services such as contract sterilization or automated components, are suppliers required to conduct process validation?
- Is the type and extent of controls over a supplier based on the results of the firm's evaluation of the supplier?
- Does the firm have current contact and name information for its suppliers?
- Does the firm have a written supplier control plan for at least its high-risk/critical suppliers?
- Does the firm retain complete and accurate records of supplier qualification?
- Is the incoming acceptance testing done by the firm commensurate with the level of risk posed by the supplier? What mitigating factors (history with supplier, risk of supplied component, etc.) are documented and incorporated?

FDA Inspection FAQs

- What documentation does the device firm have to show that the supplier was the actual manufacturer or component maker?
- For critical components, has the device firm documented its own supply chain (at least through tier 2 suppliers)?
- How does the firm document evaluation of suppliers whom it is unable to audit?
- How does the device firm document its ongoing oversight of suppliers?
- Does the executed contract/quality agreement with the supplier define the specific responsibilities of each party?
- Are the types of oversight to be exercised by the device firm described in the contract/quality agreement?
- How does the firm document “intended use” for its tier 1 suppliers?
- Compare the firm’s supplier selection and evaluation process to actual records – are supplier requirements defined before or after the supplier is chosen?
- Does the firm select suppliers based on the ability of the supplier to meet specified requirements? How is this verified within the firm? Are there any CAPAs resulting from suppliers who were not chosen through this method?

Example Inspection Red Flags

- Supplier **evaluations are incomplete** or missing
- Supplier **evaluations do not address process validation**
- No **documented recent audits** of critical suppliers
- Contract/quality **agreement has not been signed** by an officer of the company
- Supplier **contact information is out-of-date**
- Supplier **requirements not referenced** in the supplier qualification files
- Supplier qualification **SOPs are not cross-functional**
- Supplier **COAs contain similar test values** across batches
- Company has **no records retention or recordkeeping policy**

Frequently Requested Records

- audit reports/certificates of the supplier (see CPG section 130.300)
  - yours (including consultant on your behalf)
  - third-party regulator or accreditation organization (especially if ISO or FDA/EMA-based)
- correspondence with supplier regarding supplied material/outsourced activity
- supplier dossier contents
- meeting minutes with supplier
- CAPAs relating to supplied materials/outsourced activity
- change controls relating to supplied materials/outsourced activity
- validations performed by supplier (your records reviewing their validation)
  - process validations
  - equipment qualifications
  - computerized system validations
- acceptance SOPs and documentation for incoming materials/components

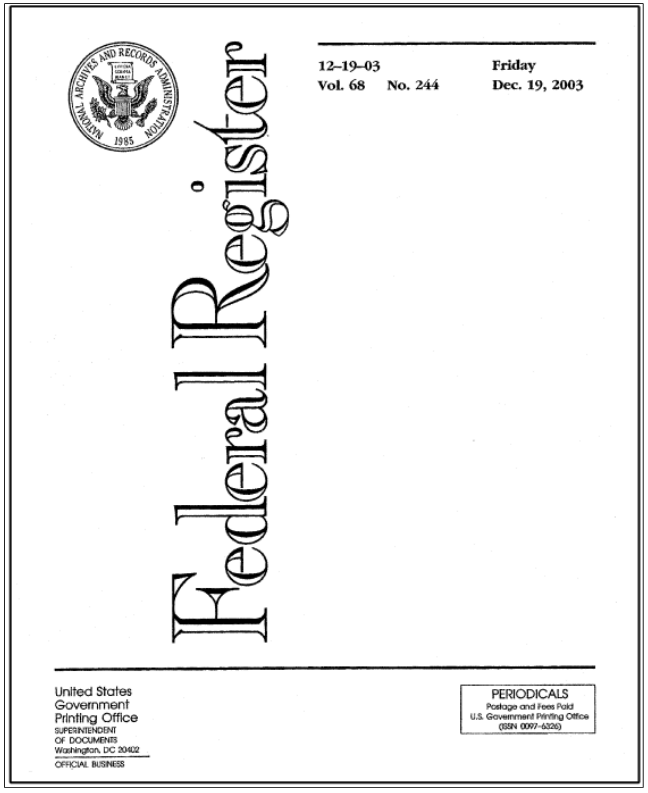
Translation

your recordkeeping proves … or disproves

effective supplier oversight

“So…what should we keep?”

FDA Requirements (820.50)



"establish and maintain procedures"

"establish and maintain records of acceptable suppliers, contractors, and consultants. "

"purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service…."

"all records required by this part shall be maintained…."

"this section does not apply to the reports required by…and supplier audit reports used to meet the requirements of 21 820.50(a) Evaluation of suppliers, contractors, and consultants…."

FDA Requirements (820.50)

So we need:

SOPs

list of acceptable suppliers

change control

audit reports

Is that it…?

"establish and maintain **procedures**"

"establish and maintain **records of acceptable suppliers**, contractors, and consultants. "

"purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to **notify the manufacturer of changes** in the product or service…."

"all records required by this part shall be maintained…."

"this section does not apply to the reports required by…and **supplier audit reports** used to meet the requirements of 21 820.50(a) Evaluation of suppliers, contractors, and consultants…."

ISO Recommendations


INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

Reference number
ISO 13485:2003(E)

© ISO 2003

"establish documented procedures"

"purchasing information shall describe the product to be purchased.... "

"shall maintain relevant purchasing information, *i.e.* documents and records"

"records of ... any necessary actions arising from the [supplier] evaluation shall be maintained"

"records of the verification shall be maintained"

21 CFR 820 Intent

GHTF/IMDRF Recommendations

GHTF/SG4/N84:2010

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers
Part 5: Audits of Manufacturer Control of Suppliers

Authoring Group: Study Group 4 of the Global Harmonization Task Force

Date: August 27, 2010

Dr. Larry Kelly, 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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SG4-N84: Guidelines for Regulatory Auditing of QMS of Medical Device Manufacturers – Audits of Manufacturer Control of Suppliers (2010)

- Supplier agreements
- Change management SOPs
- Specifications and requirements
- Documented list of the risks identified for the products and services supplied, and linkages to design, development and production/distribution planning
- Documented supplier requirements
- Capability assessment of the supplier (*e.g.*, qualification)
- Contracts (and amendments)
- Purchase orders
- Audits reports of supplier
- Correspondence with supplier
- Minutes of meetings with suppliers
- CAPAs relating to products and services supplied
- Verification that received products match requested products
- Acceptance procedures for incoming products

(online at www.imdrf.org/documents/documents.asp)

Vendor Dossier – Initial Records

- Initial supplier questionnaires (short "can we do business with you" form)
- Secondary due diligence documents (for virtual companies as suppliers)
- Summarized selection research (reference DMR/DHF as "intended use")
    - list any known supplier regulatory enforcement actions (WLs, EIRs, etc.)
- Qualification audit reports (yours)
- Vendor certifications, awards, licenses, *et al* (at time of qualification)
- Responsibility matrix (may be an appendix in contract/quality agreement)
- Key correspondence (regarding product/service/materials supplied)
- Summary of important meetings with supplier
- Copies of (or pointers to in other filing locations):
    - legal/quality agreements
    - purchase order

Vendor Dossier – Ongoing Records

- Periodic audit reports (yours, 3rd party, etc.)
- Communication matrix
- Any annual supplier copies of their certifications, accreditations, awards, licenses, *et al*
- Supplier improvement plan (if any)
- Supplier re-evaluations (to date)
- Formal correspondence (decision communication related to product, CAPAs, compliance, recalls, component/material/services supplied, etc.)
    - include any annual compliance statement, statement of independence, etc.
    - be cautious about email (often culturally informal)
- Summary of important meetings with supplier
    - summarize date, subject(s), attendees
    - summarize decisions taken (associated with product, supplied material/component/service)
- Scorecard for the supplier (annual or at least relatively recent – or pointer to QSMR review thereof)
- Copies of (or pointers to in other filing locations):
    - incoming review/acceptance records
    - validation reviews of supplier validation activities
    - CAPAs associated with supplier (services/materials/components)
    - change orders associated with supplier (services/materials/components)
    - (budgets/funding associated with supplier)

“Why wouldn’t we just keep everything?”

Question to Consider

An FDA investigator is reviewing your supplier control files and comes across a meeting memo stating,

> "Mike at the supplier said we should recall the product. Jim [your CFO] expressed concern about the cost of conducting a recall and the effect of a recall on the bottom line. After considerable discussion, we decided not to recall the product."

How do you expect the FDA to interpret?

Question to Consider

Instead of an FDA investigator, imagine the following scenario:

- Mary Jones is injured using your product
- Mary hires a lawyer who files a product liability lawsuit against your firm
- Discovery occurs (court orders you to turn over all documents related to production and design of the product … this includes the memo)
- Memo is released to the jury (and inevitably to blogs, newspapers, etc. around the world)

a) How will the jury interpret this memo?

b) How will your shareholders interpret the memo?

c) How will your current customers interpret the memo?

d) How will potential customers interpret the memo?

Retaining Records

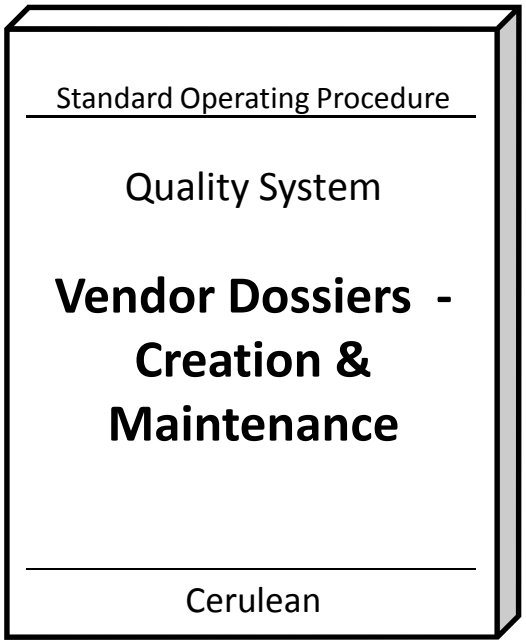
Documents are very persuasive

Documents say **“what they say”**

- judges, juries and lawyers are *extremely skeptical* of after-the-fact “that’s not what I meant” explanations

*Slide courtesy of Nancy Singer, former DOJ prosecutor

SOP: Supplier Dossiers



- Only retain those documents need to retain to prove compliance and/or support contract execution
- Cross-link to company records management policy & RRS
- Create a dossier contents checklist
  - (dossier table of contents)
- Audit against regularly
  - what's missing, what's out-of-date, etc.
- Upon contract end, archive as "supporting material" with contract

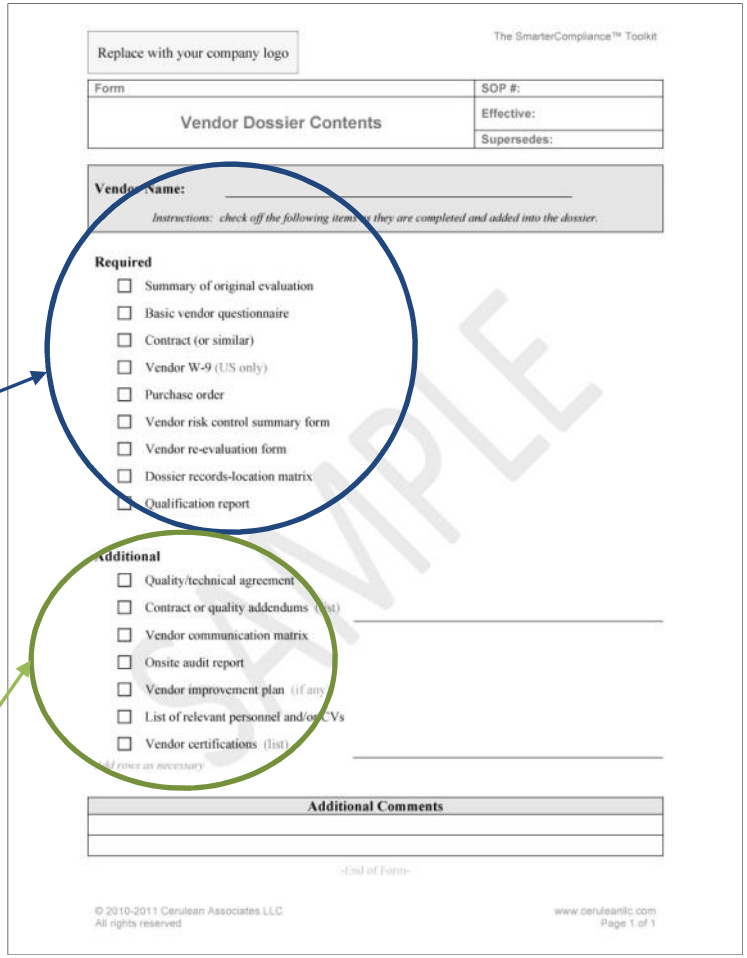
Sample Dossier Content Checklist

In every dossier:

- table of contents to dossier
- (index is the matrix)

required records

optional documents


Replace with your company logo

The SmarterCompliance™ Toolkit

Form	SOP #:
Vendor Dossier Contents	Effective:
	Supersedes:

Vendor Name: _____

Instructions: check off the following items as they are completed and added into the dossier.

Required

- ☐ Summary of original evaluation
- ☐ Basic vendor questionnaire
- ☐ Contract (or similar)
- ☐ Vendor W-9 (US only)
- ☐ Purchase order
- ☐ Vendor risk control summary form
- ☐ Vendor re-evaluation form
- ☐ Dossier records-location matrix
- ☐ Qualification report

Additional

- ☐ Quality/technical agreement
- ☐ Contract or quality addendums (list)
- ☐ Vendor communication matrix
- ☐ Onsite audit report
- ☐ Vendor improvement plan (if any)
- ☐ List of relevant personnel and/or CVs
- ☐ Vendor certifications (list)

Add rows as necessary

Additional Comments

-End of Form-

Records to Have on Hand

- Approved vendor list
- Conditional vendor list
- Disqualified vendor list (if have)
- Overall process flow (from initial selection to contract end, all on 1 page)
- Overall supplier control plan/program (if have)
- Supplier qualification compliance timeline (and progress-to-date; show plan for rest of year)
- Current SOPs on purchasing controls/supplier quality management

Verify their currency regularly!

Remember!

Suppliers maintain records on **your** behalf

Translation

Verify the controls your supplier has

so you (and FDA) can rely on the data

Step 3: Qualification

Basic → Remote → Onsite → Personnel

Review:

- SOPs
- Record retention rules
- IT policies
- 21 CFR 11 validation efforts

Audit Review Elements

SOP/Policy on Data Archival

- which departments are involved (IT, document control, etc.)?
- who is in charge of archived (*i.e.*, no longer used/needed) electronic records?
- how often are the archives brought back from archive and sampled for consistency/integrity?
- does the SOP/policy discuss developing data migration plans when archived data reaches a certain age (*i.e.*, older than 6 years)?
- is a defined records retention schedule and/or policy referenced?
- does the policy/SOP give any indication on how missing/corrupt data archives are to be handled?

Audit Review Elements

Part 11 System Validation Report

- are the report's review and approval dates reasonably AFTER the protocol's original approval dates?
- is there a data map in the report?
- for any user testing conducted, are there screenshots highlighting various points?
- is there a written executive summary with conclusions?
- for any gaps to be closed or remediation to be done, is there a written plan with reasonable timeframes?
- has the overall master validation plan has been updated?
  - *Tip: asking this last question will tell you if the supplier has a MVP!

e-Record Red Flags at Your Supplier

You know you're in for trouble if your supplier…

- Sees Part 11 compliance in **"old school"** terms ("we validated everything")
- Often **misspells acronyms** and terms in their literature/website
    - HIPAA, FDAAA, Sarbanes-Oxley, validate, qualification, compliance
- Tries to push **its own validation consulting** services to you
- Claims software/computers were bought **"Part 11 certified"**
- Complains that **off-the-shelf systems cannot be validated** because don't know code details
- Has **no records retention** schedule or policy
- IT and the Quality group have a **dysfunctional relationship**
- Has **no IT policies** (or those that exist are clearly just *pro forma*)
- Has **failed previous third-party audits** on IT compliance, Part 11 or Annex 11

Key Points

- Supplier oversight control is a Top 5 enforcement for FDA
- FDA uncovers poor supplier control through 4 pathways
- Investigators focus on your records (and recordkeeping)
- Have a supplier dossier for each supplier
- Start by creating dossiers for your critical suppliers
- Review your suppliers' recordkeeping controls (and Part 11)

Interactive Exercise