From Questionnaire to Audit

documenting the qualification of your suppliers

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FDAnews Medical Device Quality Conference
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Agenda

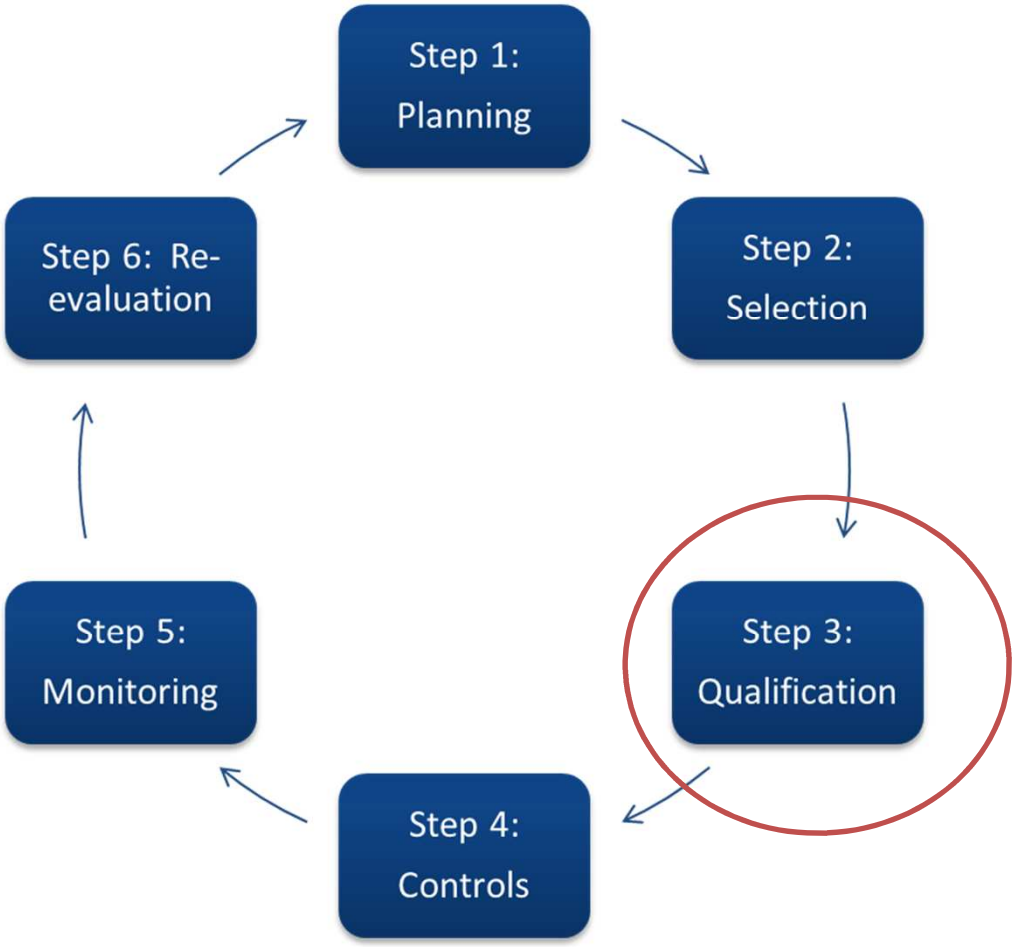
basic questionnaires

remote v onsite auditing

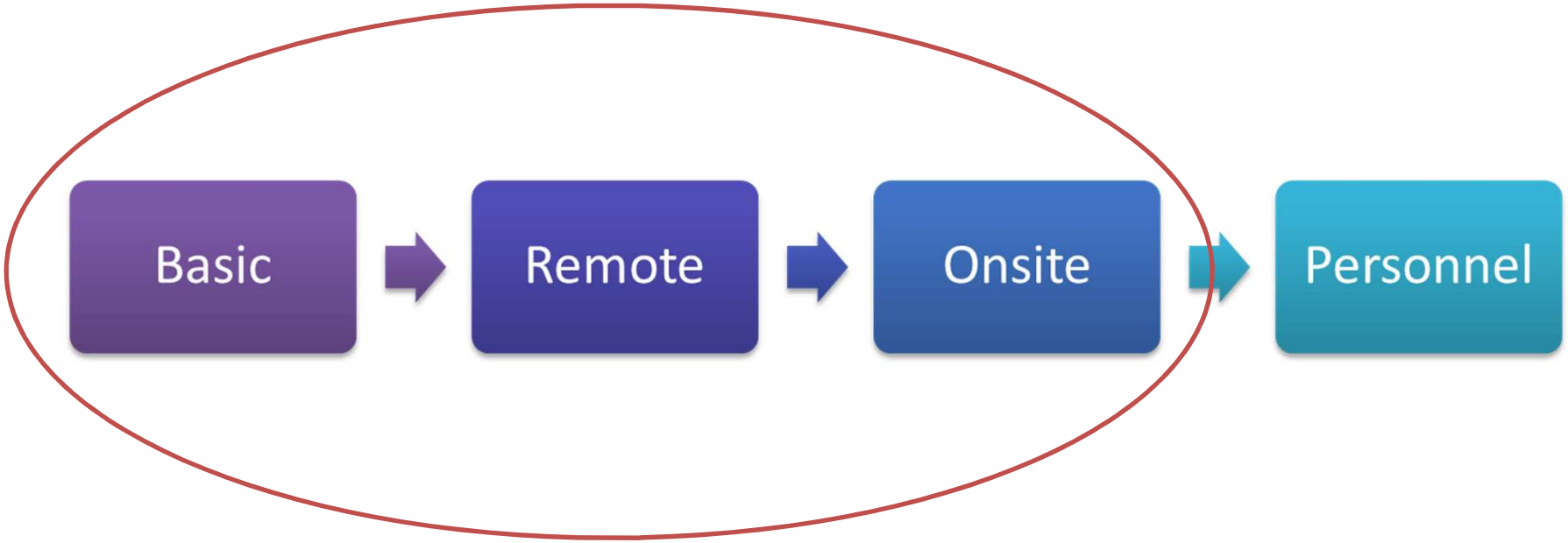
periodic re-evaluations

one technique for critical suppliers only

Overall Process



Step 3: Qualification



Step 3: Qualification

all 651 suppliers get basic questionnaire

small subset get remote audit

smallest subset get onsite audit

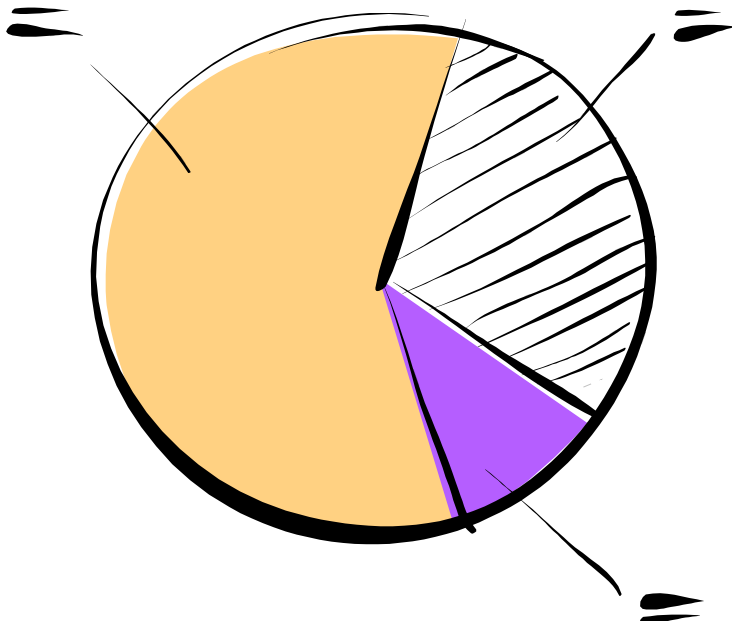
all 651 suppliers get some form of contract and re-evaluation

Questionnaire Goal

Obtain **basic** qualifying information quickly

- key contact information
- financial viability
- experience providing regulated services/materials
- identify special considerations relevant to you
- determine any obvious **red flags**

Questionnaire Goal



Pareto's Principle (80/20)

Results quickly show:

- should we proceed with this supplier?
- need more scrutiny **now**?

Does **NOT** replace an onsite audit, remote audit or any further due diligence

Question to Consider

Your firm has decided to implement a basic supplier questionnaire. This questionnaire will be sent to **ALL** suppliers. Which type of questionnaire has the best chance of being received positively (and returned)?

a) 6-page questionnaire with detailed questions?

b) 1-page questionnaire asking basic business information?

c) 3-page questionnaire that requires supplementary documents to be submitted (quality manual, etc.)?

d) 1-page questionnaire of basic information that requires supplementary information/documents to be sent?

Question to Consider

Keep in mind the previous question and your answer.

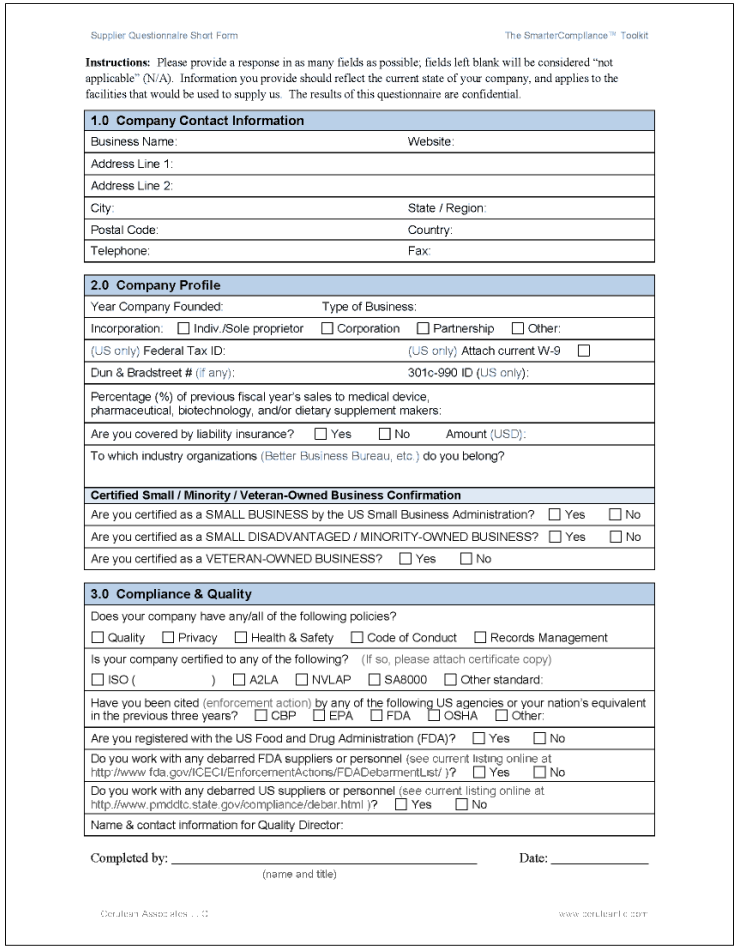
Would your answer change (which type of questionnaire would be received positively by **all** your suppliers) if …?

a) The questionnaire was on paper and came with an SASE?

b) The questionnaire was a PDF form emailed to your key contact at the supplier?

c) The questionnaire was web-based with a secure link (https)?

Handout



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:
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Name & contact information for Quality Director:

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

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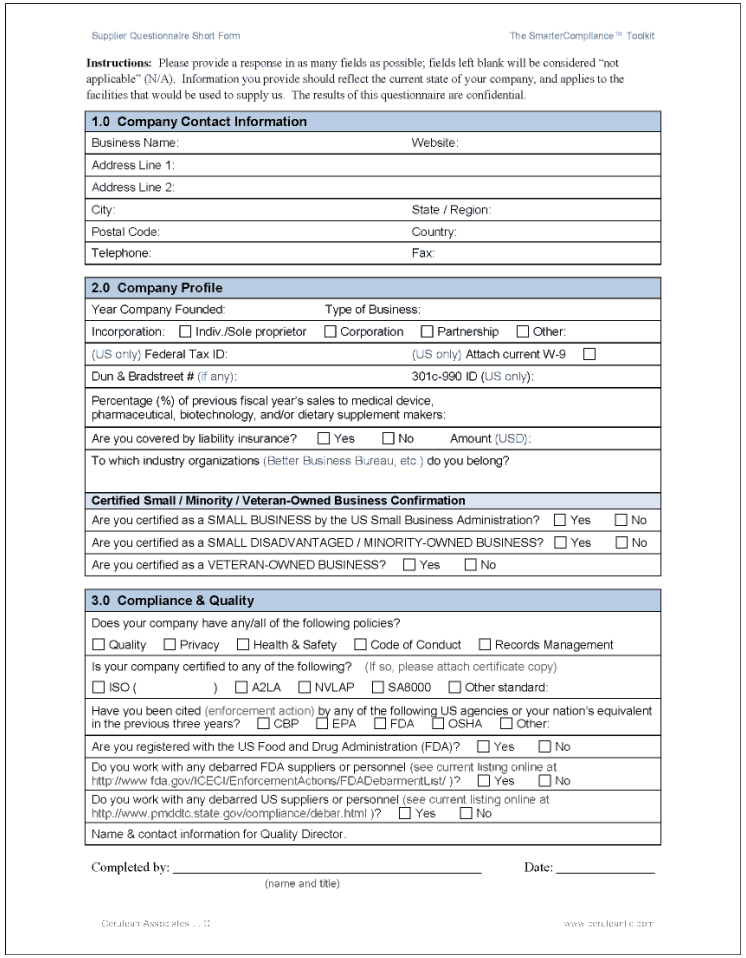
- MS Word version
- Adobe PDF version

Questionnaire Structure



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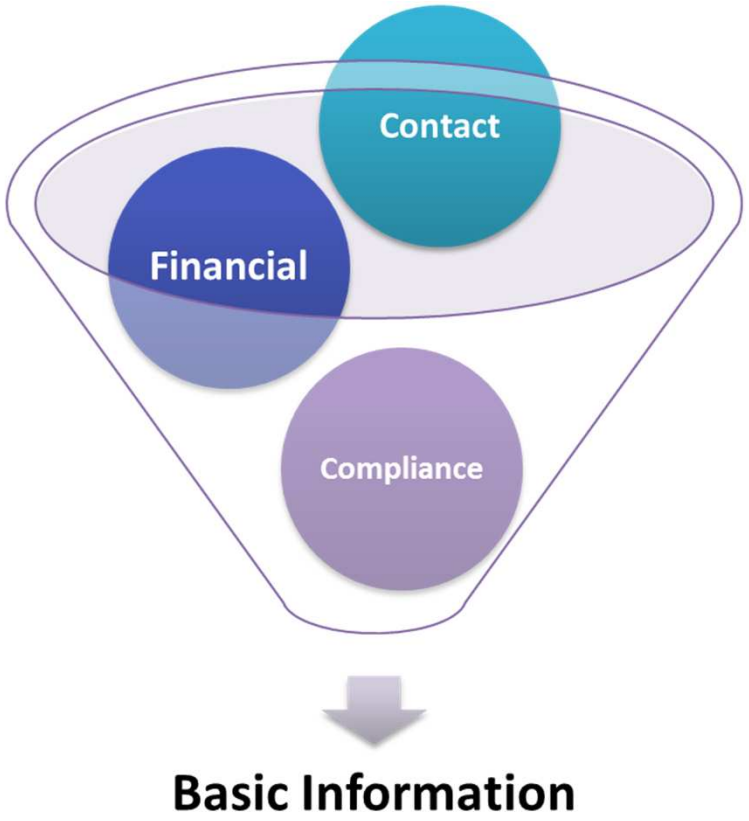
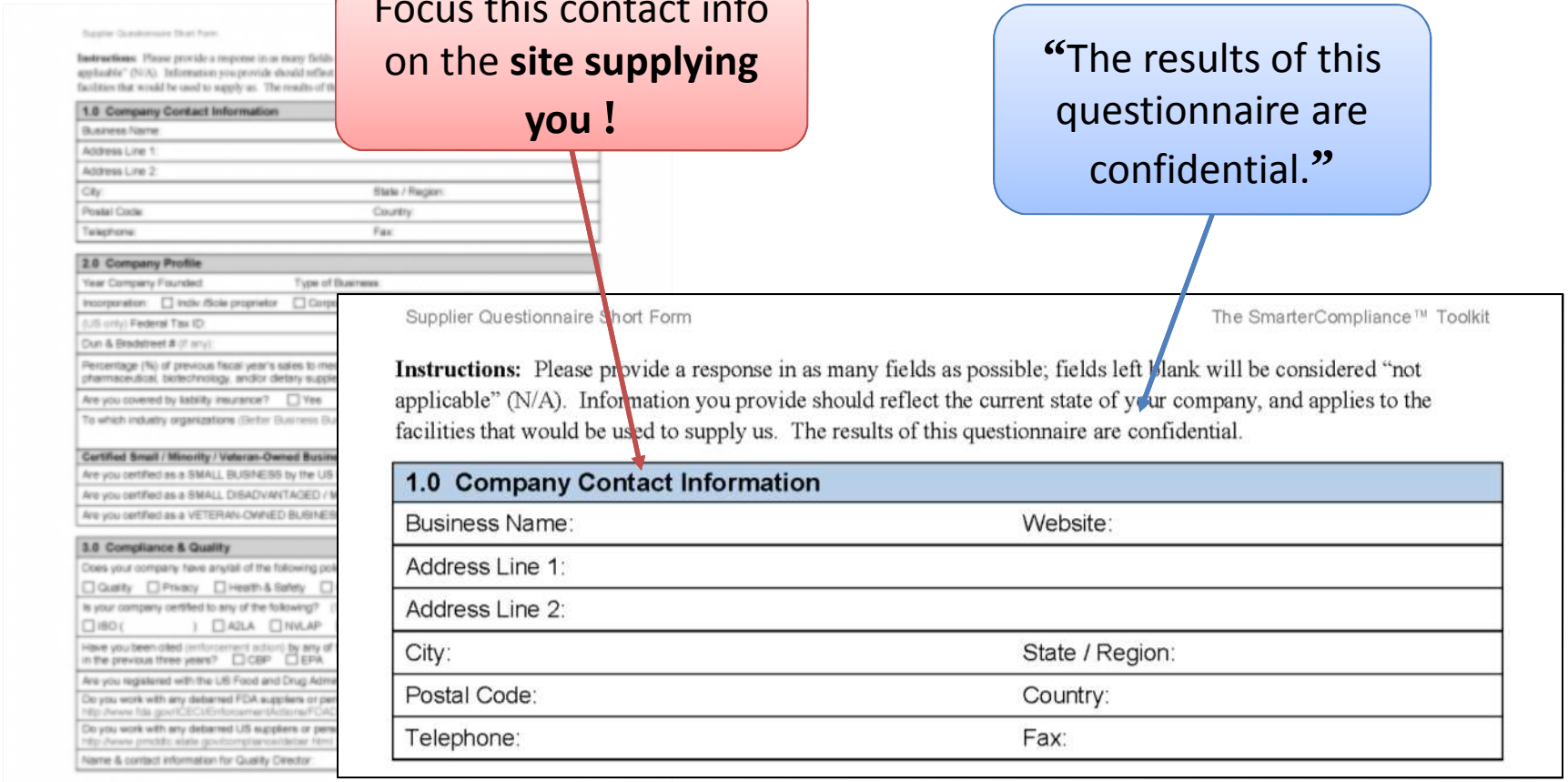


Questionnaire Structure

Focus this contact info on the **site supplying you !**

"The results of this questionnaire are confidential."



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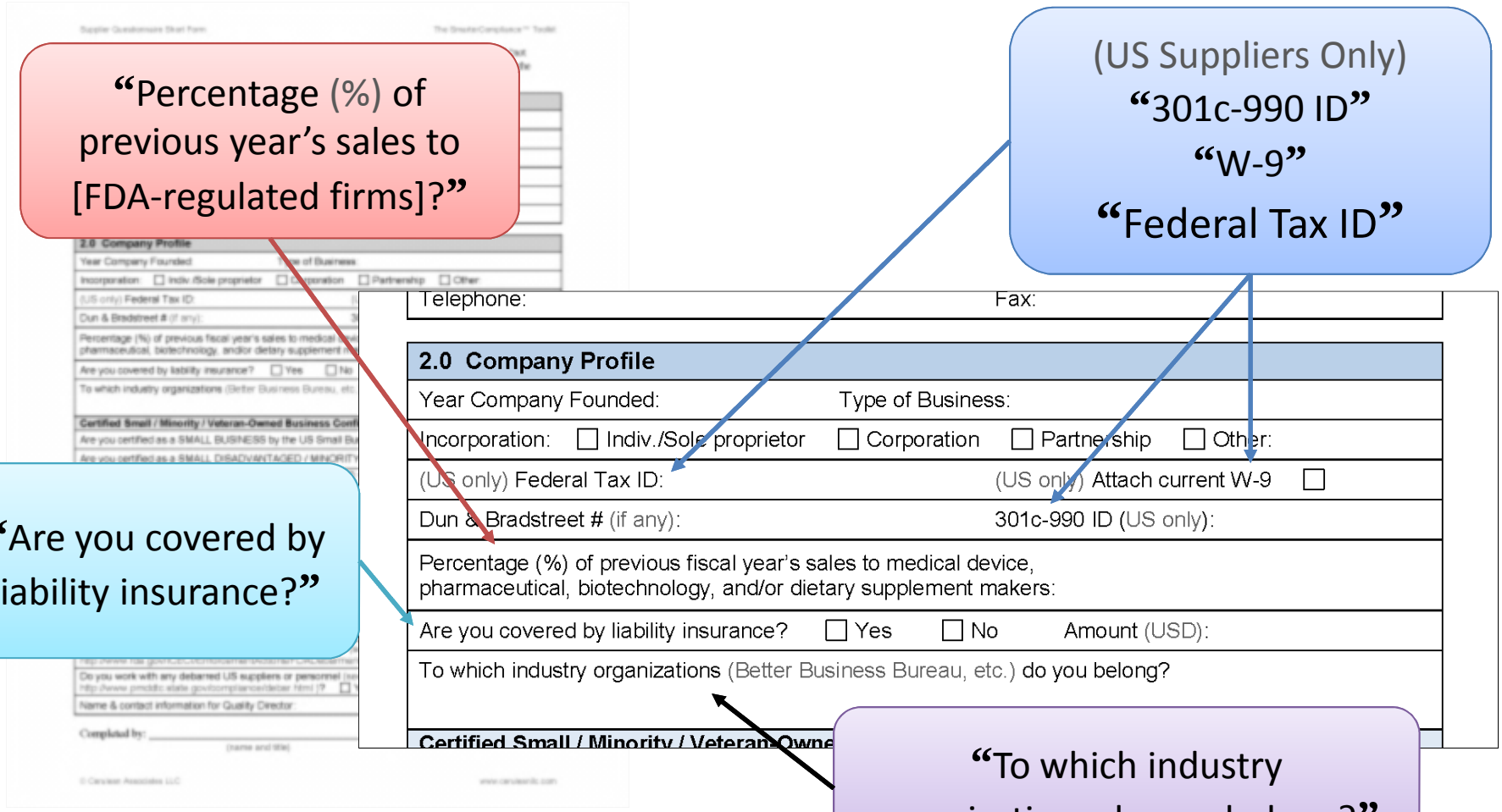

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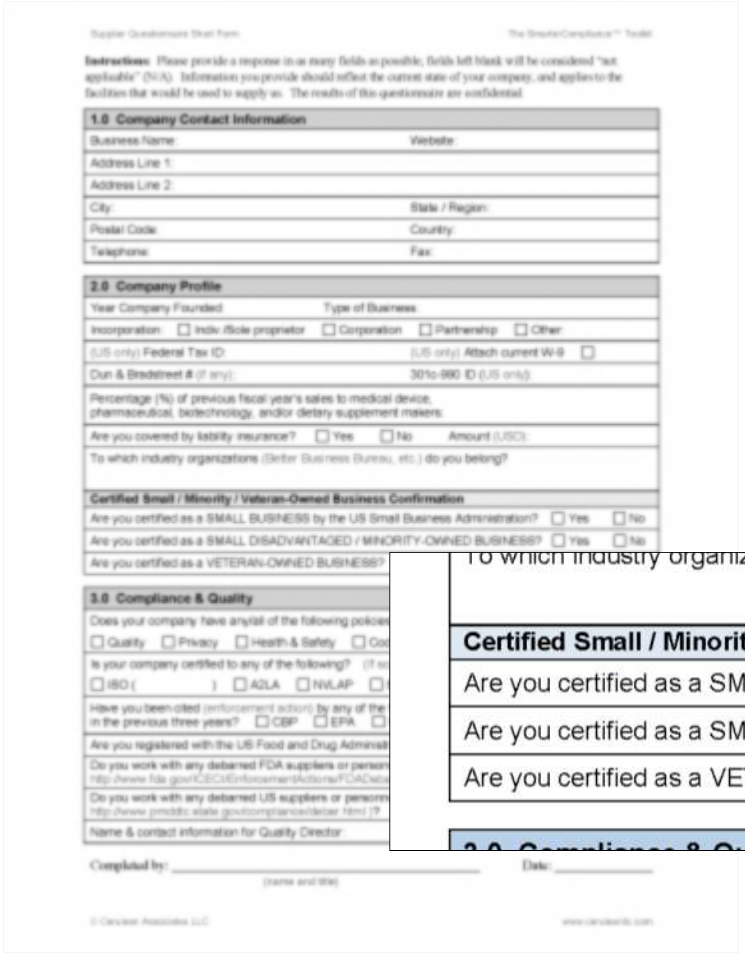

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Replace/eliminate these questions as relevant to your business.

(industry awards, union status, etc.)

To which industry organizations (Better Business Bureau, etc.) do you belong?

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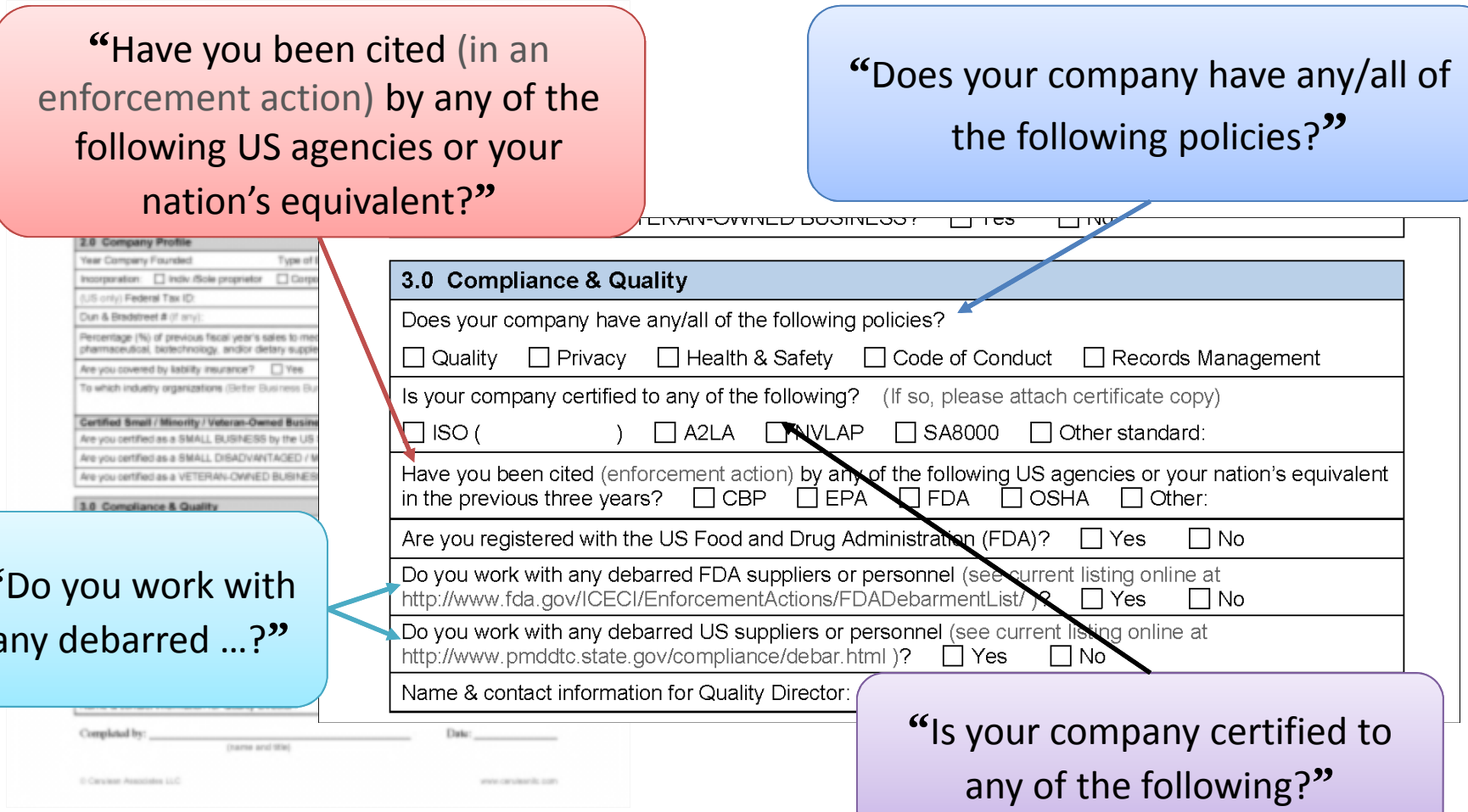
Questionnaire Structure

"Have you been cited (in an enforcement action) by any of the following US agencies or your nation's equivalent?"

"Does your company have any/all of the following policies?"

"Do you work with any debarred …?"

"Is your company certified to any of the following?"



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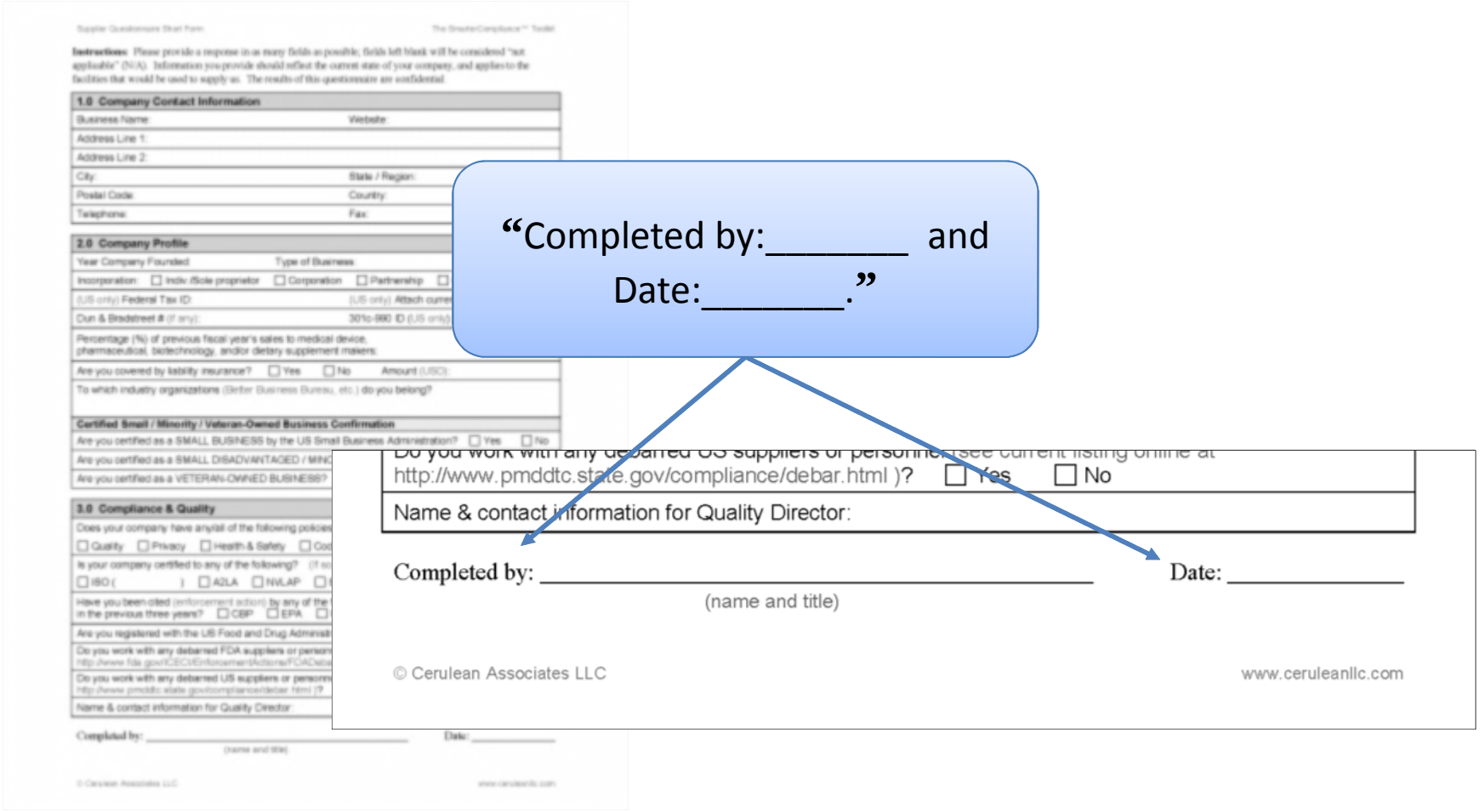
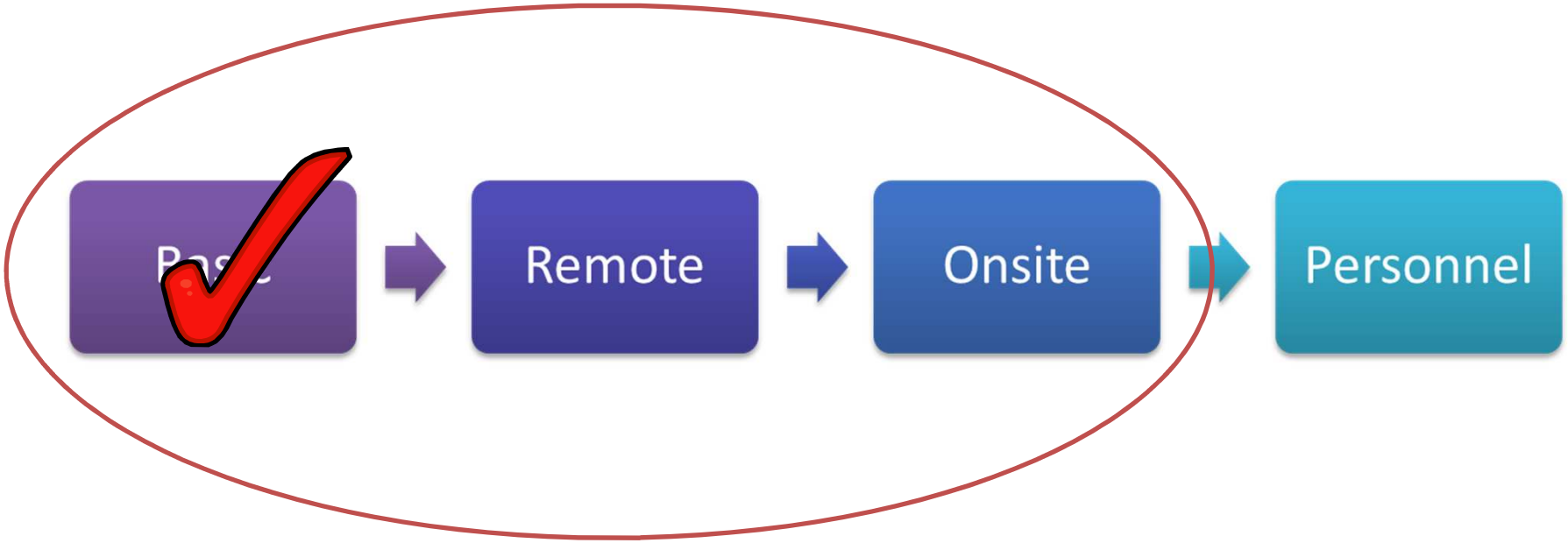


Question to Consider

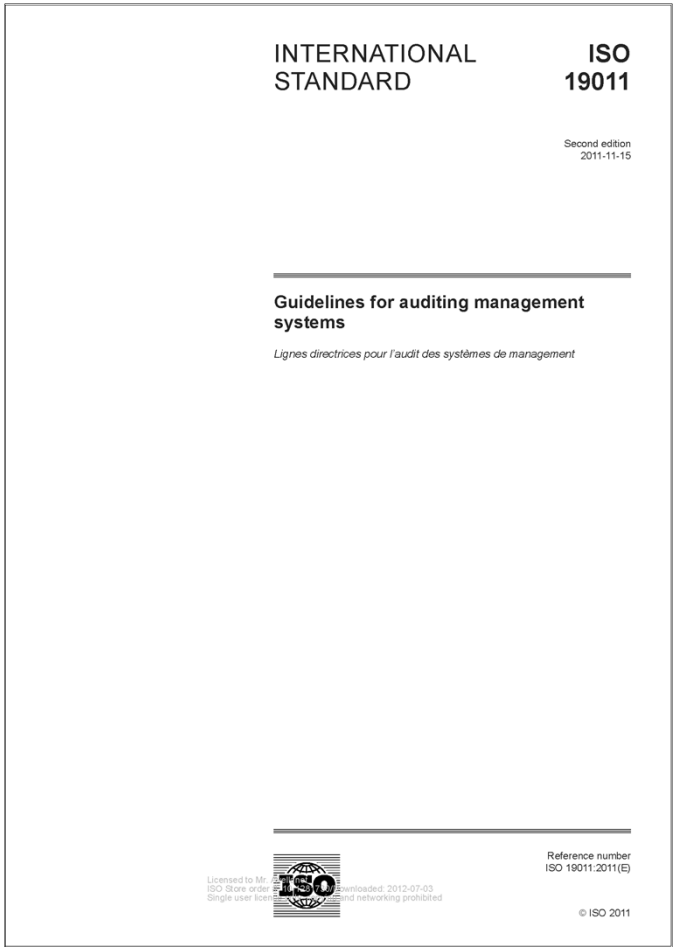
Three of your suppliers want to know why they should complete and return the questionnaire. Do you tell them…?

a) “It’s required by FDA.”
b) “It’s required by our quality system.”
c) “We need the information on it to set you up in our systems such as our accounts payable system.”

Step 3: Qualification



Remote Audit


INTERNATIONAL STANDARD

ISO 19011

Second edition
2011-11-15

Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

Reference number
ISO 19011:2011(E)

© ISO 2011

ISO 19011 Guidelines for Auditing Management Systems (2011)

- Annex B.1
- Review SOPs critical to your processes or requirements
- Do they conduct annual quality system management reviews (QSMR)?
- How do they manage their suppliers?

Remote Audit

ISO 19011:2011 §Annex B.1

> “Remote audit activities are performed at any place other than the location of the auditee, regardless of the distance. The feasibility of remote audit activities can depend on the level of confidence between an auditor and an auditee’s personnel.”

Onsite v. Remote Auditing

Onsite Audit Methods

- Face-to-face interviews
- Checklists with auditee participation
- Document review with auditee participation
- Product sampling
- Onsite facility walkthroughs
- Work observation
- Analyze data

Remote Audit Methods

- Interviews **via telecon/web**
- Checklists **without** auditee participation
- Document review **without** auditee participation
- Observation **via surveillance**
- Analyze data

“Are onsite audits always necessary?”

QSR Requirements

21 CFR §820.50(a)(1)

> “Each manufacturer shall evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.”

QSR Requirements

Do you see the words "**onsite**" or "**audit**" anywhere…?

21 CFR §820.50(a)(1)

"Each manufacturer shall evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented."

ISO Requirements

ISO 13485:2003 §7.4.1

> **“**The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements.
>
> Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.**”**

ISO Requirements

ISO 13485:2003 §7.4.1

What about here? Are the words "**onsite**" or "**audit**" anywhere…?

"The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.

Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained."

Five Threshold Questions

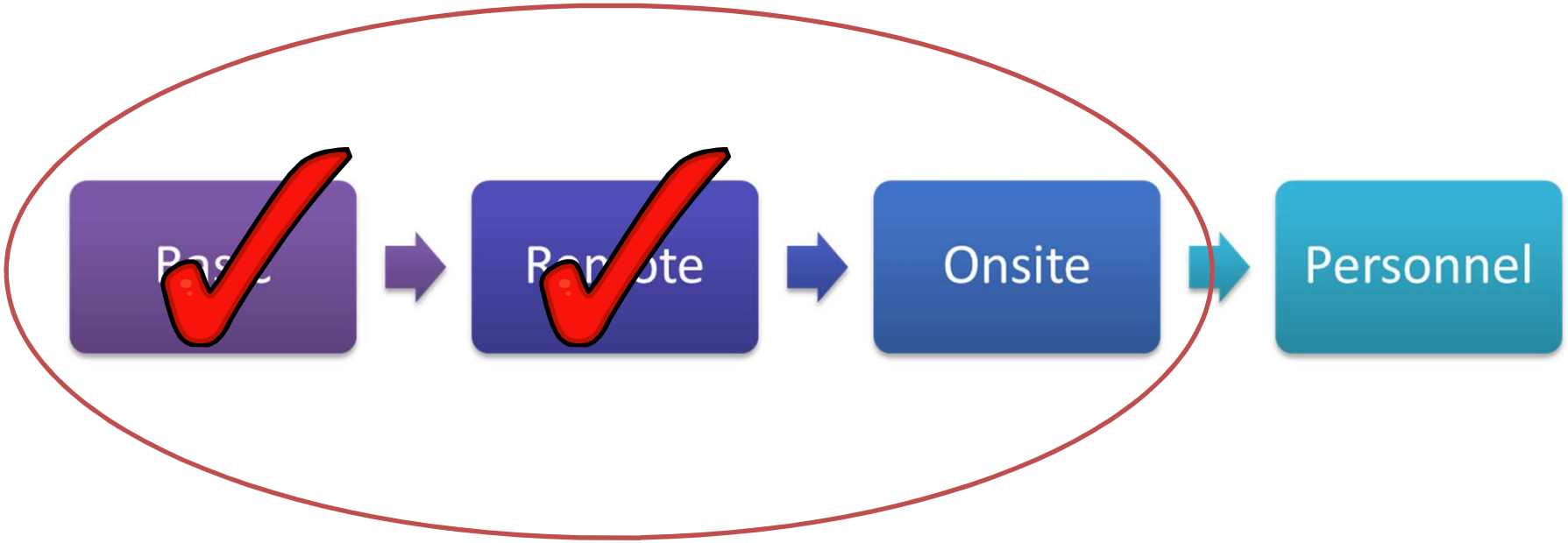
1. Are there any specific **regulatory/statutory citations** requiring an onsite audit?
2. Is the material/service being purchased **directly critical** to our product's safety and/or efficacy?
3. Have **post-market conditions changed** to necessitate a "fresh look" at the supplier?
4. Is there a **government investigation** into the supplier or a loss of 3rd party accreditation?
5. Has an independent party determined that **our** (or our supplier's) **supplier controls are inadequate**?

Five Questions in Action

	Example: CMO	Example: Consultant	Example: Part Maker
Specific regulations or laws requiring an onsite audit?	NO* (*guidance strongly suggest firms conduct onsite audits of CMOs, CROs)	NO	NO
Material/service being purchased critical to our product's safety or efficacy?	**YES**	NO	**?**
Have post-market conditions changed to necessitate a "fresh look" at the supplier?	NO	NO	NO
Government investigation into the supplier or a loss of 3rd party accreditation?	NO	NO	NO
Independent party determined that our supplier controls are poor?	NO	NO	NO

Interactive Exercise

Step 3: Qualification



"Should I Use a 2nd or 3rd Party Auditor for an onsite audit?"

1st vs. 2nd vs. 3rd Party Audits

Internal Auditing	External Auditing	
	Supplier Auditing	Legal/Regulatory/Certification Auditing
1st party audit	**2nd party audit**	**3rd party audit**
Example: You audit yourself	Example: You audit your supplier OR You hire someone to audit your supplier	Example: FDA audits your supplier DEA audits your supplier SEC audits your supplier ISO accreditor audits your supplier CE mark accreditor audits your supplier

3rd Party Audit Usage

Rely upon for:

- outside observer impressions against written standards
- systemic overview of a supplier (e.g., NOT confined to your concerns – may not even touch upon your concerns, risks, etc.)
- your initial qualification/re-qualification activities:
  - supplier selection (GHTF/IMDRF phase 2)
  - remote audits (GHTF/IMDRF phase 3)
  - supplier re-evaluation (GHTF/IMDRF phase 6)

2nd Party Audit Usage

Rely upon for:

- your (or outside expert's) impressions against written standards and your concerns
- process-focus on supplier's controls
  - also use outside expert for more systemic view if needed
  - Part 11 and data integrity, specific cGCP controls, etc.
- your initial qualification/re-qualification activities:
  - remote audits (GHTF/IMDRF phase 3)
  - onsite audits (GHTF/IMDRF phase 3)
  - supplier re-evaluation (GHTF/IMDRF phase 6)

1st Party Audit Usage

Rely upon for:

- insider observer impressions against internal standards
  - remember the infinite variety of biases!
- stand-in if you cannot do any auditing (remote or onsite)
- your initial qualification/re-qualification activities:
  - supplier selection (GHTF/IMDRF phase 2)
  - remote audits (GHTF/IMDRF phase 3)
  - onsite audit preparation (GHTF/IMDRF phase 3)
  - supplier monitoring (GHTF/IMDRF phase 5)
  - supplier re-evaluation (GHTF/IMDRF phase 6)

Two Practical Tips

1. Do **not** duplicate a 3rd party audit
   - tend to be systemic
   - if need detail, ask for:
     - audit report
     - corrective action plan/schedule (CAR)

2. Your audit should be **process-driven** or **risk-driven**
   - what are the supplier processes most important to fulfilling your needs?
   - what risks do you need to mitigate b/c you are outsourcing?
   - what supplier controls directly impact:
     - your needs AND
     - the supplier's processes most important to your needs?

Preparing for the Audit

Step 1: Establish control objectives

- Determine the important supplier processes
- Determine the specific criteria
  - example: production process requires validation
  - example: hosted SAP production system must be validated
  - example: anti-counterfeiting/diversion controls must be in place (GDPs)

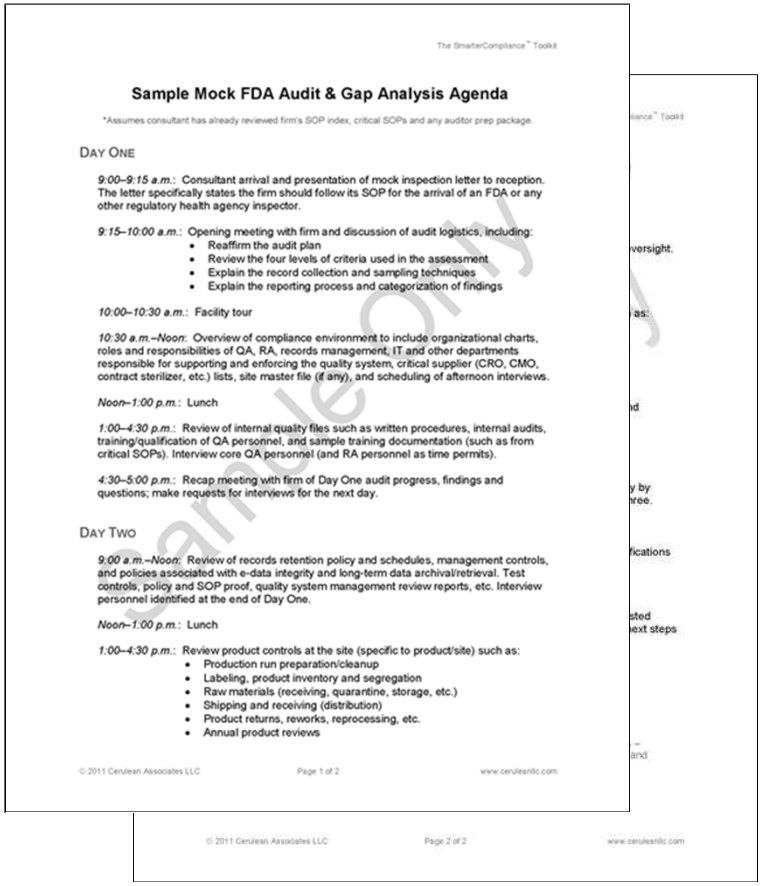
Step 2: Identify specific references to be used/relied upon

- ISO, FDA, USP, IMDRF, MDSAP, etc. guidelines
- Legal/regulatory requirements
- Your internal policies
- Supplier's own SOPs

Step 3: Use this information to develop an audit checklist

Example Audit Agenda

- Allow 15-30 min. for introductions and scope review
- Allow 30 min. for a facility walkthrough (do *not* get sidetracked!)
- Break audit "targets" into 2-4 hour sets (*i.e.*, CAPA for 3 hours, Validation for 2½ hours, etc.)
- Conduct a 30-min. recap at the end of each day
- Leave a 2 hour buffer for every 2 days onsite
- Do not forget to budget time to synthesize notes from audit
- Expect a 1 hour closeout meeting



The SmarterCompliance™ Toolkit

Sample Mock FDA Audit & Gap Analysis Agenda

*Assumes consultant has already reviewed firm's SOP index, critical SOPs and any auditor prep package.

DAY ONE

9:00–9:15 a.m.: Consultant arrival and presentation of mock inspection letter to reception. The letter specifically states the firm should follow its SOP for the arrival of an FDA or any other regulatory health agency inspector.

9:15–10:00 a.m.: Opening meeting with firm and discussion of audit logistics, including:
- Reaffirm the audit plan
- Review the four levels of criteria used in the assessment
- Explain the record collection and sampling techniques
- Explain the reporting process and categorization of findings

10:00–10:30 a.m.: Facility tour

10:30 a.m.–Noon: Overview of compliance environment to include organizational charts, roles and responsibilities of QA, RA, records management, IT and other departments responsible for supporting and enforcing the quality system, critical supplier (CRO, CMO, contract sterilizer, etc.) lists, site master file (if any), and scheduling of afternoon interviews.

Noon–1:00 p.m.: Lunch

1:00–4:30 p.m.: Review of internal quality files such as written procedures, internal audits, training/qualification of QA personnel, and sample training documentation (such as from critical SOPs). Interview core QA personnel (and RA personnel as time permits).

4:30–5:00 p.m.: Recap meeting with firm of Day One audit progress, findings and questions; make requests for interviews for the next day.

DAY TWO

9:00 a.m.–Noon: Review of records retention policy and schedules, management controls, and policies associated with e-data integrity and long-term data archival/retrieval. Test controls, policy and SOP proof, quality system management review reports, etc. Interview personnel identified at the end of Day One.

Noon–1:00 p.m.: Lunch

1:00–4:30 p.m.: Review product controls at the site (specific to product/site) such as:
- Production run preparation/cleanup
- Labeling, product inventory and segregation
- Raw materials (receiving, quarantine, storage, etc.)
- Shipping and receiving (distribution)
- Product returns, reworks, reprocessing, etc.
- Annual product reviews

Conduct the Audit

- Communicate your plan to the potential supplier
- Conduct the on-site audit
- Provide a (summary) report to the potential supplier*
  - Supplier Corrective Action Report (SCAR) to track any non-conformances
- Decide if you will select the potential supplier

***Note*:** If this is for a current supplier (or a necessary supplier), you are accountable for working with them to close any gaps or compliance nonconformances

Take Action

For any nonconformities, **request corrective action**

- don't bother if you don't select the supplier
- if you do not select supplier, ask your legal department if it's okay to provide your audit report to the supplier

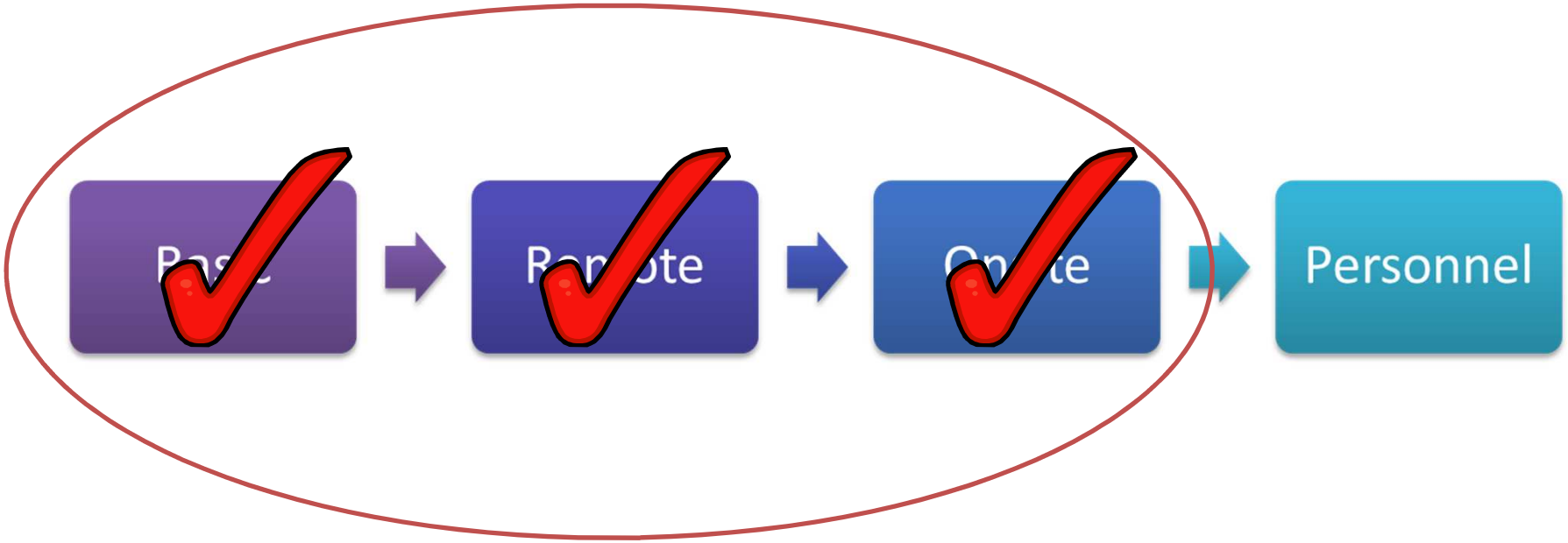
Use your impressions AND your audit results to **suggest improvements** to their corrective action plan

- don't be afraid to suggest consultants to them as necessary
- "We know that people have had good experiences with _____"

Follow-up with another assessment

- consider an outside expert if did original yourself (or vice versa)

Step 3: Qualification



Key Points

- Start with a basic red flag questionnaire to every supplier
- Then conduct remote audits
- Use 5 threshold questions to determine onsite audit needs
- Document any audit follow-ups (SCAR)
- Recognize that you may have to assume controls

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