It’s not the supplier’s fault?

Supplier Management

Speaker

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Framework

- A 3-year initiative to streamline & simplify supplier management.
  - Global effort
  - All supplier types in scope.
  - Full lifecycle; selection, approval, maintenance, sun-setting
  - In 2016, 11 projects
  - Focus in 2016 process / procedures
  - Focus in 2017 will be the electronic systems

Supplier Management

Supplier Management is a relationship between you & your suppliers.

- As a company develops / acquires new technology it must adapt.
- When things go wrong, fixes implemented by the supplier only addresses half the problem. You want to prevent the problems, not simply react to them.
- Expecting the supplier to address the issue if they don't understand how they integrate into your process or finished device will never fully address the problem.

Supplier Management

§ 21 CFR Part 820.50 Purchasing Controls

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

- (a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall: (1) 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**. (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, **based on the evaluation results**. (3) Establish and maintain records of acceptable suppliers, contractors, **and consultants**.
- (b) Purchasing data. Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product **and services**. 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 so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.

Supplier Management

Preamble to § 21 CFR Part 820 (search word Supplier)

- The early drafts of the regulation suggested the FDA would extend the authority for inspections & the regulations to our suppliers. Industry pushed back and they agreed that enforcement would suffice via regulations on the device manufacturer.
- They clearly state you can not inspect quality into the device.
- FDA views consultants as a provider of service & as such purchasing controls apply to consultants.
- "service" means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing, among others. Second, FDA believes that all suppliers of such services must be assessed and evaluated, just like a supplier of a product. As always, the degree of control necessary is related to the product or service purchased.

What could go wrong?

3. Your firm failed to establish and maintain the requirements that must be met by suppliers, contractors, and consultants. Your firm failed to evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements, and document the evaluation, as required by 21 CFR 820.50(a).

For example your firm failed to implement its established procedures for purchasing controls. The Amgen Operating Standard for Managing Contractors (**(b)(4)**, version **(b)(4)**, dated December 1, 2012) requires that contractors be evaluated, monitored, and approved. With regards to the **(b)(4)** located in Building **(b)(4)** of your firm's facility, upon request, your firm could not certify that **(b)(4)**, the contractor that serviced the equipment on May 22, 2013, had been evaluated.

In your response you commit to ensuring that service providers conducting preventive maintenance for the X-ray equipment "are evaluated and maintained to the appropriate quality standard." However, your response is not adequate because you did not describe how appropriate employees will be trained on the new procedures, and you did not provide in your response whether your firm intends to review its records to ensure that those suppliers, contractors, and consultants currently being used by your firm have been appropriately evaluated.

7. Failure to establish and maintain procedures to ensure all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. [Reference: FDA 483 Item 7] For example, your firm failed to establish purchasing control procedures and to define and implement adequate quality controls which must be met by suppliers and contractors. Additionally, there was no documentation demonstrating your firm is being notified of changes made by contract suppliers. According to a contractor's service report, dated August 31, 2009, a new chemical product was added to the cleaning operation; it does not appear firm management was notified of the change before implementation.

We reviewed your response and concluded it is inadequate as purchasing control procedures relating to the cleaning, drying, and sterilization operations were not included.

What could go wrong?

1. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers and contractors, as required by 21 CFR § 820.50(a). For example, your firm failed to evaluate suppliers and contractors to ensure their adherence to the QS Regulation. Your purchasing control procedure is inadequate in that the written survey sent to suppliers fails to include any requirement to demonstrate adequate process validation, calibration, or maintenance of equipment. In addition, your firm uses a contractor to produce tubing by **[redacted]** for its Command Huber Infusion Set and you failed to determine if the inner/outer diameter of the tubing is altered by the heat used during sterilization process (FDA 483, Item #1).

We have reviewed your response and have concluded that it is inadequate because the survey that you will provide to suppliers only requires a reply of yes or no to questions of whether processes have been validated and if validation documentation is available. Your firm should request documentation from the supplier in order that it can be reviewed to assure it is adequate. In addition, the documentation that you supplied of 30 samples of tubing measured for inner and outer diameter pre- and post-sterilization is inadequate to show that sterilization does not affect tubing diameter because it is unclear whether these 30 samples are from one lot or multiple lots. If the 30 samples are from one lot, you should include samples from multiple lots to demonstrate consistency over multiple lots. If the 30 samples are from multiple lots, you should identify how many samples are from each lot and why each number is statistically relevant to demonstrate consistency.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm does not have an agreement with its supplier, **(b)(4)**, which defines responsibility for device attributes and quality requirements. Specifications for the device are not defined between **(b)(4)** and Epimed. Further, although **(b)(4)** is listed on your firm's Approved Supplier List, IHR-603, Revision 4, as a critical supplier, your firm failed to follow its own procedure in requiring critical suppliers to have a Change Notification Contract. Your firm's procedure, QAP-601, Rev. 18, Supplier Assessment, requires a file for each supplier that includes product specifications and supplier assessments; however, upon request, no supplier file for **(b)(4)** was provided to the investigator.

The adequacy of your firm's response dated June 7, 2012, cannot be determined at this time. Although your firm opened CAPAs **#(b)(4)**, **#(b)(4)**, and **#(b)(4)** to obtain documentation from the original specification developer, **(b)(4)**, and to address changes to the complaint handling, design, and supplier control procedures, no revised procedures or evidence of implementation were provided.

What could go wrong?

OBSERVATION 4

Device packaging and/or shipping containers are not designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution.

Specifically,

Protocol #90088394 approved on site on July 2012 for the Packaging Integrity Performance Qualification of (b) (4) Products (b) (4) at Arecibo Site, and executed to provide documented evidence to demonstrate that the packaging tray integrity of (b) (4) units is maintained after a (b) (4) (b) (4), fails to report impact on product manufactured at Woodridge, Minnesota-US and (b) (4) at Arecibo, Puerto Rico or justification for lack-of . The protocol includes only tests conducted on product manufactured at Caguas (PR) transferred to Arecibo (PR)- but fails to include tests on product manufactured at Woodridge and shipped to Arecibo (as proposed on PMA P810002/S080) or documented evidence to support the lack of such tests.

In addition, protocol # 90088394 reports that functional tests on product is not required because it was completed under protocol #873526(January 2008), which only includes tests on product manufactured at Caguas (PR) and (b) (4) at Minnesota. No documented evidence is included with either protocol to support the firm's conclusion of no impact on the product and seal integrity under different environmental conditions (including shipping) for the new proposed (b) (4) site vs. the two

Internal or Supplier?

- To conclude you are one company you must operate under one quality system (no site specific procedures) & under one internal audit program.
- If this is not true, than each manufacturing site is viewed as independent and thus, a supplier to another manufacturing site. So, movement of materials & subassemblies between locations falls under purchasing control requirements.
- Just know your validations MUST confirm the full process is validated. This includes all locations of the production process and movement of materials during the process.

Supplier Management
Step 1

Scope the program:

- Identify the requirements for your company.
  - What regulations apply? What guidance documents should be followed?
- Agree who / what are the suppliers.
  - This is where you highlight service suppliers & consultants.
  - What about interplant transfers?
- Who is engaging suppliers?
  - Who does the sourcing? What departments are involved?
- What procedures are used to manage suppliers?
  - Find all the bits & pieces. Good luck!

Supplier Management
Step 1 Gaps

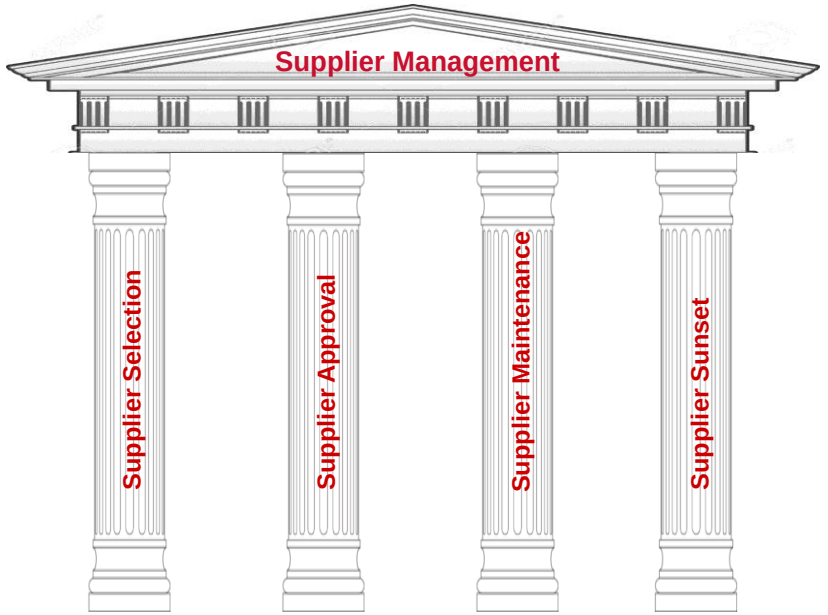
- Are you agreed on who is considered a supplier by the regulators; i.e., FDA, ISO, etc.?
- Are there too many cooks in the kitchen? Do you really have control over onboarding new suppliers? Keep in mind this includes consultants & service providers.
- What about other groups? As an example, who ensures consultants for Clinical services are approved? You laboratories? Facilities & maintenance?
- Do you have a procedure for management of 3PLs that conflicts with your top level procedure for supplier auditing?
- What is being done in your regional offices?
- Where are the approve suppliers listed? One spot or all over the place?

Supplier Management Step 1 Fixes

DMAIC = Define, Measure, Analyze, Improve, Control

- Pull together key representatives across the organization involved in supplier management.
  - New Product Development / Sourcing
  - Global Supply Chain / Buyer Planners
  - Contracts & Payment
  - Receiving Inspection
  - Supplier Quality
- Highlight the regulatory requirements and your internal procedural requirements.
- Get agreement on the scope of supplier management for your company.

Supplier Management Step 2



Define the process:

- Map your current state process.
  - Leave the conference room.
  - Walk the process.
  - Interview people.
  - The process map may very depending on supplier type.
  - Consider breaking out by element or phase of supplier management.

Supplier Management
Step 2 Gaps

- Did you find procedures you never knew existed?
  - If your company has had multiple owners / names I bet you have some old procedure somewhere that is still active.
- Who did you meet you never knew was involved in supplier management?
  - If no one new, then you missed something.
- What did your suppliers say?
  - They LOVE you right? (hee hee hee)
- Boxing Day

Supplier Management
Step 2 Gaps

- Talk to your suppliers. What do they think?
  - Your suppliers work with other companies. – Benchmark!
  - They can impact your reputation. – Would they use your product based on how you manage them?
  - They could be a customer.
  - Do they realized they are supplying to a medical device manufacturer?

Supplier Management
Step 2 Gaps

DMAIC = Define, Measure, Analyze, Improve, Control

- Gather data!!!!!
- Interviews, surveys, trending data, etc. DIG!!!!
- Example: VOC – Auditee Questionnaire.
  - What is your initial impression of the supplier audit program?
  - What would you like to see changed?
  - What do we do well?
  - What is your expectation for follow up after the on-site audit has completed?
  - Do you feel our audit staff is adequately trained / qualified to perform supplier audits?
  - Has the interactions with our audit staff been acceptable?

Supplier Management
Step 2 Fixes

DMAIC = Define, Measure, Analyze, Improve, Control

- Review the data.
  - Were there any new discovers?
  - What was the feedback? The good, the bad, & the downright ugly? (be honest)
- Lay out the ‘should be’ program.
  - This sets the total goal for your project(s). Sets one clear vision for the teams.
  - Get full buy-in from management on the goal.
- Brainstorm solutions.
- Prioritize the work.
  - Divide & conquer.
  - Tackle the easiest ones w/ the biggest bang for the bucket first.
    - You want early wins to keep the teams motivated.

Supplier Management
Step 2 Fixes

DMAIC = Define, Measure, Analyze, Improve, Control

Strong communication across the organization is a must.

- Involve others. Let people help.
- Do NOT assume you are the only one that understands.
- Set a program to report the results.
- It has to be part of management goals!

Supplier Management
Step 3

Monitor / Improve:

- Get agreement across the organization on what & how to monitor the program.
  - This includes internal metrics as well as supplier metrics.
  - If on average it takes 90 days to complete a supplier CAPA investigation, is that acceptable? If not, who is to blame? How can you fix it?

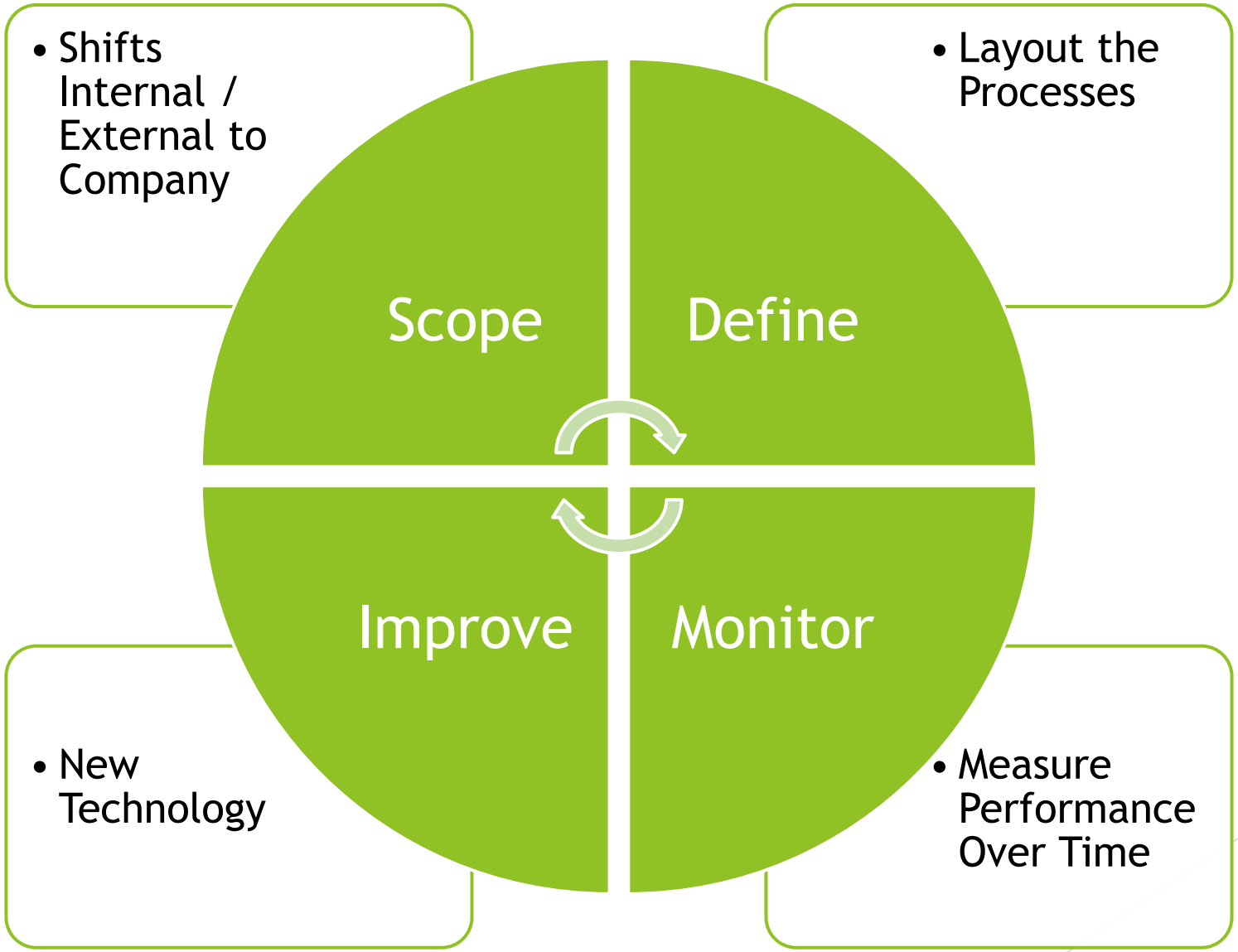
Supplier Management
Step 3 Gaps

- Is your monitoring program driving improvements or is it driving bad behavior?
- Are you spending more time trying to make a green dot on your management review slide or on actually finding & fixing the problems?
- Do people feel they are being heard when they speak up about issues?
- Does management even show up?
- Do you work with your suppliers?

Supplier Management Step 3 Fixes

- Your suppliers have to be engaged & involved. It's a partnership, NOT a dictatorship.
- The data has to identify the issues.
- You have to react to the data.

Summary


• Shifts Internal / External to Company
• Layout the Processes
Scope
Define
Improve
Monitor
• New Technology
• Measure Performance Over Time

Supplier Management
What else?

- What is the point behind the UDI program?

Supplier Management
What else?

- Maybe we can learn something from other industries?

The **Production Part Approval Process** (**PPAP**) is a standardized **process** in the **automotive** and aerospace industries that helps manufacturers and suppliers communicate and approve production designs and **processes** before, during, and after manufacture. Jul 30, 2014

Production Part Approval Process (PPAP)

Verification of Material Acceptance in the Automotive Industry

The Production Part Approval Process (PPAP) was initially developed by AIAG (Automotive Industry Action Group) in 1993 with input from the 'Big Three' – Ford, Chrysler, and General Motors. If your materials are intended for use in automotive parts, you must complete the PPAP to meet the requirements of top automotive manufacturers' quality systems (QS9000). Once you submit your material samples to an A2LA Accredited Laboratory, such as Intertek, we can generate data and help you prepare your PPAP submission for approval.

To meet material specifications, your PPAP material may be subject to the following tests:

- Charpy Impact
- Density
- Flammability
- Flexural Properties Testing
- Fogging
- Heat Aging
- Heat Deflection Temperature
- Linear Thermal Expansion
- Melt Flow Rate
- Mold Shrinkage / 3D Measuring
- Multiaxial Impact
- Plastics Tensile Testing
- Poison's Ratio
- Vicat Softening Temperature