JABIL

Supplier University

- Change Management

Mar 2015

Agenda

- Purpose
- What is Change?
- What is Change control? The importance?
- An effective Change control process
- Jabil requirement
- Summary

Purpose

- To introduce the importance of change control
- To introduce the basic knowledge of change control
- To introduce Jabil requirements on change control
- To set up better communication between Jabil and supplier

What is Change

- Change is a constant, natural occurrence in a manufacturing process. Changes can be driven by the need for continuous improvement, yield increase, defect decrease, throughput increase, etc. They can also be driven by changing customer requirements.

- A Change can be requested by any functional department. It could be a document change, material change, specification change, equipment change, process change, method change, system change, etc.

Change control

- What is Change control
  The process of identification, documentation, validation, verification, review, and approval of changes before their implementation

- Why change control is important?

  - The risk of change
  - Current quality issue we meet
  - ISO / regulation requirement

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Risk of Change

We need change to make improvement, but change also brings risks:

- ✓ Impact quality performance / cause quality issue / recall
- ✓ Cause production line down
- ✓ Cause customer line down
- ✓ Impact the quality of customer products
- ✓ Impact end users
- ✓ Lose money / time / market

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Current situation

Currently, Jabil have RTV (Return-To-Vendor) cases and customer issues, which caused by bad change control, almost every month.

- Some supplier make changes without notifying Jabil in advance or getting approval from Jabil

- Some design changes are not communicated sufficiently and implemented well at supplier

- Change control failure at supplier may result in:
  - ✓ IQC Rejection / Line down
  - ✓ Jabil products quality issue
  - ✓ Customer returns at Jabil
  - ✓ Jabil customer product quality issue
  - ✓ Malfunction at end user

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ISO / Regulation requirement

ISO and regulation at some countries have clear/strict requirements on change control:

- ISO 9001:2008
  - ❖Section 7.3.7 “Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.”

- FDA regulations on Medical Devices

  21 CFR 820 – FDA GMP
  - ❖820.30 “(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.”
  - ❖820.70 “(b) Production and process changes. Each manufacturer shall establish and maintain process, or procedures for changes to a specification, method, process, or procedure.…”

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An effective Change control process

- Because of the importance of change control, we need to set up an effective change control process for change management.
- Changes occurring during Medical Device Product Design or Manufacturing must be fully documented, reviewed, and approved.
- Approvers of Change Control documents must be established for each Functional Department.

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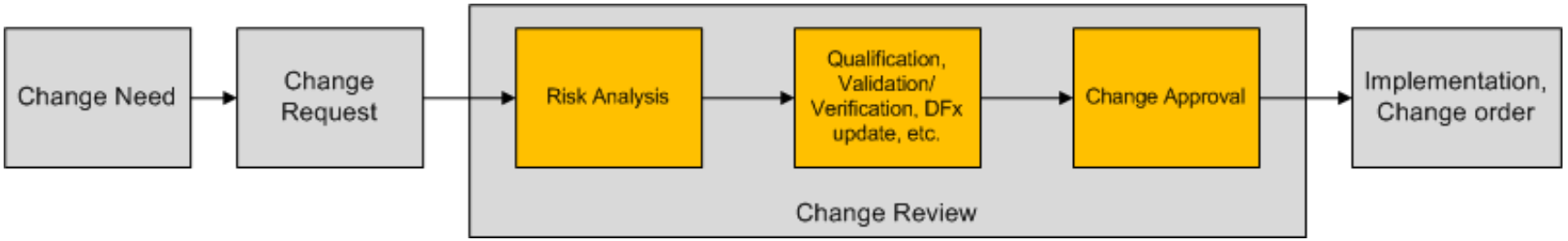
An effective Change control process

A typical change control process



An effective Change control process

- Change Request

  ❖When Change is needed, a documented Request is completed.

  ❖ A Change Request may be initiated by anyone in the Company.

  ❖ A Change Order is the mechanism by which the Change Request is approved, indicating implementation requirements.

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An effective Change control process

- Change Request Requirements

  - Change Requestor
  - Type of Change
  - Description of Change
  - Rationale or Justification for Change
  - Impact on current products or processes
  - Impact on documentation
  - Impact on validated processes & equipment

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An effective Change control process

- Risk Analysis

  - Whenever a Change is Requested, a corresponding Impact Analysis to Product, Process, and Safety must be considered from a Risk perspective.

  - Introduction of additional Risk due to Requested Changes must be fully understood and potentially mitigated prior to implementation.

  - Risk Analysis techniques must be applied prior to implementation of changes

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An effective Change control process

- Risk Analysis

  - If a Risk Analysis has been previously performed, review to determine if the proposed change will impact any existing process risk controls and revise accordingly.

  - If the proposed change introduces any new process risks, revise the analysis to include any new controls.

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An effective Change control process

- Validation/Verification Impact

  - If a new process or piece of equipment is being introduced, indicate that Validation or Verification is required.

  - Summarize the rationale and strategy for the validation/verification decision.

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- DFx Impact
  - If a Requested Change impacts manufacturability, test, or assembly operations, then an impact assessment on DFx must be performed and reviewed prior to Change implementation.

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- Materials/Tooling Cost

  - Change impacting new materials must be reviewed from a cost perspective prior to Change implementation.

  - Change impacting tooling changes must be reviewed due to cost and lengthy tool modification and qualification times.

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An effective Change control process

- Regulatory Impact

  - All requested Changes must be evaluated from a Regulatory standpoint, with special emphasis given to impact on Product Intent for Use, FDA Device Listings, and pertinent Agency (UL/CSA/ETL) file updates and retesting requirements.

An effective Change control process

- Customer Approval/Notification

  Change Requests must take into account required Customer interaction, such as the following:

  ✓Customer owned material/tooling
  ✓Changes impacting customer’s design
  ✓Changes impacting customer’s production flow

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- Approvals

  - Change Requests must be submitted to Functional Approvers, QARA, and Company Management personnel at a minimum.

  - Special approvals may be needed if Change deals with Safety, Facilities, or Warehouse operations.

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An effective Change control process

- Implementation

  - Requirements associated with the Change, such as training, material consumption, documentation updates all must be completed prior to Change Implementation – this is controlled by the **Effective Date**.

An effective Change control process

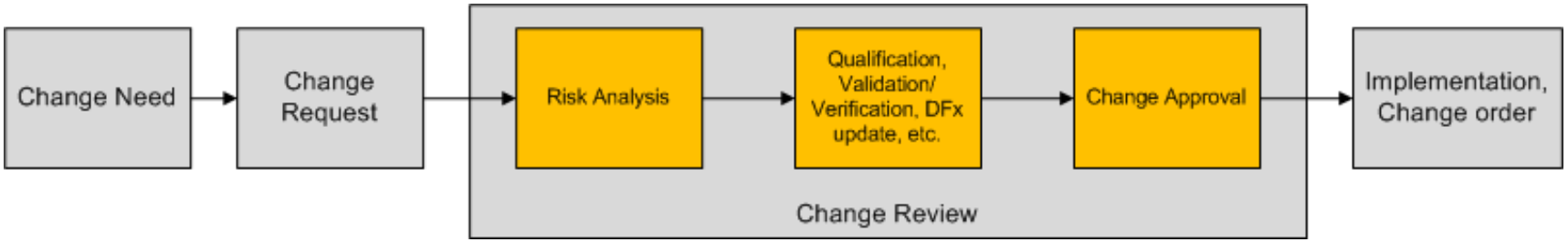
- Change Order

  - When the Change Request is fully documented, including all Implementation Requirements, the Change is approved to be implemented on the Effective Date.

  - All Change Orders are immediately controlled within the Document Control System.

The product (batch) before/after changes must be identifiable.

An effective Change control process



Records of Change Review shall be maintained.

Jabil requirement

- Jabil has defined its requirement to supplier on change control in **Jabil Supplier Requirement Manual** - 6.11 Product Change Notice
  http://media.jabil.com/documents/JABIL-Supplier-Requirements-Manual.pdf

- As Jabil supplier, you are required to submit a Product Change Notice (PCN) for any proposed change including the following:
  - ✓ Change in manufacturing process
  - ✓ Change in material or change in material source
  - ✓ Change in manufacturing location
  - ✓ Change in part construction / design (i.e. Die Shrink)
  - ✓ New or modified tooling
  - ✓ End Of Life

- To submit a Product Change Notice, suppliers must send it via e-mail to: pcn@pcnalert.com or to jabil_pvt@pcnalert.com.

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Jabil requirement

- You can find the guidelines for the submission in **Jabil Supplier Requirement Manual**
- Submission of a Product Change Notice to Jabil does not indicate approval of a proposed product change. Jabil reserves the right to reject any proposed change, require additional information or data to be supplied or seek customer(s) concurrence prior to granting approval.
- Suppliers must maintain records of the date of implementation in production of each change.
- For every Process Change Notice submitted, suppliers are required to review the impact to material composition and submit an updated full material disclosure report / declaration.

Summary

Change control is very important to you and your customer.

From this course, you have learned:

- What is change and change control
- The importance of change control
- An effective change control process
- When to notify Jabil about your change? How?
- If you have any question on change communication with Jabil, you can email to: pcn@pcnalert.com or to jabil_pvt@pcnalert.com

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Thank You

Looking forward to a good business cooperation with you

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