

**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,

# 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

# 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

# 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

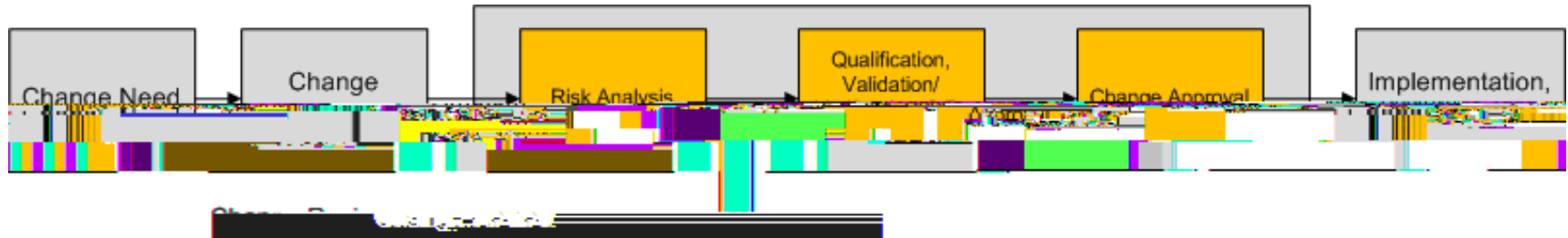


# An effective Change control process

Because of the importance of change control, we need to set up an effective change control process for change management.

# 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.

# 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

# 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

# An effective Change control process

## Risk Analysis

If a Risk Analysis has been previously performed,



# An effective Change control process

## 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.



# An effective Change control process

## 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.

# 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

# An effective Change control process

## 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.

# An effective Change control process

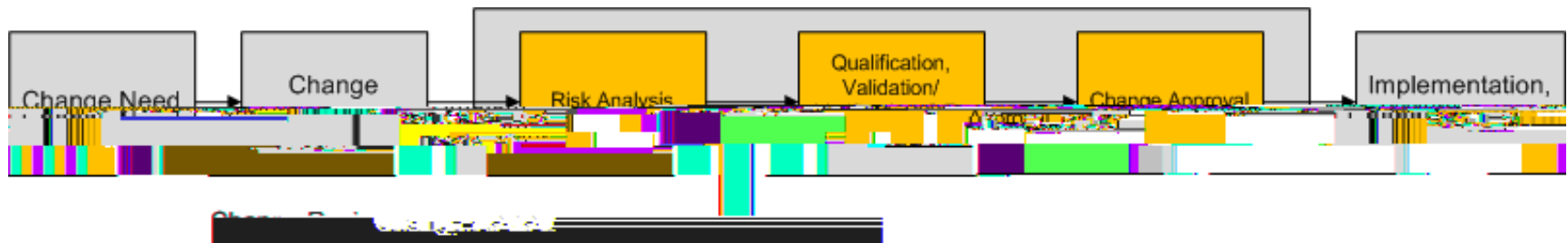
Implementation

# An effective Change control process

## Change Order

When the Change Request is fully documented, including all Implementation Requirements, the Change is approved to be

# 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**



# 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](mailto:pcn@pcnalert.com) or to [jabil\\_pvt@pcnalert.com](mailto:jabil_pvt@pcnalert.com)

**Thank You**

*Looking forward to a good business cooperation with you*