

IPAC-RS Workshop
Basel - September 24-25, 2007

Managing Change Panel

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What does Change Mean to us ?

Change Means to us :

Any **considered modification** to the....

- **Product Specification** (Design, Technical / Functional Specs, Dimensions, Material...)
- **Equipment used along the Manufacturing Process** (Moulding tools, Automation Equipment, Handling / Packaging Equipment, Measuring / Quality Control Equipment)
- **Process** (Sequential Flow, Process parameters...)
- **Production Environment** (Clean Room class, conditions parameters...)

.... Which can **potentially impact** or introduce a **Risk** to the :

- **Product Quality / Patient Safety**
- **Qualification Status of the Equipment** used along the **Manufacturing Process**
- **Validation Status of the Process**
- **Conformity to Regulations**
- **Health and Safety of the personnel**

What triggers change control processes ?

- **Our Change Control Process can be initiated from :**
 - A Product or A Process Change **Request** from a **Customer**
 - A Corrective / Preventive Action coming from a **Problem Solving Analysis**
 - A Corrective / Preventive Action coming from a **Customer Complaint Analysis**
 - A Corrective / Preventive Action identified through an **Audit**
 - An Optimisation Action identified through **Continuous Improvement**
 - A Change **initiative** from a **member of personnel**
- **It is followed up by :**
 - The designated Change Request **Coordinator**
 - The **QA representative** for the relevant Production Area / Project
- **It is Reviewed and Approved by :**
 - The Coordinator **Line Manager**
 - The **QM representative** for the relevant Production Area / Project

How do you assess the impact of a change ?

- **1st step : Scale of the Change**
 - **What part of the supply chain & manufacturing process** is potentially impacted by the Change ?
 - **Who (internal & external)** needs to be informed / consulted as part of the assessment ?
 - **2nd step : Detailed assessment from each party (our supplier(s), internally, customer)**
 - **How** does this change impact us ?
 - **What** are the risks ?
 - **How** can we **evaluate** the risks / and **what** do we need to **Qualify** or **Re-Qualify** ?
- The Impact Assessment must be :
- **Focused** on the Risk to the **Product Quality / Patient Safety**
 - Aiming at Identifying all the **Qualification requirements**
- Risk assessment tools such as FMEA can be used.**
- **3rd step : Implementation /Validation Plan** (+cost / ressources) -> **Decision**
? (for change implementation)

Tool used to enhance Communication

- **Quality Agreements**

- To be established with all parties (customers, suppliers) involved

- **Change Control SOP & Change Request Template**

- Part of the Quality System

- Defines Scope / Process Flow / Deliverables / Responsibilities

- Shared with Customers

- Used as tool & reference to follow up changes implementation

- **Validation Master Plan**

- To be established for each new Project / Product to be developed and approved by the Customer

- Includes reference to the applied Change Control SOP (or specific strategy to be applied)

- **Regular Reviews with Customer(s) ...Supplier(s) on Project Status**