

Change Control – Perspective from a Pharmaceutical Company


Putting all of the pieces together



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Agenda

1. Defining Change
2. Impacts of Change
3. Approve/Notify Agreements
4. Change Control Process




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Definitions

- **Change Control**
 - “A process that ensures that changes to materials, methods, equipment and software are properly documented, validated, approved and traceable” (PS 9000:2001, § 3.7)
 - IPAC-RS guideline (§ 3.3) adds the additional requirement “The process includes evaluation to determine whether validation is required and the level of validation required”

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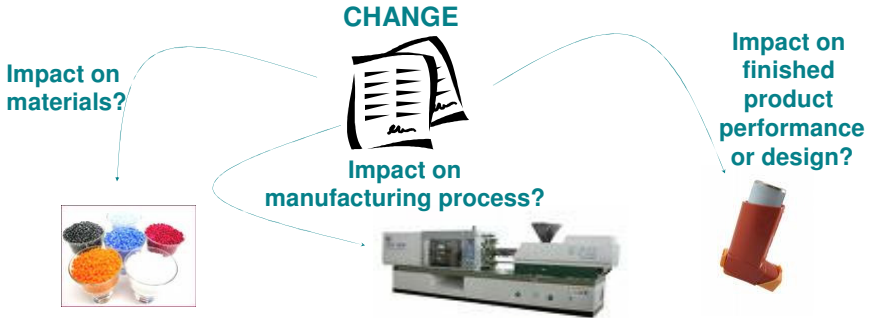
IPAC-RS Guideline – Key Points

- **Change Control Procedures**
 - OINDP suppliers should establish written procedures for the:
 - identification,
 - documentation,
 - appropriate review, and
 - approval of changes affecting the quality of products and/or processes, equipment, systems and methods
 - Procedures should ensure changes will be implemented in a controlled manner
 - An independent group (i.e., Quality Unit), should have responsibility and authority for management/approval of changes



IPAC-RS Guideline – Key Points

- **Change Evaluation:**
 - Anticipated changes should be evaluated to determine impact on component quality and validation status





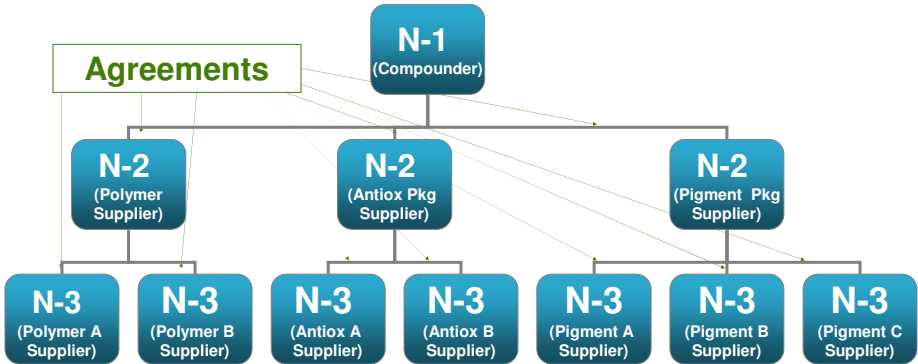
IPAC-RS Guideline – Key Points

- **Partnership between Supplier/Pharma**
 - Customers and suppliers should agree on notification of changes
 - Customers and suppliers should agree on approval of changes
 - Terms agreed should be reflected in a supply agreement and/or quality agreement



IPAC-RS Guideline – Key Points

- **Suppliers should ensure that THEIR suppliers have adequate change control programs in place**





What is a Change?

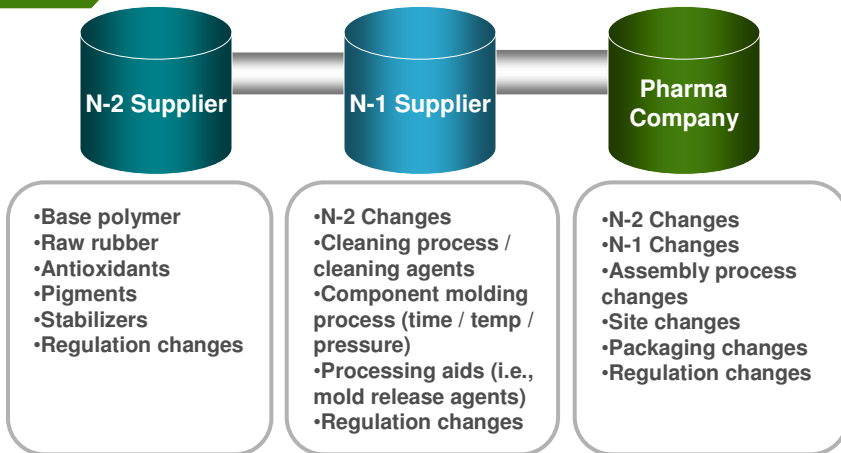
- What constitutes a change varies from product to product and from company to company and includes:
 - Product changes (materials, manufacturing, specification)
 - Facility changes (those which impact product or quality)
 - Documentation changes to controlled documents (batch records, methods, etc)
- **Important!**
 - Meeting product specification does not mean that the product has not changed and has not been impacted.

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Supply Chain Linkages: Sources of change



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Impact of Changes

- **Changes can happen at any time during a product's lifecycle**
- **The impact of the change needs to be balanced against the cost of making the change (safety, time and money)**
- **Impact of change may require amendments to registered details**

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Importance of Change Control

- OINDP products are considered “high risk” due to the pulmonary route of administration
- OINDP devices are comprised of multiple components typically fabricated from different materials
 - Changes to these components may impact product performance and dose delivery

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Consequences of Unapproved/Unanticipated Changes

- **Best Case:** unapproved change is detected by receipt/incoming by customer
 - Results in supplier investigation (time/resources); material scrap; customer production delays
- **Worst Case:** unapproved changes to material/component causes final product failure in the field
 - Customer (OINDP Mfg) **RECALLS** the product
 - Time must be spent on investigations to determine the cause and implement corrective actions

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Change Agreements

- **For each product, the supplier and pharmaceutical company need to decide on what changes need prior approval**
 - Define what constitutes a change
 - Define which types of changes require notification/approval
 - Define how changes will be implemented
- **Suppliers should have agreements with their suppliers regarding changes**

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No prior approval

- The following are examples of changes that wouldn't normally require prior approval:
 - Editorial changes to procedures (typographical, grammatical/presentation updates or which provide additional detail/clarity in describing an existing established practice)
 - Environmental control changes which do not affect the processes or product
 - Operator safety changes which do not affect the process or the product.
 - Like-for-like changes of equipment or parts.
 - Routine and preventive maintenance updates that do not have an associated change to an operating parameter.
 - Changes to procedures that do not describe activities directly involved in the manufacture, packaging, analysis or release of product (i.e., training or document control procedure changes).
- **If in doubt, consult with customer!**

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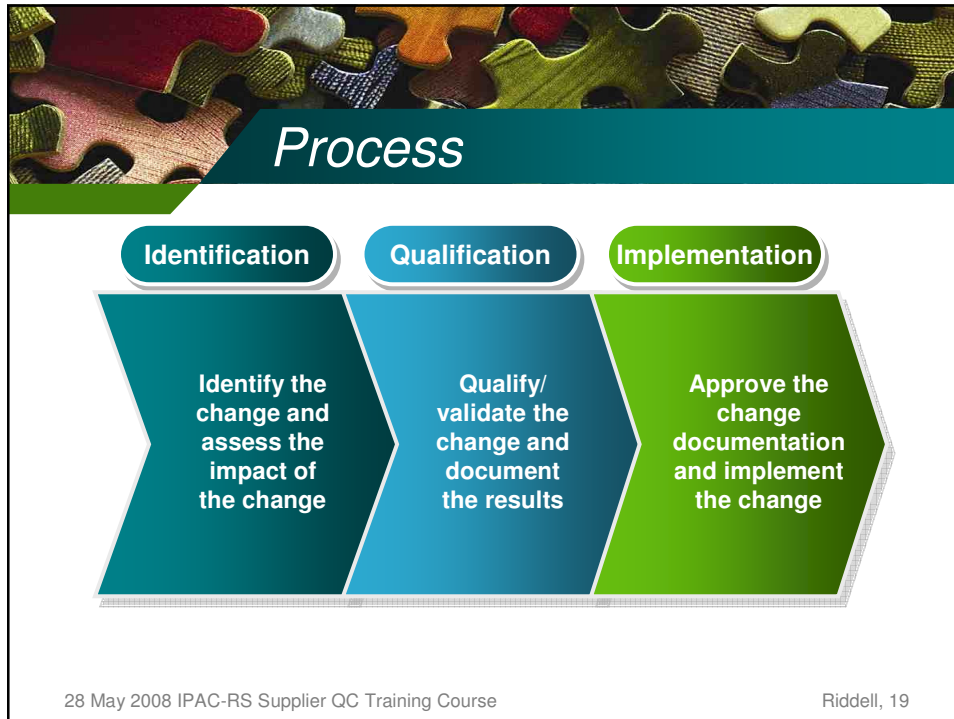


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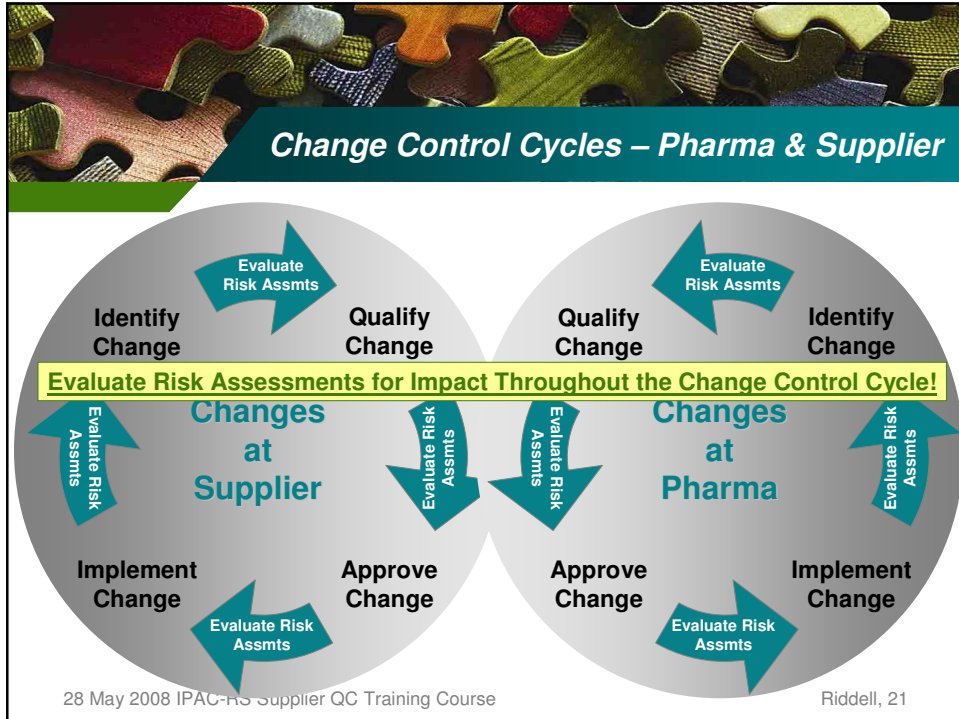
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- Process**
- **Identify Change**
 - Perform and document risk assessment to determine whether change should be made
 - Determine whether change requires notification/approval
 - **Document change proposal and studies to perform which will support change**
 - Gain agreement with pharma/customer if required
 - **Execute studies to qualify/justify change**
 - **Review results from studies justifying change**
 - Perform risk assessment to determine whether the studies adequately justify the change
 - **Document change along with justification documents**
 - **Approve and Implement change**
 - **Update supplier and customer risk assessments to determine whether the change introduces any additional risks to the product**
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- Conclusions**
- Changes must be formally documented and approved via a change control process
 - Change Agreements need to be in place between supplier and pharma
 - Need to evaluate risk assessments throughout change control process
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Questions?



Thank you!