Change Management: A necessary Evil or a Powerful Tool?

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Regulatory Requirements

Health Canada – GMP guide for drug products (GUI-0001)

- Establish a **change control system** to provide for ongoing process optimization and continuing state of control.
- Evaluate and approve planned **changes** before implementing them.
- Regulatory notification and approval of **changes** must be done as required.
- Validate critical steps of manufacturing processes and key **changes** to the process
- Validate **changes** to production processes, systems, equipment, materials or suppliers that may affect product quality and/or process reproducibility before implementing them.
- Quality must document, evaluate and approve all **changes**, identifying them with the appropriate effective date.

Regulatory Requirements

Health Canada – GMP guide for drug products (GUI-0001)

- Vendor must inform drug fabricator of any **changes** in the processing or specifications of raw material
- Annual Product Quality Reviews – must include all **changes** carried out to the process, analytical method, raw materials, packaging materials or critical suppliers
- Agreement – must include a requirement for **changes** to be governed by a **change control system** and approved by the contract giver and contact acceptor
- SOPs – must establish a formal system to review and approved **changes** to SOPs

Regulatory Requirements

FDA – 21 CFR Part 211 – cGMP for Finished Pharmaceuticals

- There shall be written procedures for production and process control, including any **changes**, shall be drafted, reviewed, and approved.
- **Changes** in master production and control records shall be appropriately controlled by authorized personnel.
- Specifications, standards, sampling plans, test procedures shall be drafted, reviewed and approved by quality, including **changes** in such documents.
- Must provide agency with notification of **changes** in manufacturing, packaging and labeling.

What is Change Control?

A written procedure that describes the action to be taken if a change is proposed

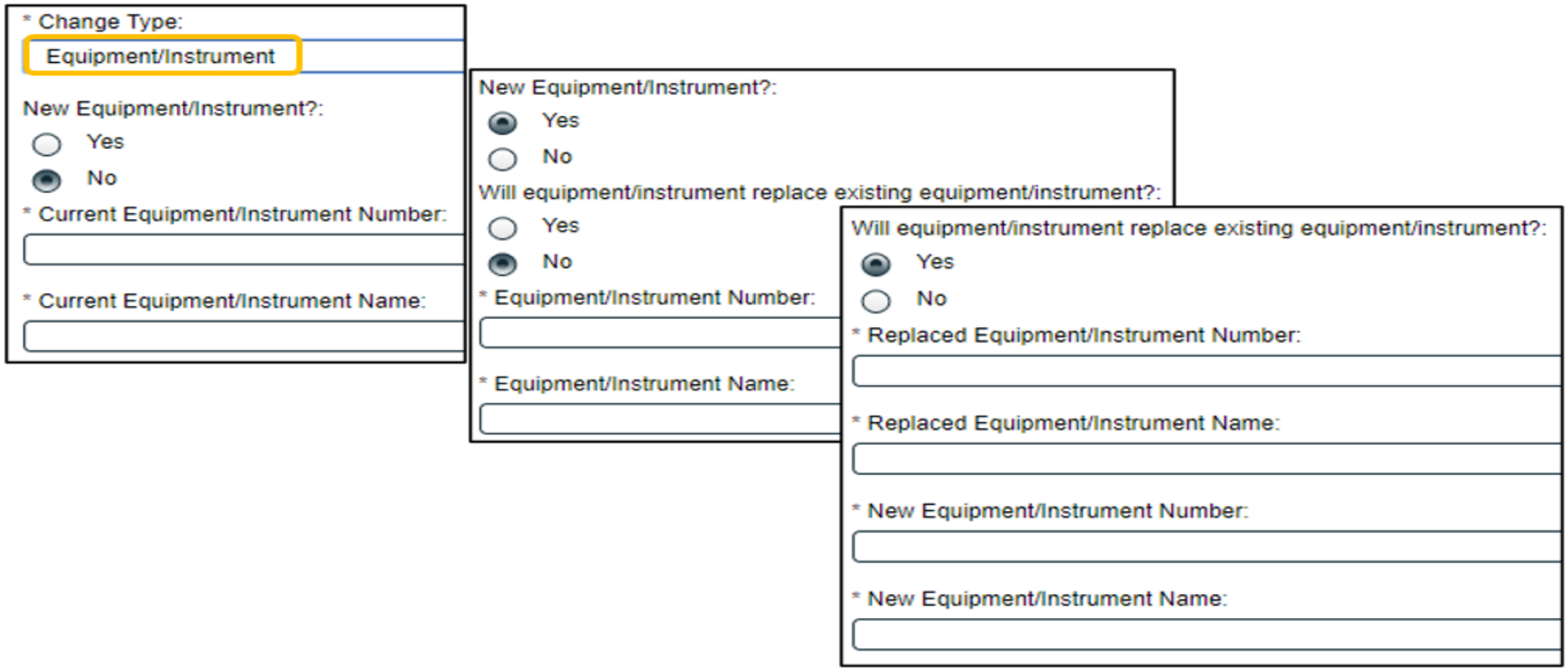
a) to facilities, materials, equipment, and / or processes used in the fabrication, packaging, and testing of drugs, or
b) that may affect the operation of the quality or support system.

Paper or Electronic?

Change Control Request

- Unique document number (ex: CC-2026-001)
- Change Type: Process, Material/Supply, Supplier, Equipment/Instrument, Facility, Utility, Computer System, Support System, Quality System Documentation, Method, Specification, Other
- Description of Proposed Change
- Justification / Reason for Change and Proposed Implementation Date
- Impact of Change & Assessments
- Change Classification
- Secondary Tasks (Actions)
- Effectiveness Verification

Example of Change Type - Equipment



Impact of Change & Assessments

The proposed change must be assessed by

- Regulatory Affairs - Submission / Drug Establishment License
- Validation – VMP / Qualification / Revalidation / Cleaning
- Quality Control – Nitrosamine / Elemental Impurities / Residual Solvents / Stability
- Quality Assurance – SOP / Documentation / Quality Agreement / Audit
- Engineering – Calibration / PM
- Multi-Disciplinary Team - FMEA

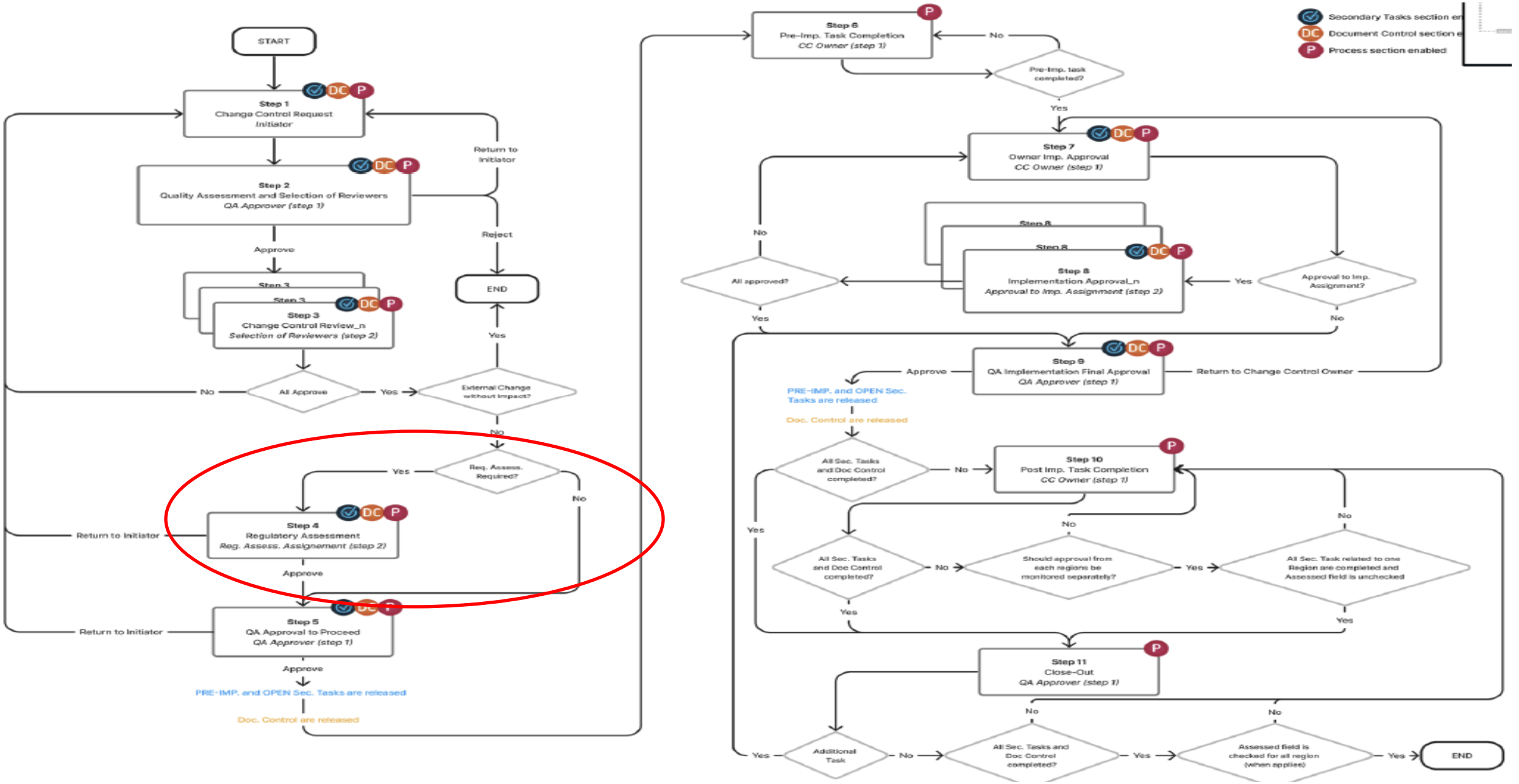
Regulatory Impacts

The assessment by Regulatory Affairs (RA) is very important.

The RA team must be involved to determine if there's an impact on the product submissions, the Drug Establishment License (DEL) and identify the regulatory approval delays, before the change can be implemented. This may have an impact on the time and cost of the change.

It may be necessary for senior management to get involved in NDS, SNDS, and ANDS changes that include time delays and extra cost

Consult Health Canada's Guidance document Post-Notice of Compliance (NOC) Changes to evaluate the risk level of the change as well as the supporting data required.


START
Step 1
Change Control Request
Initiator
Step 2
Quality Assessment and Selection of Reviewers
QA Approver (step 1)
Return to Initiator
Reject
Approve
END
Step 3
Change Control Review_n
Selection of Reviewers (step 2)
All Approve
No
Yes
External Change without Impact?
Yes
No
Req. Assess. Required?
Yes
No
Step 4
Regulatory Assessment
Reg. Assess. Assignement (step 2)
Return to Initiator
Approve
Step 5
QA Approval to Proceed
QA Approver (step 1)
Return to Initiator
Approve
PRE-IMP. and OPEN Sec. Tasks are released
Doc. Control are released
Step 6
Pre-Imp. Task Completion
CC Owner (step 1)
No
Pre-Imp. task completed?
Yes
Step 7
Owner Imp. Approval
CC Owner (step 1)
No
All approved?
Step 8
Implementation Approval_n
Approval to Imp. Assignment (step 2)
Yes
Approval to Imp. Assignment?
No
Yes
Step 9
QA Implementation Final Approval
QA Approver (step 1)
Approve
Return to Change Control Owner
PRE-IMP. and OPEN Sec. Tasks are released
Doc. Control are released
All Sec. Tasks and Doc Control completed?
No
Step 10
Post Imp. Task Completion
CC Owner (step 1)
Yes
No
All Sec. Tasks and Doc Control completed?
No
Should approval from each regions be monitored separately?
Yes
All Sec. Task related to one Region are completed and Assessed field is unchecked
Yes
Yes
Step 11
Close-Out
QA Approver (step 1)
No
No
Yes
Additional Task
No
All Sec. Tasks and Doc Control completed?
Yes
Assessed field is checked for all region (when applies)
Yes
END
Secondary Tasks section en
Document Control section e
Process section enabled

Change Classification

Minor: The proposed change is assessed to not have an impact on the validated state, stability and/or regulatory submission of the product / process / equipment and on the quality, safety, efficacy and integrity of the product.

Major: The proposed change is assessed to have an impact on the validated state, stability and/or regulatory submission of the product / process / equipment or on the quality, safety, efficacy and integrity of the product.

Examples of Secondary Tasks (Actions)

- Create (or revise) SOP for use, cleaning, calibration of equipment
- Revise Master Batch Record (MBR)
- Train appropriate personnel on SOP and MBR
- Create calibration sheet
- Add equipment to calibration schedule
- Create preventive maintenance (PM) sheet
- Add equipment to PM schedule
- Assess cleaning validation matrix
- Determine equipment clean and dirty hold times
- Assess process validation impact

Effectiveness Verification

- DO NOT forget to have an effectiveness verification for the proposed change.
- An effectiveness plan is implemented to ensure that actions identified are efficient and have not impacted other systems negatively.
- A justification must be provided if an effectiveness plan is not provided.

Change Control Approval to Proceed

Once the change description, related tasks, assessments, implementation dates and effectiveness plan have been defined and accepted, the change can be approved by **Quality Assurance** (QA) to proceed.

Implementation Phase

Tasks defined are carried out and completed within identified implementation date. Proof of completion is attached (linked) to the Change.

Implementation dates may be extended, however they must be documented, justified and approved by QA with a new due date.

When all tasks are completed, the effectiveness verification can be performed.

- If the change is deemed to be NOT effective – A deviation is initiated and the impacts are assessed.

Change Control Final Approval

Your Change Control system (paper or electronic) should allow you to:

- Add additional tasks at any time during the implementation of the Change
- Reassign a task to another person
- Extend implementation dates (with justification)
- Request proof of completion or additional information
- Cancel a task or the entire Change

Once all tasks and the effectiveness verification have been completed, the Change is reviewed for completeness by QA and a final approval decision is made.

Powerful Tool?

With the support of other quality systems, such as Annual Quality Product Reviews (APQR) and Quality Management System Reviews (QMSR), and management elements, such as Key Performance Indicators (KPIs), we can **detect potential trends** from **cumulative changes** to products, processes, methods, material and equipment.

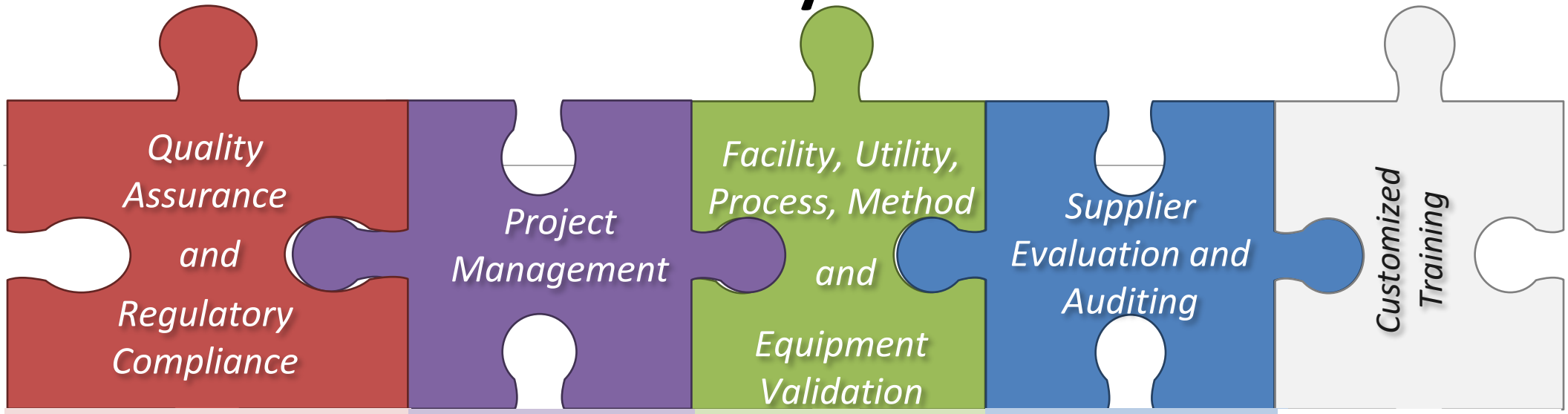
Once a negative trend is detected, then a CAPA is identified to continuously improve the systems and processes.

Conclusion

The Change Control process, often seen as a necessary evil, can become highly effective when using SOLABS QM10:

- Users are able to search for, view and track changes at any stage
- Documents can be filtered by individual, department, dates, etc.
- Email notifications and reminders are sent to the responsible parties (review, approval, implementation, etc.)
- Summary Reports and Graphs for APQR, QMSR, KPIs
- Audit Trails with details of every step in the process

Services Provided by GMP Consultants



AQPR, Batch Review & Release, CAPA, Change Control, Data Integrity, DEL, Deviations, GDP, Mock Inspections, Quality Manual, Regulatory Submissions, Risk Assessments, SOP, Stability Program, etc.

Liaison w/ 3PL, Continuous Imp., Tech. Transfer, Prod. Launches

VMP, URS, FAT, SAT, IQ, OQ, PQ, Protocol Writing and Execution, Issuing Reports

Supplier Assessments, Quality Agreements, Audits, etc.

GMP Training, GDP, Human Errors, Investigation techniques, Inspection Readiness, etc.

Questions?

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