Change Management and Equipment Qualification

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Change - Module Outcomes

On completion of this module the participant should be able to:

- Interpret cGMP requirements for change management
- Develop a Change Management SOP
- Describe the GMP rules for Prospective Equipment Qualification
- Describe the GMP rules for re-validation of Equipment
- Assess the compliance of existing “legacy” equipment
Module Topics

- GMP Rules for Change
- Change Management Systems
- Equipment Qualification
  - Prospective
  - Re-qualification
  - Assessing legacy Equipment

Is Change Management a QA Responsibility?

- Every Department is involved in Change Management
- Production, Regulatory Affairs, Development, Engineering, Quality Control IT as well as Quality Assurance.
- Many regulatory citations and product recalls originate in poor change control practices.
- Change control is one of the hardest QS elements to manage!
Some Lessons Learnt

- Manufacturer of sterile saline changes the bottle seal (initiated by purchasing) - alters the heat penetration during autoclaving ..... Unsterile units manufactured ....... leading to deaths.

- Manufacturer used a different granulation process for sustained release tablet - particle size different and tablet fast releases - causes uncontrolled rapid release of active ..... Heart attacks result.

- Manufacturer substitutes a new software program without validation – update causes product formulation error leading to recall.

Document Change and Change Management

- **Document Change** and **Change Management** are NOT the same thing.

- A document change can be due to
  - Editorial change (Minor)
  - As a final step in Change Control – an action as a result of an implemented change

- Change control is much more than simple document update.
Why Have Change Control Procedures?

- Maintain compliance to the Marketing Authorisation
- Assess whether regulatory approval is required
- Ensure that any changes that are made preserve product quality (ISPE)
- Co-ordinate changes across all impacted groups
- Maintain currency of procedures and instructions
- Stay in control and within compliance

Who is Involved in Change Control?

**Regulatory Affairs**
- Checking the change and advising any regulatory impact
- Liaise with Regulators
- Submission of Requests and Documents

**Quality Assurance**
- Classifying the change request
- Assessing impact of change - level
- Forwarding requests to the Technical Committee
- Managing the change control procedure - (see co-ordinator)
- Chairing the Technical (Change Control) Committee;
- Monitoring that change actions are implemented

**Technical (Change Control) Committee**
- Meeting regularly to review all major change requests;
- Review and approval of all major changes;
- Liaising with regulatory authorities, where required.

**Change Co-ordinator/Specialist**
- Co-ordinating requests
- Organising approvals
- Reviewing change plans
- Ensuring validation is undertaken
- Post change verification of implementation

**Document Administrator/Control**
- Maintaining the change request register;
- Filing completed change reports.
Change control scope includes, but is not limited to

- Product Formulation
- Manufacturers of Active Pharmaceutical Ingredients (APIs)
- Batch scale up or down beyond +/-10%
- Manufacturing and packaging process steps (CPP/CQA impact)
- Cleaning and sanitising programs
- Labelling and packaging components;
- Critical starting materials;
- Direct impact equipment;
- Direct impact services or facility;
- Laboratory test methods and specifications (for both starting materials and finished products);
- Stability program, storage conditions and expiration dating;
- Sub-contract facilities or operations.

Examples of Change Control Scope

<table>
<thead>
<tr>
<th>Product Changes</th>
<th>Process Changes</th>
<th>QC Changes</th>
<th>Equipment Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation and Container/Closure</td>
<td>Validated Steps</td>
<td>Critical Quality Attributes (CQAs)</td>
<td>Processing Equipment</td>
</tr>
<tr>
<td>Starting Materials API Source</td>
<td>Critical Process Parameters (CPPs)</td>
<td>Critical Material Attributes (CMAs)</td>
<td>Pharmaceutical Services (Water, Gas, HVAC)</td>
</tr>
<tr>
<td>Printed Matter</td>
<td>Batch Scale Up/ Down</td>
<td>Test Methods and Specification</td>
<td>GMP Facility</td>
</tr>
<tr>
<td>Indications Market Claims Use Directions</td>
<td>Cleaning Sanitation Sterilisation</td>
<td>Laboratory Instruments</td>
<td>Critical GMP Related Computers</td>
</tr>
</tbody>
</table>
What are CQAs, CPPs and CMAs

Critical Quality Attribute (CQA)
- A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

Critical Process Parameter (CPP)
- A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

Critical Starting Material (CSM or CMA)
- Critical Quality Attribute(s) of a Starting Material

Significance of CQAs, CPPs and CMAs

- Critical means the parameter or attribute has a potentially significant impact on product quality, safety, purity, identify or strength.
- Therefore ANY change to a CQA, CPP or CMA has a potentially significant impact
- Therefore it should be treated as a major change and should be validated.

- Its important to know and understand your CQAs, CPPs and CMAs
Regulatory Agency Requirements and Rules for Change Management

- Regulator is a key stakeholder in change since they have approved the marketing of the product.
- MUST manufacture in compliance with the Marketing Authorisation, but able to supplement
- Significant penalties apply for non-compliance, including criminal sanctions in the USA

Regulatory Change Requirements

- Regulatory Agencies all have explicit requirements for either prior approval, notification of intention or “self assessable” (annual reporting)
- Rules are different for Rx, OTC, CM and device products
- Common requirement is that validation of change needs to be assessed per GMP rules.
- Many Regulatory Agencies have change guidance eg TGA (Appendix 12) and FDA (SUPAC)
FDA and (Post Approval) Change Control

Prior Approval Supplement - FDA Evaluation (Major/Significant)
- Must wait for FDA approval (3 - 18 months)
- May initiate an inspection
- May submit a “comparability protocols” for FDA approval

Notification of “Changes Being Effected” (Moderate)
- File notification of intention to change
- Company is fully responsible for control of changes/validation
- wait 30 - 60 days then change if no response

Annual Report System (Minor Change)
- Effect change without reference to FDA
- Company is fully responsible for control of changes/validation
- Record in the Annual Report

Possible Change Control Levels

**Minor Change**
The change is unlikely to have a detectable impact on critical attributes of the product or process. Change is procedural or editorial in nature only.

**Moderate Change**
The change could or may have a significant impact on critical attributes of the product or process.

**Major Change**
Change is likely to or will have a significant impact on critical attributes of the product or process.
Change and Risk Assessment

- Any planned changes to the facilities, equipment, utilities and processes, which may affect the quality of the product, should be formally documented and the impact on the validated status or control strategy assessed. (EU cGMP – Annex 15)

- The likely impact of the change of facilities, systems and equipment on the product should be evaluated, including risk analysis.

- The need for, and the extent of, requalification and re-validation should be determined.
Make up of Change Control Committee

The Change Control Committee (CCC) is made up from persons representing some or all of the following:

- Regulatory Affairs
- Quality Assurance/Authorised Person
- Technical Services (Validation / Stability)
- Production
- Development*
- Engineering*
- Laboratory*
- IT*

* As needed

- CCC generally meets monthly to specifically look at major changes
Change Request Form

1. Description and reason for change - tracking #
2. Initial review of Change Request - “Impact/Risk assessment”
3. Classification of Change - Major or Minor
4. Proposed change action (if Major)
   - Plan or protocol
   - Stability programs
   - Validation
   - Verification of equivalency (for products)
5. Documents required to be updated (Major and Minor)
6. Post change Verification of Change Impact (Major)
Impact Assessment and Classification

Impact / Risk Assessment (circle whether the change is major or minor)

<table>
<thead>
<tr>
<th>Minor Change/Low impact</th>
<th>An impact or risk assessment is generally not expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Change/High Impact</td>
<td>A impact/risk assessment may be required if the change involves a change to a CPP, CQA or CSM or is complex in nature.</td>
</tr>
<tr>
<td>Regulatory Change? Yes / No</td>
<td>Determine if the proposed change must be approved or notified to a regulatory agency before implementation.</td>
</tr>
<tr>
<td>If Yes the rate as Major/High Impact</td>
<td></td>
</tr>
<tr>
<td>Impact / Risk assessment required? Yes/No</td>
<td></td>
</tr>
<tr>
<td>Approved by (QA Representative)</td>
<td></td>
</tr>
</tbody>
</table>

Documents impacted

<table>
<thead>
<tr>
<th>Documents Affected by the Change:</th>
<th>Document No.</th>
<th>Responsibility</th>
<th>Target Date</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

SECTION 3 – Change Management Plan

Regulatory Agency Approval required? Yes / No –

If Yes, indicate date of approval Date: ..................

<table>
<thead>
<tr>
<th>Proposed Action: Mandatory for Major changes and optional for Minor changes</th>
<th>Responsibility</th>
<th>Target Date</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<td>3.</td>
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<tr>
<td>4.</td>
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</tr>
</tbody>
</table>

Is verification of the effectiveness of the implemented change required? Yes / No By:

<table>
<thead>
<tr>
<th>Actual Action Implemented (if different from above):</th>
<th>Responsibility</th>
<th>Target Date</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
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</tr>
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</table>

Change Implementation Checked and Closed out by: Date:
Documents Impacted by Change

- Product Documents;
  - Registration Dossier / Regulatory Filing
  - Master Manufacture / Packaging Instructions;
  - Protocols or Methods;
  - Specifications;
- Records, Work Instructions, Standard Operating Procedures;
- Engineering Drawings & P&IDs;
- Contract Agreements;
- Validation Documentation

Different Change Systems - Engineering Changes

Document Control as a Result of Engineering Change

- Update Drawings and P&IDs
- Update Manuals
- Update Operator Instructions
- Review Safety
- Review Maintenance and Calibration programs
- Review IQ/ OQ programs for major changes
Equipment Changes - Impact Assessment Strategy

- Product Contact Equipment?
- Controls a CPP or a CQA?
- Used in CIP/SIP or Sterilization?
- Failure or alarm has direct effect on product quality?
- Preserves product quality?
- Etc……

Formulation Change

New Product?
- Regulatory Approval
- Validation Expected

Active Ingredient
- Regulatory Review
- Change to CQA/CSM?
- Minor change

Excipient
- Regulatory Approval
- Validation
Changes to Process Conditions (From FDA SUPAC - Immediate Release Solid Oral Dose)

<table>
<thead>
<tr>
<th>Process Change</th>
<th>Significance</th>
<th>Approval Level</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 Changes</td>
<td>Level 3</td>
<td>Prior Approval</td>
<td>Expected</td>
</tr>
<tr>
<td>Level 2 Changes</td>
<td>Level 2</td>
<td>Regulatory Affairs</td>
<td>QA Decides per GMP</td>
</tr>
<tr>
<td>Level 3 Changes</td>
<td>Level 1</td>
<td>QA Decision</td>
<td>Not expected</td>
</tr>
</tbody>
</table>

Changes in Batch Size - (Scale Up / Scale Down)

- Post-approval changes in the size of a batch from the registered details requires assessment of change impact.
- All scale-up changes should be properly validated and where required submissions to regulatory agencies.
- The dose form has a large input to the impact eg.
  - Biological products (are at highest risk of impact)
  - Sterile products
  - Topicals Suspensions
  - Tablets and capsules (microdose/narrow therapeutic range)
  - Other oral dry products
  - Liquids solutions (are at lowest risk of impact)
Comparability Protocols - FDA Initiative

- A comparability protocol is a detailed, written plan for assessing the effect of specific CMC (Chemistry and Manufacturing Control) changes in the identity, strength, quality, purity, and potency of a specific drug product as these factors relate to the safety and effectiveness of the product.
- Describes the changes that are covered under the protocol and specifies:
  - the tests and studies that will be performed
  - including the analytical procedures that will be used
  - and acceptance criteria that will be achieved
- To demonstrate that specified CMC changes do not adversely affect the product.
- Protocols are to be submitted to FDA prior to commencing the change.

Changes to Pharmacopeias

- Expected to keep current with monographs
- Generally Reg. Affairs or QA take this responsibility
- Considered a minor change, except if
  - A RM is a critical material
  - Change in testing technology – new instrumentation
  - Change to a Finished Product Specification
- Generally involves document only change:
  - Specifications
  - Test Methods
In Summary
Change Control (CC) Systems

- Change Control is a cross-functional responsibility
- Must have a change control program (SOP/Change Request) and technical review system
- Identify & document what are Major and Minor changes in the SOP
- Assess “Risk /Impact” and verify implementation post change
- Focus on CPPs and CQA impacted changes
- Must ensures practices match drug application commitment per Marketing Authorisation

Qualification, Re-qualification and Assessment of Legacy Equipment
The Impact “Spectrum”

How we design and choose to use these systems can affect their impact!

Direct Impact equipment associated with a CPP or CQA is higher risk.

Impact Assessment - Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Impact</td>
<td>Water purification systems, product pumps and vessels, product sieves, product temperature control systems, product mixing systems.</td>
</tr>
<tr>
<td>In-direct Impact</td>
<td>Coating pan drive motors, temperature monitoring probes, instrument air</td>
</tr>
<tr>
<td>No Impact</td>
<td>Plant cooling water</td>
</tr>
</tbody>
</table>
System Impact Categories

- **Direct Impact System**
  - System in direct contact with product or contains one or more critical components

- **Indirect Impact Equipment or System**
  - System that contains no critical components, but may support a direct impact system.

- **No Impact Equipment or System**
  - No contact with product. Presents no risk to product or process.

**Critical Component:**
Component of equipment or service whose failure may pose an unacceptable risk to product quality, e.g., temperature controlling probe in an autoclave.

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**Decision Matrix**
Based on Risk (Impact / Complexity)

<table>
<thead>
<tr>
<th>Criticality of System</th>
<th>Complexity of System</th>
<th>Initial Qualification Required?</th>
<th>Re - Qualification Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Impact</td>
<td>Simple / Off the shelf</td>
<td>Yes IQ/OQ/PQ</td>
<td>Assess the need for re-qualification</td>
</tr>
<tr>
<td></td>
<td>Complex/Novel</td>
<td>Yes DQ/IQ/OQ/PQ</td>
<td>Periodic Re-Qualification Expected</td>
</tr>
<tr>
<td>Indirect Impact</td>
<td>Simple / Off the shelf</td>
<td>Commission Only</td>
<td>Not expected M &amp; C Only</td>
</tr>
<tr>
<td></td>
<td>Complex/Novel</td>
<td>Maybe IQ/OQ</td>
<td>Assess Reliability Only</td>
</tr>
<tr>
<td>No Impact</td>
<td>Simple / Off the shelf</td>
<td>Commission Only</td>
<td>Not expected Maintenance Only</td>
</tr>
<tr>
<td></td>
<td>Complex/Novel</td>
<td>Commission Only</td>
<td>Not expected Maintenance Only</td>
</tr>
</tbody>
</table>
Traditional V Model
(Applied to Direct Impact Systems)

- (URS) User Requirements Specification
- Functional Specification
- Design Specification
- PQ
- OQ
- IQ
- FAT, SAT, Commission
- Commissioning

Risk Based Qualification - 21st Century

- The PQ is a true test of acceptability ... the URS is therefore the most important document
- If PQ is the most important (replicate the tests to provide consistency) the IQ/OQ are sub-ordinate (conduct test only once)
- Activities that are a paperwork exercise should be eliminated/ Only data which serves a useful purpose should be collected.
- Different types of equipment and systems (custom, COTS, simple, complex etc...) require different levels of attention
- Supplier standard inspection and test documents can be used and not replicated by the company

ISPE A White Paper on Risk-Based Qualification for the 21st Century 2005
Qualification and Validation Principles

- It is a requirement of GMP that manufacturers identify what validation work is needed to prove control of the critical aspects of their particular operations.

- Significant changes to the facilities, the equipment and the processes, which may affect the quality of the product, should be validated.

- “A risk assessment approach should be used to determine the scope and extent of validation.”

PIC/S Code of GMP- Annex 15 Clause 1

What the PICs Rules Say – Re - Validation – Annex 15

- 45. Facilities, systems, equipment and processes, including cleaning, should be periodically evaluated to confirm that they remain valid.

- Where no significant changes have been made to the validated status, a review with evidence that facilities, systems, equipment and processes meet the prescribed requirements fulfills the need for revalidation.
Rationale for Qualification Review

- undertaken where it is expected/assumed that there has been little or no change in the system, which would affect the validated state.
- Above assumption is verified by a historical, retrospective review of key data sources, combined with a physical inspection of the system.
- the review would identify any changes relative to the IQ/OQ/PQ documentation and report these with recommendation to management.

Aim of Equipment Reviews

- original documentation is formally reviewed in light of the changes in regulatory and industry expectation;
- the aging process has not adversely affected the system’s “fitness for purpose” as defined in the original validation documentation;
- minor gaps in the original documentation or in the system identified as part of the review of the system are addressed as part of the review process;
- significant changes to systems or components, which have been initiated outside of the change control process, are brought to the attention of Quality Assurance and are addressed as part of the change control procedure.
**Recommended Approach**

- Identify candidate process lines/unit operations on a priority basis.
- Identify within the selected process line the critical equipment.
- Identify which items are used for in-process testing only and ensure they are calibrated.
- Conduct a retrospective audit using modification of checklist “Audit Checklist for Equipment Retrospective Review”, for each item of equipment commencing with the highest priority unit operation.
- Ensure all specific CPPs are reviewed – modify the checklist accordingly.
- The need for IQ and OQ re-qualification is based on the outcome of the assessment.
- Obtain QA Approval of report and decision.

**Priority Considerations**

- Product/Process Line higher Risk to Consumer Health
- GMP criticality of the equipment or service – level of control required
- Historical performance of the equipment (control, reliability, breakdowns etc.)
- Production utilisation importance (high use etc.)
**Decision Tree on What to Do**

1. **Direct Impact?**
   - Yes: **Existing IQ/OQ Package exists?**
     - Yes: **Is it current and complete?**
       - Yes: **Agree Next Review**
       - No: **Update Re-Val Schedule**
     - No: **Determine Priority and Timeframe**
   - No: **Assess Equipment via Checklist**
     - Yes: **Remediation Task List**
     - No: **Remediation Task List**

2. **Requires Re-Val?**
   - Yes: **Develop IQ/OQ Protocol**
   - No: **Execute Protocol**

**General Acceptance Criteria for Assessment**

- meets the audit checklist criteria including specific critical variables control
- P&IDs & Schematics are current and reflect the system as built
- calibrated and maintained to written programs
- operated to written procedures
- sequences for PLC and other control mechanisms are verified
- generally meets current GMPs for construction, cleanability and surface finishes
- **Critical process parameters defined and in control**
# Assessment Checklist

<table>
<thead>
<tr>
<th>#</th>
<th>Item and Attribute</th>
<th>OK ?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Item Drawings, Procedures and Manuals Review</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;IDs &amp; schematics all present, current-match as built condition ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>SOP for operation published ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>SOP for cleaning and sanitation published ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>SOPs for maintenance and calibration published ?</td>
<td>✔</td>
</tr>
<tr>
<td>2</td>
<td><strong>Automated (Control) Systems Review</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All PLC controllers verified as functional ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>PLC controller sequence verified/documentated ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>SCADA or equivalent interfaces in place ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>SCADA or equivalent interfaces verified ?</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>Automated instructions secured and retrievable ?</td>
<td>✔</td>
</tr>
</tbody>
</table>

## Additional Areas for Assessments

<table>
<thead>
<tr>
<th>#</th>
<th>Item and Attribute</th>
<th>OK ?</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td><strong>Physical Inspection / Construction</strong></td>
<td>✔</td>
</tr>
<tr>
<td>4</td>
<td><strong>Monitoring Instruments</strong></td>
<td>✔</td>
</tr>
<tr>
<td>5</td>
<td><strong>Operation &amp; Records</strong></td>
<td>✔</td>
</tr>
<tr>
<td>6</td>
<td><strong>Preventative Maintenance and Safety Programs</strong></td>
<td>✔</td>
</tr>
<tr>
<td>7</td>
<td><strong>Assessment of any Critical Process Parameter(s)</strong></td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>Summary of Conditions and Recommendation</td>
<td>✔</td>
</tr>
<tr>
<td></td>
<td>Remediations / Corrective Action List</td>
<td>✔</td>
</tr>
<tr>
<td>#</td>
<td><strong>Remediation without IQ/OQ</strong></td>
<td>By/ when</td>
</tr>
<tr>
<td></td>
<td><strong>Remediation with IQ/OQ</strong></td>
<td>✔</td>
</tr>
</tbody>
</table>

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What historical data to look at

- Engineering data:
- Preventative maintenance program / records in place and actioned
- Repair maintenance history is logged
- drawings generally and specifically registered P&IDs & Schematics,
- Calibration data for CPPs
- statutory documentation / certificates / safety etc,

Quality Assurance data such as audit and non – conformance reports
- change control records,
- Physical inspection:

Physical Inspection Includes

- “fit for purpose” against in-house and statutory regulations,
- review registered P&IDs & Schematics against actual installation,
- Product contact surfaces are inert – no pitting rust discolouration, staining etc
- Connected services are integral – no leaks, drips etc.
- Product contact components are in good repair eg. dyes and punches, pumps etc.
- Equipment seals are in good order and are being maintained
- Filters are on a change program and integral
- Measuring instruments are working and calibrated
- Piping is labeled correctly
- Lubricants are documented and used
- Spare parts are available
Outcomes from Reviews

No changes noted, with the equipment in good operational and validated condition:
- report to be approved and filed with the original validation documentation,
- the review date is reset to the date of approval of the completion report,

Minor changes or shortfalls in equipment or documentation which do not affect the operation or validated state of the equipment [e.g., minor non-critical modification not captured on P&IDs]:
- provide a deficiencies list as part of the report,
- carry out rectification works identified in the deficiency list via the appropriate quality systems [e.g., change control] where applicable,
- report and closed out deficiencies list to be approved and filed with the original validation documentation, and
- reset the review date to the approval date of the completion report,

Significant changes in equipment or documentation which potentially affect the validated status, where these have not been captured by a validation exercise as part of the change control procedure:
- complete the report with the actions agreed by Quality Assurance and the system owner and file with the original validation documentation.
- provide a deficiency list as part of the report, which is to be actioned before sign-off of the review.
- raise the issue with the relevant validation group and with Quality Assurance to determine the steps to meet the relevant compliance requirements.
- The review date must not be reset where the review has triggered a revalidation exercise. This will occur out of the qualification exercise.

The decision to formally re-qualify equipment is based on the outcomes
Re-Validation Timeframes

- No hard and fast GMP rule – risk assessment decision

- Some examples that industry use:
  - Critical Sterile Products Equipment – mandated annual PQ/PV but no mandated IQ/OQ
  - Direct Impact Equipment
    - Higher risk equipment with CPP attached – 3 years
    - Medium risk – 5 years
  - Indirect Impact Equipment - > 5 years maybe 10
  - No Impact Equipment – not relevant

Suggested Risk Based Review Periods

3 years for:
- sterilisation equipment used for process equipment and components, and for terminal sterilisation of products,
- lyophilization equipment used for the preparation of raw materials and completion of finished product, and

5 years for:
- equipment and services rated as quality critical with direct product contact,
- non-critical systems which may be subjected to more frequent change, or,
- system with a short operating life, and

10 years for:
- quality critical systems with indirect product exposure,
- systems which are historically stable, with minimal exposure to change.