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White Paper

Introduction to Good Process Record Management (GxP)

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Document History

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Good Electronic Record Management

Introduction

The regulatory requirements concerning systems and equipment involved in GxP relevant processes are not only limited to the aspects regarding their qualification and the related process validation. Indeed, already since a long time, regulatory agencies defined rules to enable consistent and clear documentation of processes: these are the requirements concerning "process records".

The use of process control systems – DCS or PLC (SCADA) – has a significant impact on the requirements concerning the generation and management of paper, electronic or hybrid (paper and electronic) records. The available technologies make possible the deployment of efficient solutions for saving and archiving information. Nevertheless, it is necessary to control the technology to avoid a cause of non compliance.

As opposed to analytical equipments which are used sequentially, infrastructure equipment – like purified water systems or HVAC equipments – as well as some production equipments operate continuously, excepted during revision periods. This constraint must be clearly specified and considered by the elaboration of strategies for information collecting, saving, restoring, archiving and retrieving.

It is essential that the objectives of activities concerning record management are understood correctly.

Which records?

The process records impacted by regulatory requirements could be of various types:

- Electronic
- Paper
  - Handwritten reports: journal, dossier, folder
  - Paper rolls or discs of paper recorders
  - Hard copies of electronic records

The concerned records could be:

- Measurements of physical values
- Process events
  - Warnings, alarms
  - Messages generated during sequences
- Parameter lists (recipes)
  - Warning and alarm limits
  - Set-points
- Verification and calibration reports of measuring devices
- Application software of process control systems.

The following part of this presentation will be focused on electronic records!

Every record has own dynamic (rate of change): e.g., history files are modified by each new measurement, application software is only modified when sequences of event require change.

It is obvious that the specific rate of change of each kind of record must be taken into account by defining the record management strategy.

Record life cycle

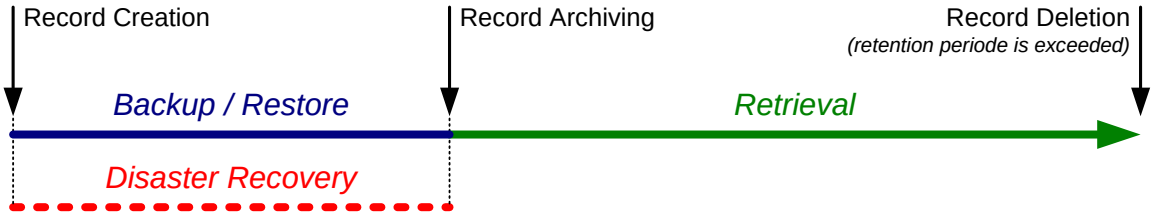
Like the system life cycle describes the system life from business needs identification until the system retirement, until retirement phase including development and operational phases, the record life cycle described the record life from its generation until its deletion.

Identification and definition of record management activities

The basic activities concerning record management are:

- Backup
- Restore
- Archiving
- Retrieval
- Deletion.

The elaboration of strategies regarding business continuity planning requires the definition of disaster recovery activities. Such activities are established using the above mentioned basic activities.



The figure above shows the different record management activities in relation with the record life cycle.

Requirements and constraints

By developing the User Requirements Specification (URS), it is essential to define the requirements concerning the record management and to identify the underlying regulatory requirements.

The regulatory requirements concern:

- Record integrity
- Record readability
- Record access control
- Change traceability.

The requirements regarding record management for a specific system concern:

- System availability
- System reliability
- Data size / data volume
- Record availability
- Definition of the maximal acceptable information loss.

These requirements are crucial for establishing an appropriate system design.

Qualification and formalism

The technical resources concerning record management which have been formally specified and implemented must obviously be qualified. Such qualification must not be limited to IQ and OQ activities. One or more SOPs formalizing record management activities are necessary. The described procedures must be tested, exercised and trained during OQ and PQ steps. Every modification concerning resources and strategy for record management must be based on a formal change request and include the needed re-qualification activities for the system.

Risk management and record management

The definition of record management strategies must take into account the risks related to the concerned records and the resulting criticality. This recognized approach is supported by both regulatory agencies as well as by working groups within the industry, e.g.: the GAMP Forum. This approach is a necessity for limiting the waste of human as well as technical resources and to improve the efficiency of record management activities.

For those reasons, it is necessary to identify clearly which information must be considered and what are the requested availability and reliability.

Conclusion

Record management requires the same rigor like system qualification.

1. During the specification phase, it is essential to identify requirements, constraints and needs regarding record management and to evaluate the record criticality.
2. The design and realization phases must take into account identified requirements, constraints, needs and risks.
3. The qualification phases must control the correct installation and operation of the resources used for record management.
4. Procedures related to record management must be described in a formal and binding manner in form of SOP(s).
5. Change control procedures apply to all record management resources. By every kind of modification (hardware or software related or operational), a re-qualification of involved resources must be planned and performed.
6. Record archiving and deletion must be planned, executed and controlled.

It is appropriate to use a similar approach as described for managing important and vital records concerning the operational capability of an organization (Good Business Practice), even if these records are not directly impacted by the pharmaceutical good practice (see for example SOX-404).

Acronyms & References

Acronyms

DCS	*Distributed Control System*
IQ	*Installation Qualification*
OQ	*Operational Qualification*
PLC	*Programmable Logic Controller*
PQ	*Performance Qualification*
SCADA	*Supervisory Control, And Data Acquisition*
SOP	*Standard Operating Procedure*
SOX	*Sarbanes-Oxley*
URS	*User Requirements Specification*

References

- ✓ European Good Manufacturing Practice, Annex 11
- ✓ GAMP 4 – Guide for the validation of automated systems
- ✓ ISO/IEC 17999:2000
  - Information Technology: Code of practice for information security management
- ✓ ISPE / GAMP: Good Practice Guide :
  - A risk-based approach to compliant Electronic Records and Signatures
- ✓ ISPE / PDA: Good Electronic Records Management (GERM)
- ✓ PIC/S PI011-2:
  - Good practices for computerized systems in regulated "GxP" Environments
- ✓ US FDA:
  - 21 CFR Part 11 – Electronic Records, Electronic Signatures
- ✓ Guidance for Industry
  Part 11, Electronic Records; Electronic Signatures – Scope and Application.

Useful links

GAMP	*www.ispe.org/gamp*
ISPE	*www.ispe.org*
PIC/S	*www.picscheme.org*

Remark

- ✓ Une version française de ce document est disponible à l'adresse suivante :
  www.kereon.ch/wp