Conditions and requirements for the implementation of process validation

This text is an excerpt from the GMP Compliance Adviser, Chapter 7.A.3 – Conditions and requirements for the implementation of process validation

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Human resource management

The implementation of validation activities necessitates suitably qualified personnel, especially for planning, managing, carrying out and evaluating the measures. Just like any other limited resource, the use of personnel in the area of validation must be organised in a process-oriented way (human resource management).

Human resource management includes all processes with regard to the recruitment, development, deployment and release of staff and therefore corresponds to the Human Resources Department of the company. The actual organisation of the individual departments of the company depends on HR policy. However, there are also some specifications that result from the regulations affecting medicinal products and the EU GMP Guidelines.

Validation personnel have to report in a defined way (see Annex 15, No. 1.3). However, the involvement of a quality management or quality assurance function is not mandatory. An appropriate supervision of HR activities must be ensured.

Information and documentation management

A substantial amount of data accumulates during a validation. This data must be properly processed to ensure that relevant knowledge can be derived from it for the company and that it can be used for decision-making and taking action. This information must be communicated internally and shared with third parties. To ensure this knowledge is always available, it must be documented so that it is retrievable at a later date. This requires an effective information and documentation management system.

An information and documentation management system is meant to guarantee the acquisition of information, and its distribution (communication) and application. Information and documentation management systems are the basis for successful knowledge management. Management tools, like other cross-departmental functions, are used over the entire life cycle of the product (see Figure 1).
To make this work, an infrastructure is required that provides information and communication tools and appropriate organisational provisions.

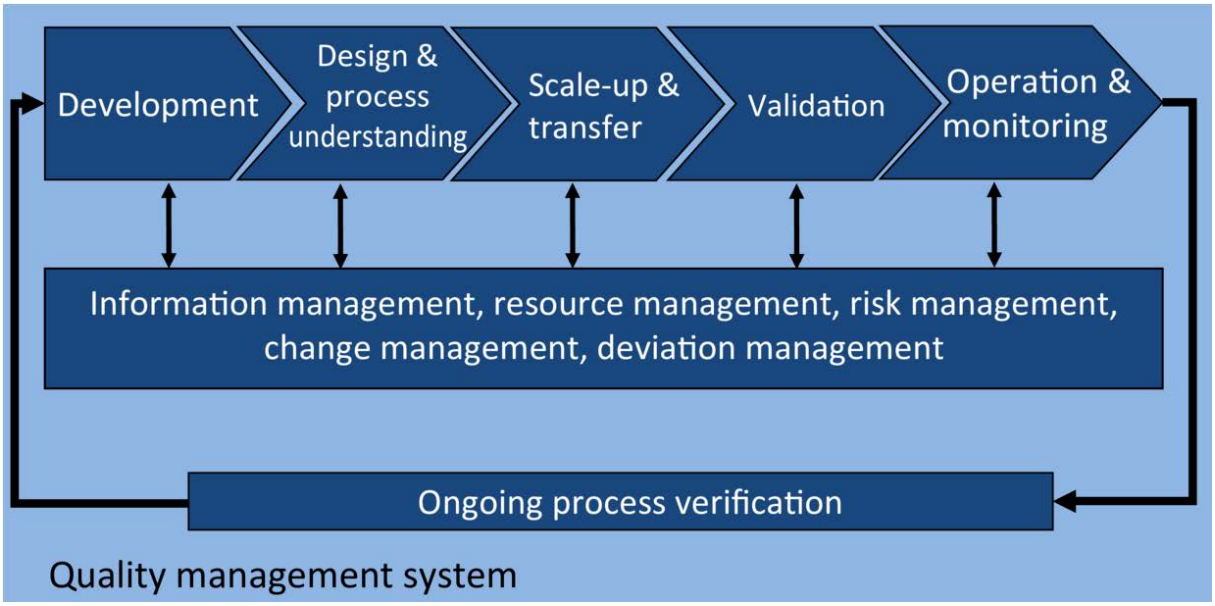

Figure 1 Information management during the life cycle

All the required documents (SOPs, records, checklists) should have been checked, approved and implemented beforehand. This applies in particular to the instructions on implementing the process validation and the SOP on dealing with changes and deviations.

Communication processes must be actively managed. It is also important that the following questions are answered:

- What events trigger an obligation to inform?
- Who is responsible for communicating the information?
- Who should receive the information?
- What communication channels are available?
- How are the communication processes and content controlled?

It is a statement of corporate culture based primarily on economic considerations whether communication processes are defined in advance or whether the individual organisational units can use their own processes. It is obvious that information that is critical to the achievement of validation objectives, in particular, must be communicated in a safe way. To reconcile fast communication processes with the realities of a hierarchical organisational structure is a real challenge.

Resource management

Just like every other part of a GMP-regulated company, the different process validation activities require adequate resources, e. g.:

- a sufficient time budget
- financial resources
- technical resources
- hardware and software

These resources must be provided using an appropriate infrastructure (rooms and facilities, supply systems, transport and communication equipment), on schedule and in the required quantity and quality.

Resources are normally only available in limited quantities. Their use in certain areas or projects must therefore be planned and prioritised. Appropriate planning and management tools should be in place (resource management).

Validation projects are often not planned based on the available resources, but are outsourced because of market pressure, customer requirements, sales or product management. But if no information on capacities is available, it cannot be determined how many validation projects the organisation and personnel can deal with. In addition, the amount of effort that will be required during certain phases of the respective project cannot be determined. This leads to uncontrollable capacity bottlenecks that slow the validation process down.

The EU GMP Guidelines expect that senior management provides the resources so that the specified validation targets can be achieved. For this reason, the available resources are taken into consideration when the authorities are assessing to the extent to which a company can meet its validation obligation.

An effective resource management system helps to:

- quickly identify free resources
- create transparency about which resources are used and when
- reschedule resources, if necessary
- prevent congestion

The criteria for the use of resources should be mainly pharmaceutical risk factors. Economic factors come second in this context.

Risk management

A risk-based approach should be taken so that the scope and depth of the required validation activities can be justified. This is stipulated in Annex 15 of the EU GMP Guidelines and other documents. A risk management system that takes over the assessment, control, communication and review of the risks is required to do this. It should ensure that:

- The assessment of the quality risk is based on scientific knowledge and experience of the process and focuses on patient safety.
- The validation effort during implementation and documentation corresponds to the degree of risk.

Risk management starts during the design development phase. Process development studies should lay the foundation for the process validation. These studies should identify, among other things, the critical process parameters and critical quality attributes of the starting materials that are to be monitored or controlled because they may affect the quality of the finished product. The sterilisation procedure chosen should be justified at this point in time for sterile medicinal products. All of the dosage strengths, dosage forms and packaging types of a medicinal product as well as the different manufacturing sites or equipment should be taken into consideration.

During the risk assessment, an understanding of the process capability and process robustness is paramount. Measures for risk control (risk reduction, process improvement) should be developed on that basis.

For further information on the principles and applications of risk management, please refer to Chapter 19 Quality Risk Management.

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