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Regulatory Requirements for Computerised Systems

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Fundamentally, the use of computerised systems in GxP environments requires a consideration of regulatory requirements. This consideration should always be undertaken against the background of potential risks in terms of patient safety, product quality, data integrity and compliance requirements. In addition to the requirements for specific processes such as development, production and packaging, general requirements for the use of computerised system (requirement for electronic storage of data) and the validation process (requirement for validation documentation) must also be met.

In a consideration of these requirements, there are therefore three main types of requirements that can be distinguished:

1. Specific requirements for the process
   - Example: Entries in records should be made directly after performing an activity. The entries should be indelibly and should clearly identify the person making the entry.
2. General requirements for computerised systems
   - Example: Computerised systems should have sufficient controls to prevent unauthorised access or changes to data. There should be controls to prevent omissions in data. There should be a record of any data change made, the previous entry, who made the change, and when the change was made. Written procedures should be available for the operation and maintenance of computerised systems.
3. Requirements for the validation of computerised systems
   - Example: The introduction of a computerised system should be planned. The entire life cycle must be considered on a risk basis and full and transparent validation documentation must be approved before productive use.

These different regulatory requirements find their way into various documents, as shown in *Figure 1*.

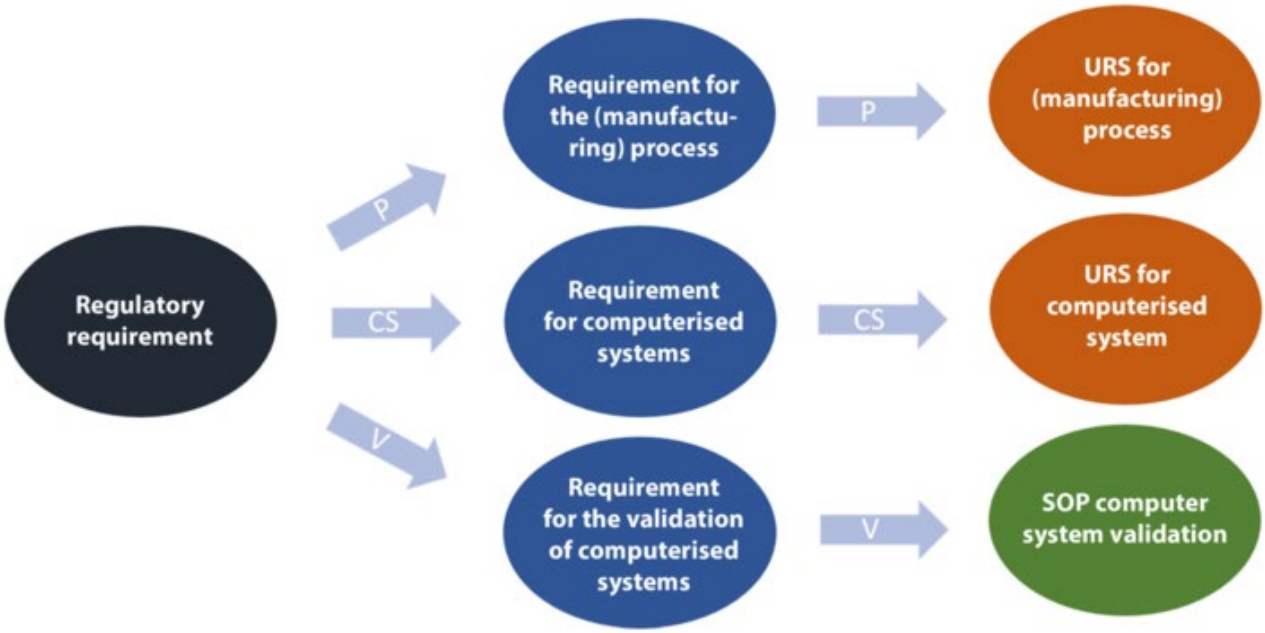

Figure 1 Division of the regulatory requirements for processes, computerised systems and validation with the associated documents

Requirements for computerised systems must be implemented for the digitised processes. In a pharmaceutical company, the regulatory requirements for the validation process must be incorporated into a procedural instruction.

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