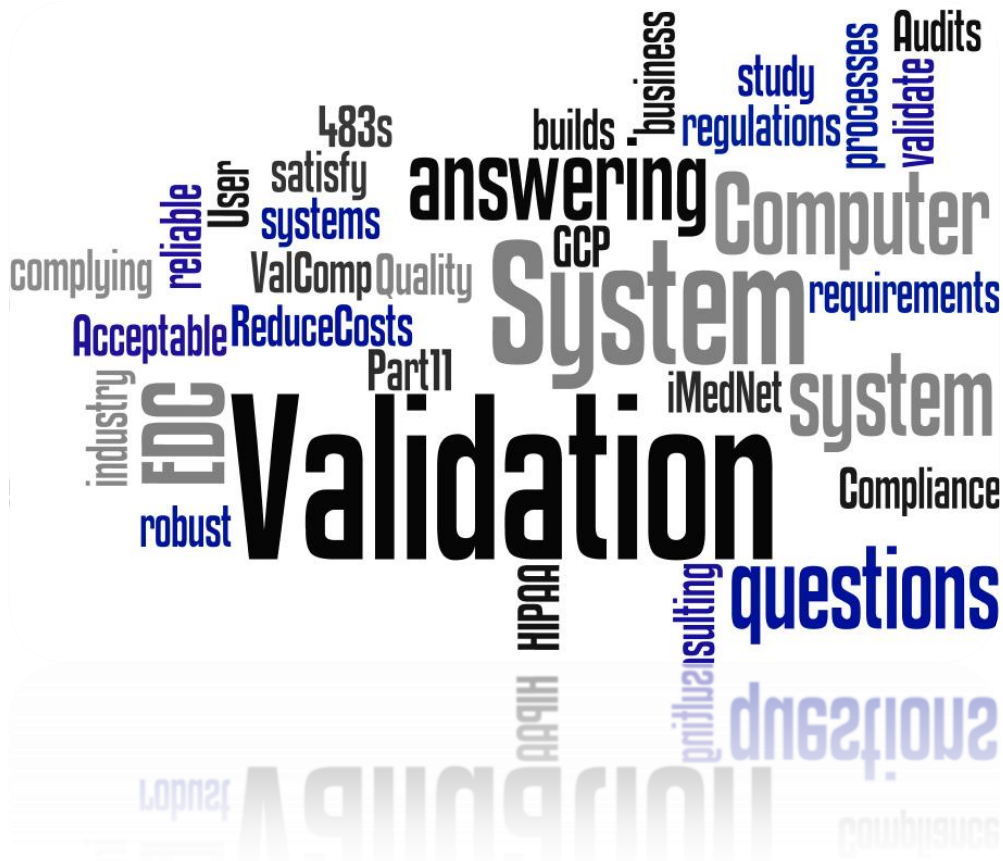


Computer System Validation – what you need to know!

Computer system validation (also known as computer validation or CSV) is part of the particularities which **have an impact on Good Manufacturing Practice in the pharmaceutical and clinical industry**. This system validation is seen as something that is more than just a compliance necessity. Why is that so? The answer is simple. CSV represents a highly pivotal aspect in the sectors mentioned above because it is a way of exploring different business computer systems so that one company or another **can bring quality to another level and can also boost effectiveness**.



More importantly, computer validation is a process that **includes documenting and clarifying** that a given computer system is successfully managed so it meets a number of previously set system requirements. When we talk about electronic record compliance, adequate validation of computer systems becomes of ever increasing importance due to the fact that it results in reliability, assurance, accurate performance and detecting changed or incorrect files which configure in the records and archives. It is of fundamental significance to remember that in every clinical research programme and project, IT systems are expected to **be validated in accordance with a set of international regulations**.

Initially, CSV was established to **guarantee proper development and maintenance of top-class computer systems**. However, with the expansion of its functions, there appeared to be a vast number of [benefits](#). For example, the foremost advantage of computerized system validation is ensuring that regulatory interventions while producing and distributing different medical products are avoided. Otherwise this type of intervention may result in expensive delays or even costly fines.

Other benefit is that CSV is able to prevent defects. In other words, **this includes discovering errors, misunderstandings and inaccuracies in the earliest phase possible**. Last but not least, validation makes it possible for organizations and companies to promote system quality.



When a CSV audit is being carried out, there are several details which the auditor needs to remember. In order to perform the task in a comprehensive way which **promises substantial assessment of the computer system management practices** and whether or not the computerized system functions in compliance with all regulatory requirements, the auditor should go through the software development documentation; assess the computer room hardware; inspect all of the operational documentation; and, finally, **examine the overall network design** and how it is being dealt with.

To summarize, computer system validation is accepted as **an on-going business operation** which provides the evidence that a computer system performs according to its defined specifications and Operating Procedures. What is more, CSV also serves the purpose to make sure that there is 100% system quality, reliability and accuracy. Lastly, such validation **encourages more profitable, beneficial and responsible actions**.

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