ARITHMOS

HOW CAN YOU CHANGE YOUR APPROACH FROM COMPUTER SYSTEM VALIDATION TO COMPUTER SOFTWARE ASSURANCE?

Computer System Validation (CSV) can prevent software problems before reaching the usage environment.

Anyway, delays and cost increases during the different phases of a project are often attributed to CSV activities, in particular during the Test phase.

Now more than ever it is time to rethink our traditional CSV approach. An approach that aligns with Computer Software Assurance (CSA) will result in the implementation of the computer system software in an efficient and innovative manner while remaining in compliance with regulatory requirements & GAMP 5.

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A strong Quality Management System allows you to change your approach from CSV to CSA.

HOW IS IT POSSIBLE?

VENDOR QUALIFICATION PROCESS

It allows to assess the vendor quality level and the validation documents. It allows to leverage the vendor documentation, reducing the internal validation effort.

RISK MANAGEMENT PROCESS

A well-structured risk management process allows assigning the right risk level to each system function on the bases of the evaluated impact on the patient safety, product quality and the data integrity. It also allows to take different test approaches and define the necessary evidence.

CHANGE MANAGEMENT PROCESS

If the validation process is supported by a robust change control process, it is ensured that only relevant functions affected by the change should be tested.

QUALIFIED PERSONNEL

Aware and trained personnel, supported by a robust standard operating process, will allow to structure the test scripts effectively, reduce the documents issue and the tester errors.

IS YOUR QUALITY SYSTEM MANAGED PROPERLY?

WOULD YOU LIKE TO REDUCE YOUR EFFORT FOR THE TEST PHASE?

With our team of experts, we can support you in Computer System Validation activities through a Strategic Support Model and through a Consultancy Model.

Contact us for more information:

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