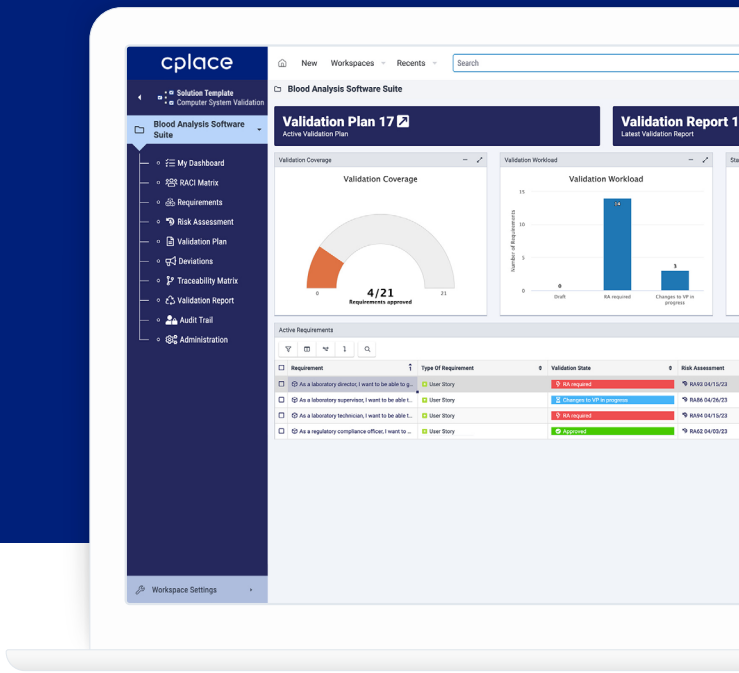
cplace

Pharmaceutical project validation and quality risk management

Computer System Validation (CSV)



solution templates

GAMP® 5 or "Good Automated Manufacturing Practice" is a non-mandatory guideline for pharmaceutical and food companies. The guide aims to deliver a cost-effective framework of good practice to ensure that computerized systems are effective and of high quality, fit for intended use, and compliant with applicable regulations.

The cplace *Solution Template Computer System Validation* combines the fundamental, most used features of GAMP® 5 to simplify the application of the guidelines, the appropriate operational controls, and the relevant documentation. Through risk minimization early in the process and through process standardization, organizations can reduce costs associated with rework, downtime, and product recalls. This helps ensure patient safety, product quality and data integrity. The *Solution Template* is suitable for both agile and traditional waterfall approaches to project management.

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In collaboration with

accenture

Validation-ready structure (incl. traceability matrix functions & meta data)

Accompanying system and business risk analysis and assessment

RACI Matrix defining responsibilities and deliverables

Business Challenge

Software validation is mandatory before a pharmaceutical company can introduce or develop new GMP-critical software. Companies must be able to present complete documentation demonstrating that the software meets the applicable GxP regulations and the predefined requirements in practical use in a reproducible way. Every change during the entire life cycle of the software must comply with a formal change control process.

Customer Benefits

The cplace *CSV Solution Template* efficiently supports the process and documentation of software validation through key process deliverables. From the validation plan to the requirements catalog, from an accompanying risk assessment to the final validation report, the *Solution Template* supports users according to their roles and responsibilities at every step of the process. This includes the validation of relevant business objects (e.g., epics or user stories), test cases and test runs, as well as reviews and approval mechanisms.

Special Features

1. Role-specific functionality: GAMP® 5-compliant validation affects different roles in pharmaceutical companies. The cplace *Solution Template CSV* guides the users through the validation process based on their roles, optimizing the user experience, and minimizing the risk of using the framework incorrectly.

2. Holistic method coverage: the cplace *Solution Template CSV* gives a structured overview of the different risks, potential deviations, and requirements needed to assess software in highly regulated companies. The result of this assessment is summarized in the validation report which also includes sign-off functions.

3. Open to all project management methods: All features work equally well for agile and classic approaches to project management. Therefore, companies can incorporate the *Solution Template* in every type of software project.

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