Codema Pharma
Ratings

Evaluation protocol description

RP2200/3 - *Criteria of evaluation concerning services for the pharmaceutical industry, provided through Cloud Technologies, Part 3 Software as a Service (SaaS)*

Purpose

The purpose of protocol RP2200/3 is to provide a structured checklist to be used during evaluation audit as well as during certification to prove compliance of a given SaaS technology with GxP requirements. This protocol also facilitates, through its rating system, comparison of various IaaS technology solutions for their fitness for use in the life-science area.

The protocol is designed as a tool for supplier selection and qualification prior to deployment of SaaS technology solutions in a GxP environment.

Scope

This protocol can be applied for evaluation of any cloud-based SaaS solution with existing or potential applications within a GxP environment. The following Areas of Evaluation are covered during the audit: suppliers, infrastructure, data integrity (including audit trail, data retention, electronic signatures), monitoring, data security (data confidentiality, user access and cybersecurity), isolation, certification and sustainability.

Roles and Responsibilities

- Codema Pharma Working Group 21 (IT Advanced Technologies Committee) is responsible for protocol development, review and approval
- PaaS solution provider acts as Applicant for the evaluation process and is obliged to provide all truthful and accurate information requested by Certified Body during audit
- Certified Body is responsible for conducting comprehensive, transparent and impartial audit via a team of pre-qualified auditors and evaluators; Certified Body also issues final evaluation/certification report

Methodology

Auditors from Certification Body collect and verify information against requirements in protocol. The audit may also invole physical tests, if applicable. All information collected, together with any comments, attachments and test reports is included and referred to by the auditor in the evaluation protocol.

Executed protocol is sent to Evaluators, a Technical Evaluator and a GxP-Compliance Evaluator. Their task includes a critical analysis of all data and evidence in their area of expertise in order to develop the Report and issue the certificate.

Deliverables

- Evaluation protocol, where detailed body of evidence collected during audit is presented in a structured manner
- Evaluation/Certification Report providing analysis of the data contained in the protocol, for each Area of Evaluation, including rating values, comments, recommendations, remediations and final conclusion about compliance with GxP regulations

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