

Praktik Kerja di Industri PT Mahakam Beta Farma (User Acceptance Test Change Control (CR Online) Berbasis Jaringan Terintegrasi di PT Mahakam Beta Farma) = Internship in PT Mahakam Beta Farma Industry (User Acceptance Test Change Control (CR Online) Based on Integrated Network at PT Mahakam Beta Farma)

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Abstrak

Validasi sistem komputer adalah proses terdokumentasi yang memastikan bahwa sistem berbasis komputer akan menghasilkan informasi atau data yang memenuhi serangkaian persyaratan yang telah ditentukan. Dalam melakukan validasi sistem komputer berpedoman pada CPOB (Cara Pembuatan Obat yang Baik) dan juga Rule 21 CFR part 11. Rule 21 CFR part 11 dikeluarkan oleh FDA membahas mengenai arsip elektronik dapat disamakan dengan arsip kertas dan tanda tangan tulisan tangan. Untuk menjamin bahwa sistem dapat berjalan dengan baik dan dapat digunakan oleh pengguna sesuai dengan User Requirement Specification (URS) maka tahapan terakhir yang perlu dilakukan adalah User Acceptance Test (UAT). User Acceptance Test, harus memenuhi prasyarat tahapan sebelumnya seperti Instalasi Qualification dan Operational Qualification. Dalam melakukan User Acceptance Test dokumen yang diperlukan adalah protokol User Acceptance Test yang berisi Lampiran Test Script. Dilakukan pengujian berdasarkan prosedur yang ada didalam Test Script. Sebelum melakukan User Acceptance Test perlu melalui beberapa tahap yaitu User Requirement Specification, Kualifikasi Desain, Kualifikasi Instalasi, Kualifikasi Operasional. Pada pengujian User Acceptance Test terdapat 4 kelompok pengujian, yaitu general system requirement, electronic signature, electronic record, dan back-up and recovery.

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Computer system validation is a documented process that ensures that a computer-based system will produce information or data that meets a set of predetermined requirements. In conducting computer system validation, it is guided by Good Manufacturing Practices and also Rule 21 CFR part 11. Rule 21 CFR part 11 issued by the FDA discusses electronic archives that can be equated with paper archives and handwritten signatures. To ensure that the system can run properly and can be used by users in accordance with the User Requirement Specification (URS), the last stage that needs to be done is the User Acceptance Test (UAT). User Acceptance Test must meet the prerequisites of the previous stages such as Installation Qualification and Operational Qualification. In conducting the User Acceptance Test, the required document is the User Acceptance Test protocol which contains the Test Script Attachment. Testing is carried out based on the procedures in the Test Script. Before conducting the User Acceptance Test, it is necessary to go through several stages, namely User Requirement Specification, Design Qualification, Installation Qualification, Operational Qualification. In the User Acceptance Test there are 4 test groups, namely general system requirements, electronic signature, electronic record, and back-up and recovery.