

Praktik kerja di Industri PT Mahakam Beta Farma periode 1 Maret - 28 April 2023, Penyusunan prosedur kualifikasi instalasi dan kualifikasi operasional sistem komputerisasi master change request online = Professional internship at PT Mahakam Beta Farma Industry for the period March 1st - April 28th 2023, Preparation of installation qualification and operational qualification procedures for master change request online computerized systems

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Abstrak

Industri farmasi saat ini tidak terlepas dari sistem komputerisasi pada proses manufakturnya. Sistem komputerisasi yang digunakan untuk pembuatan obat hendaklah divalidasi. Salah satu tahapan dalam rangkaian validasi sistem komputer adalah kualifikasi instalasi dan kualifikasi operasional. Tujuan dari tugas khusus ini adalah untuk menyusun prosedur kualifikasi instalasi dan kualifikasi operasional dari sistem komputerisasi Master Change Request Online. Prosedur kualifikasi instalasi dibuat dengan cara mengidentifikasi atribut-atribut yang terdapat pada sistem bagian Master Change Request Online. Prosedur kualifikasi operasional dibuat dengan cara mengidentifikasi cara mengoperasikan sistem bagian Master Change Request Online. Prosedur disusun berdasarkan format yang sudah ada sebelumnya yang meliputi langkah pengujian, spesifikasi, dan hasil pengujian. Prosedur kualifikasi instalasi dan kualifikasi operasional sistem komputerisasi Master Change Request Online ini dibuat dalam rangka memenuhi validasi sistem komputer.

.....The pharmaceutical industry is currently inseparable from computerized systems in its manufacturing process. Computerized systems used for drug manufacturing should be validated. One of the stages in the computer system validation series is installation qualification and operational qualification. The purpose of this special assignment was to prepare installation qualification procedures and operational qualifications for the Master Change Request Online computerized system. The installation qualification procedure was created by identifying the attributes contained in the Master Change Request Online system. The Operational qualification procedure was created by identifying how to operate the Master Change Request Online system. Procedures are prepared based on a pre-existing format that includes test steps, specifications, and test results. Installation qualification procedures and operational qualifications for the Master Change Request Online computerized system were made in order to fulfill computer system validation.