Kualifikasi instalasi dan operasional sistem komputer Change Request Online PT. Mahakam Beta Farma = Installation and operation qualification of computer system Change Request Online at PT. Mahakam Beta Farma

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Abstrak

Industri farmasi memiliki kewajiban untuk menghasilkan obat yang memenuhi persyaratan mutu, keamanan, dan efektivitas. Pada penerapan Change Request, PT Mahakam Beta Farma (MBF) melaksanakan seluruh proses menggunakan dokumen fisik. Dalam rangka meningkatkan efektivitas dan efisiensi proses serta penyimpanan dokumen, PT. MBF melakukan perubahan menjadi sistem yang terkomputerisasi. Berdasarkan CPOB 2018, penggantian operasi manual menjadi sistem komputerisasi tidak boleh mengakibatkan penurunan kualitas produk, kendali proses, atau pemastian mutu, dan tidak meningkatkan risiko terhadap proses. Oleh karena itu dilakukan validasi sistem komputer Change Request PT. MBF. Validasi dilakukan berdasarkan protokol validasi yang telah disetujui berdasarkan User Requirement Specification dan dilaksanakan melalui dua tahap yaitu kualifikasi Intalasi software dan hardware serta kualifikasi operasional software. Pada kualifikasi instalasi terdapat 82 uji yang harus dilaksanakan, terdiri dari 74 uji software, 4 uji hardware, dan 4 uji terkait instruksi kerja. Seluruh uji hardware lolos uji, 3 aspek instruksi kerja lolos uji dan 1 aspek belum terlaksana tetapi pelaksanaannya telah dijadwalkan, 67 aspek software lolos uji sedangkan 7 aspek lainnya lolos dengan catatan dan perbaikan. Pada kualifikasi operasional terdapat 62 tahap uji terkait alur kerja software dan seluruh aspek telah lolos uji. Hal tersebut menunjukan bahwa sistem CR PT. MBF telah memenuhi kualifikasi instalasi dan operasional sehingga dapat dilanjutkan dengan kualifikasi performa.

.....The pharmaceutical industry has an obligation to produce drugs that meet the quality, safety, and effectiveness requirements. In implementing the Change Request, PT Mahakam Beta Farma (MBF) performed the entire process using physical documents. To increase the effectiveness and efficiency of the processes and storage management, PT. MBF changed the system to a computerized system. Based on CPOB 2018, replacing manual operations with computerized systems may not decrease product quality, process control, or quality assurance, and doesn’t increase the process risk. Therefore, validation for the computer system was performed. The validation is carried out based on the validation protocol that was written based on the User Requirements Specification and carried out in two stages, there are installation qualification and operational qualification. In the installation qualification, there are 82 tests consisting of 74 software tests, 4 hardware tests, and 4 tests related to work instructions. All hardware tests passed the test, 3 aspects of work instructions passed the test and 1 aspect had not been performed but had been scheduled, 67 aspects of the software passed the test while 7 other aspects passed with notes and improvements needed. In operational qualification, there are 62 test stages related to software workflow and all aspects have passed the test. It could be concluded that the CR system of PT. MBF has passed the installation and operational qualifications and can be continued with performance qualification.