Protokol Kualifikasi Instalasi (KI) dan Kualifikasi Operasional (KO) Micro Balance = Micro Balance Installation Qualification (KI) and Operational Qualification (KO) Protocols

Muhammad Mishbahus Surur, author

Abstrak

Proses kualifikasi peralatan merupakan langkah penting dalam memastikan konsistensi dan akurasi data analisis di industri farmasi. Laporan ini membahas pengembangan protokol Kualifikasi Instalasi (KI) dan Kualifikasi Operasional (KO) untuk alat Micro Balance di PT. Pfizer Indonesia, yang direlokasi pada Desember 2023. Relokasi alat tersebut memerlukan kualifikasi untuk menjamin alat tetap berfungsi sesuai spesifikasi yang ditetapkan. Pendekatan metodologi menggunakan Failure Modes, Effects, and Criticality Analysis (FMECA) untuk menilai risiko terkait kompleksitas alat, sensitivitas, dan rekomendasi produsen. Berdasarkan tinjauan risiko, Micro Balance diklasifikasikan sebagai medium risk, sehingga memerlukan kualifikasi instalasi dan operasional. Protokol yang disusun mencakup verifikasi parameter teknis seperti identifikasi alat, stabilitas lingkungan, serta pengujian operasional yang melibatkan pengukuran berat terkalibrasi. Proses ini memastikan alat beroperasi optimal sesuai regulasi Good Manufacturing Practices (cGMP). Kesimpulan menunjukkan bahwa pelaksanaan kualifikasi secara sistematis mampu menjaga mutu alat selama dan setelah relokasi. Protokol ini dapat menjadi acuan dalam implementasi serupa di masa depan, mendukung kepatuhan terhadap standar Cara Pembuatan Obat yang Baik (CPOB) yang ditetapkan oleh BPOM.

.....Equipment qualification is a crucial step in ensuring the consistency, and accuracy of analytical data in the pharmaceutical industry. This report discusses the development of Installation Qualification (IQ) and Operational Qualification (OQ) protocols for a Micro Balance device at PT. Pfizer Indonesia, which was relocated in December 2023. The relocation required qualification to ensure the device operates according to the specified standards. The methodology employed Failure Modes, Effects, and Criticality Analysis (FMECA) to assess risks related to the device's complexity, sensitivity, and manufacturer recommendations. Based on the risk assessment, the Micro Balance was classified as medium risk, necessitating installation and operational qualifications. The protocols developed included verification of technical parameters such as device identification, environmental stability, and operational testing involving calibrated weight measurements. This process ensures the device functions optimally under Good Manufacturing Practices (cGMP) regulations. The findings conclude that systematic qualification implementation maintains equipment quality during and after relocation. This protocol can serve as a reference for similar implementations in the future, supporting compliance with Good Manufacturing Practices (GMP) standards established by the Indonesian Food and Drug Authority (BPOM).