

Praktik Kerja di PT. MJG Periode 3-28 Oktober 2022, Implementasi CDOB & CDAKB Mengenai Manajemen Mutu & Pengendalian Dokumen di PT. MJG = Job Training at PT. MJG Period October 3rd to October 28th, 2022 2nd - June 30th, 2022, Implementation of CDOB & CDAKB Regarding Quality Management & Document Control at PT. MJG

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Abstrak

Sediaan farmasi dan alat kesehatan menurut Pemerintah Indonesia melalui Undang-Undang No. 26 tahun 2018 tentang kesehatan harus aman, berkhasiat/bermanfaat, bermutu dan terjangkau. Keamanan, mutu, dan manfaat alat kesehatan dapat menurun akibat penanganan yang tidak sesuai selama kegiatan distribusi sehingga tiap fasilitas distribusi memiliki peranan penting dalam menjamin keamanan, mutu, dan manfaat alat kesehatan yang beredar di masyarakat. Manajemen mutu & pengendalian dokumen untuk fasilitas distribusi diatur dalam CDOB dan CDAKB, untuk itu fasilitas distribusi harus menyesuaikan manajemen mutu & pengendalian dokumen sesuai dengan yang tertera pada CDOB & CDAKB. Untuk melihat apakah manajemen mutu & pengendalian dokumen PT. MJG sesuai dengan CDOB & CDAKB atau tidak, data dalam bentuk deskriptif dikumpulkan dan dibandingkan dengan standar yang berlaku. Ditemukan bahwa manajemen mutu & pengendalian dokumen yang diterapkan oleh PT. MJG sudah sesuai dengan CDOB & CDAKB. Penerapan manajemen mutu yang sudah dilakukan oleh PT. MJG meliputi pembuatan sistem mutu seperti pembentukan struktur organisasi dan pemberian tanggung jawab dan wewenang pada masing-masing karyawan, mendapatkan sertifikasi perusahaan untuk dapat mendistribusikan barang seperti CDOB dan CDAKB serta sertifikasi ISO 9001:2015 sebagai pemenuhan sertifikasi sistem manajemen mutu standar bertaraf internasional, pelatihan personalia mengenai CDOB dan CDAKB, Audit rutin dilakukan setiap periodik, dilakukannya pengelolaan berdasarkan kontrak dan manajemen risiko mutu, serta seluruh kegiatan yang ada di PT. MJG memiliki SOP masing-masing. Pengendalian dokumen juga sudah dilakukan oleh PT. MJG dengan mendokumentasikan setiap kegiatan perusahaan dan menyimpannya selama 10 tahun.

..... Medicine and medical devices according to the Government of Indonesia through Undang-Undang Number 26 of 2018 About Health, it must be safe, efficacious/beneficial, of good quality and affordable. The safety, quality and benefits of medical devices may decrease due to inappropriate handling during distribution activities so that each distribution facility has an important role in ensuring the safety, quality and benefits of medical devices circulating in the community. Quality management & document control for distribution facilities are regulated in CDOB and CDAKB, for this reason distribution facilities must adjust quality management & document control according to what is stated in CDOB & CDAKB. To see whether the quality management & document control of PT. MJG complies with CDOB & CDAKB or not, data in descriptive form is collected and compared with applicable standards. It was found that the quality management & document control implemented by PT. MJG complies with CDOB & CDAKB. The implementation of quality management that has been carried out by PT. MJG includes establishing a quality system such as establishing an organizational structure and assigning responsibility and authority to each employee, obtaining company certification to be able to distribute goods such as CDOB and CDAKB as

well as ISO 9001: 2015 certification as a fulfillment of international standard quality management system certification, personnel training regarding CDOB and CDAKB, routine audits are carried out every period, management is carried out based on contracts and quality risk management, as well as all activities in PT. MJG has their own SOP. Document control has also been carried out by PT. MJG by documenting every activity of the company and keeping it for 10 years.