Studi Efek Samping Obat pada Pasien Rujuk Balik BPJS Kesehatan di Apotek Kimia Farma Sunter dan Pengimplementasian Supplier Risk Assessment di PT. Takeda Indonesia Bekasi = Study of Drug Adverse Effects on Patients of Program Rujuk Balik BPJS Kesehatan at Apotek Kimia Farma Sunter and Implementation of Supplier Risk Assessment at PT. Takeda Indonesia Bekasi

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Abstrak

Pemilihan dan manajemen pemasok menjadi salah satu aspek kritis dalam proses pembuatan obat agar dapat memenuhi standar mutu yang telah ditetapkan dalam CPOB di mana industri farmasi dapat menjamin keamaan pasien, memberikan produk yang bermutu dan efektif, serta dapat memenuhi permintaan persediaan obat oleh konsumen. Setiap permintaan akan material atau layanan dari pemasok perlu dilakukan proses seleksi dan kualifikasi terhadap pemasok. Dalam melakukan proses seleksi kualifikasi pemasok perlu juga dilakukan proses penilaian risiko (risk assessment). Risk assessment menyeluruh diperlukan untuk memastikan pengendalian risiko yang efektif. Laporan tugas khusus ini memaparkan proses pengimplementasian supplier risk assessment terhadap vendor-vendor yang telah disetujui di PT. Takeda Indonesia berdasarkan pedoman pada SOP (Standard Operating Procedure) yang masih efektif di PT. Takeda Indonesia Bekasi tentang manajemen kualitas untuk pemasok yag berperan dalam proses CPOB dan CDOB. Dari total 106 vendor yang ada di Approved Vendor List dan Approved Vendor List for Non Raw Material-related vendor diperoleh sebanyak 6 vendor termasuk ke dalam kategori risiko 1, 30 vendor merupakan kategori risiko 2, 44 vendor tergolong kategori risiko 3, dan sejumlah 26 vendor adalah kategori risiko 4.

.....Supplier selection and management is one of the critical aspects in the drug manufacturing process so that it can meet the quality standards set in GMP where the pharmaceutical industry can guarantee patient safety, provide quality and effective products, and be able to meet consumer demand for drug supplies. Every request for materials or services from a supplier requires a selection and qualification process for the supplier. In carrying out the supplier qualification selection process, it is also necessary to carry out a risk assessment process. A thorough risk assessment is required to ensure effective risk control. This report described the supplier risk assessment implementation process for approved vendors at PT. Takeda Indonesia based on the guidelines on SOP (Standard Operating Procedure) which was effective at PT. Takeda Indonesia Bekasi regarding quality management for suppliers in GMP and GDP processes. From a total of 106 vendors on the Approved Vendor List and Approved Vendor List for Non Raw Material-related vendors, 6 vendors were included in risk category 1, 30 vendors were in risk category 2, 44 vendors were in risk category 3, and a total of 26 vendors is risk category 4.