Laporan praktek kerja profesi apoteker di PT Aventis Pharma Jl Jend A Yani Pulomas Jakarta periode 6 Januari 28 Februari 2014 = Report of apothecary profession internship at PT Aventis Pharma Jl Jend A Yani Pulomas Jakarta on 6 January 28 February 2014

Steffianti Gunawan, author

Abstrak

[Seorang apoteker merupakan kunci di suatu industri farmasi dalam penerapan segala aspek yang tercantum dalam CPOB baik sebagai penanggung jawab produksi penjaminan mutu maupun pengendalian mutu Untuk memberikan pemahaman yang mendalam tentang implementasi CPOB di industri farmasi maka telah dilakukan Praktek Kerja Profesi Apoteker di PT Aventis Pharma pada 6 Januari ndash 28 Februari 2014 Sistem penjaminan mutu PT Aventis Pharma berdasarkan pada Sanofi Global Quality Standard dan Global IQC Directive yang sejalan dengan ketentuan CPOB BPOM untuk menjamin obat yang dihasilkan memenuhi persyaratan keamanan khasiat dan mutu Sistem penjaminan mutu tersebut meliputi 12 aspek yaitu manajemen mutu personalia bangunan dan fasilitas peralatan sanitasi dan higiene produksi pengawasan mutu inspeksi diri audit mutu dan persetujuan pemasok penanganan keluhan terhadap obat dan penarikan kembali produk dokumentasi pembuatan dan analisis berdasarkan kontrak serta kualifikasi dan validasi Tugas khusus yang dilakukan selama Praktek Kerja Profesi Apoteker ini adalah pembuatan dokumen mutu produk untuk registrasi variasi di BPOM berdasarkan peninjauan terhadap regulatory compliance Dengan melakukan peninjauan berkala akan menjamin dokumen mutu yang disiapkan sesuai dengan persyaratan mutu untuk registrasi BPOM ;A pharmacist is a key in the pharmaceutical industry in the application of all aspects listed in the GMP both in charge of production quality assurance and quality control To provide a thorough understanding of the implementation of GMP in the pharmaceutical industry it has been done Practice Pharmacist PT Aventis Pharma on 6 January to 28 February 2014 by PT quality assurance system based on Sanofi Aventis Pharma Global Quality Standards and Global IQC Directive which is in line with FDA GMP regulations to ensure that the drug is produced to meet the requirements of safety efficacy and quality Quality assurance system that covers 12 aspects of quality management personnel buildings and facilities equipment sanitation and hygiene production quality control inspection yourself quality audits and supplier approval the handling of complaints against drug and product recalls documentation manufacture and analysis based on the contract as well as qualification and validation Specific tasks performed during this Pharmacist Professional Practice is the preparation of documents for the registration of product quality variations in the FDA based on a review of regulatory compliance By conducting periodic review will ensure quality of documents prepared in accordance with FDA quality requirements for registration ;A pharmacist is a key in the pharmaceutical industry in the application of all aspects listed in the GMP both in charge of production quality assurance and quality control To provide a thorough understanding of the implementation of GMP in the pharmaceutical industry it has been done Practice Pharmacist PT Aventis Pharma on 6 January to 28 February 2014 by PT quality assurance system based on Sanofi Aventis Pharma Global Quality Standards and Global IQC Directive which is in line with FDA GMP regulations to ensure that the drug is produced to meet the requirements of safety efficacy and quality Quality assurance system that covers 12 aspects of quality management personnel buildings and

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