

Praktik kerja profesi di PT Johnson & Johnson Indonesia periode bulan April - Mei tahun 2017 = Internship at PT Johnson & Johnson Indonesia period of April-May 2017

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Abstrak

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Praktik Kerja Profesi Apoteker di PT Johnson Johnson Indonesia bertujuan agar mahasiswa profesi apoteker mengetahui dan memahami tugas, peran, dan tanggung jawab apoteker di bagian regulatory affairs suatu industri farmasi. Selain itu, kegiatan Praktik Kerja Profesi juga memfasilitasi mahasiswa dalam memahami gambaran nyata permasalahan kefarmasian di industri farmasi, khususnya pada bagian regulatory affairs. Tugas khusus yang diberikan berjudul Kajian Implementasi Perkembangan Perubahan Peraturan Kriteria dan Tata Laksana Registrasi Obat terhadap Pelaksanaan Registrasi Variasi Minor Dengan Notifikasi. Tujuan dari tugas khusus ini adalah untuk mengetahui dampak dan perbedaan ketentuan peraturan perundang-undangan registrasi obat antara peraturan terbaru dengan peraturan terdahulu serta membuat dokumen registrasi untuk Registrasi Variasi Minor dengan Notifikasi.

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ABSTRACT

Internship at PT Johnson Johnson Indonesia aims to make the pharmacist 39 s professional students know and understand the duties, roles and responsibilities of the pharmacist in the regulatory affairs section of a pharmaceutical industry. In addition, internship also facilitates students to understand the real picture of pharmaceutical problems in the pharmaceutical industry, especially in the regulatory affairs section. Specific assignment given is entitled Implementation Study of Development and Change of Regulation of Criteria and Procedure of Drug rsquo s Registration to Registration of Variation Minor with Notification. The purpose of this particular assignment is to examine the impacts and differences in the provisions of drug regulatory legislation between the latest regulations with the previous regulation and to make registration documents for Minor Variation Registration with Notifications.