Laporan praktek kerja Profesi Apoteker di PT Novell Pharmaceutical Laboratories Jalan Pos Pengumben Raya No. 8, Jakarta Barat periode 1 Juli - 29 Agustus 2014 = Pharmacist internship report at PT Novell Pharmaceutical Laboratories Jalan Pos Pengumben Raya No. 8, Jakarta Barat periode of July 1st - August 29th 2014

Mega Gustiani Utami, author

Abstrak

Praktek Kerja Profesi Apoteker di PT. Novell Pharmaceutical Laboratories bertujuan untuk mengetahui, memahami, dan mampu menerapkan tugas dan tanggung jawab apoteker di Industri Farmasi, mengetahui dan memahami peran dan tanggung jawab apoteker dalam proses pengembangan produk obat di Departemen Business Development PT. Novell dan memahami proses pengembangan produk obat di industri farmasi sesuai dengan aturan pemerintah Indonesia. Tugas khusus yang diberikan berjudul Penyusunan Dokumen Mutu Registrasi Obat Khusus Ekspor Berdasarkan Pedoman International Conference Harmonisation- Common Technical Document. Tujuan penyusunan tugas khusus ini adalah untuk mengetahui penyusunan dokumen mutu untuk obat khusus ekspor berdasarkan pedoman International Conference Harmonisation, The Common Technical Document For The Registration of Pharmaceuticals for Human Use (ICH-CTD).

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Pharmacist internship at PT. Novell Pharmaceutical Laboratories aims to know and understand the role and responsibility of Pharmacist in Pharmacy Industry, to know and understand the roles and responsibilities of pharmacists in drug product development process in the Department of Business Development of PT . Novell and to understand the process of the development of medicinal products in the pharmaceutical industry in accordance with the rules of the Indonesian government. The internship given a special assignment titled Quality Documents Preparation of Export Product Based Guidelines International Conference Harmonisation- Common Technical Document. The purposes of this particular assignment was to determine the preparation of quality documents for export product based guidelines International Conference Harmonisation , The Common Technical Document For The Registration of Pharmaceuticals for Human Use (ICH - CTD).