

Praktek kerja profesi di PT. Astrazeneca Indonesia periode Januari-Februari 2016 = Professional pharmacist internship at PT. Astrazeneca Indonesia period January-February 2016

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Abstrak

ABSTRAK

Apoteker di industri farmasi memiliki tanggung profesi untuk memastikan bahwa mutu obat yang dihasilkan memenuhi persyaratan dan tujuan penggunaannya dengan berpedoman kepada prinsip Cara Pembuatan Obat yang Baik (CPOB). Kegiatan Praktek Kerja Profesi Apoteker (PKPA) ditujukan untuk memberikan pengalaman praktis dan gambaran nyata mengenai peran, tugas dan tanggung jawab profesi apoteker di industri farmasi. PKPA ini dilaksanakan di PT. AstraZeneca Indonesia selama dua bulan di bagian pemastian mutu dengan kegiatan utama berupa induksi materi dari berbagai departemen, mengerjakan Annual Product Review (APR), mengerjakan Corrective Action Preventive Action (CAPA) dan evidence based dari self inspection serta mengerjakan gap analysis prosedur. Induksi yang diberikan berupa penjelasan singkat mengenai tugas dan fungsi dari masing-masing departemen. APR yang dikerjakan berupa dua APR dari produk packing I MY, I TW dan I AU serta satu APR dari produk repacking Z dan B. Hasilnya, semua produk packing maupun repacking dinyatakan rilis. Penerapan CAPA dan evidence based terhadap self inspection documentation error dilakukan dengan memberikan SOP ke bagian departemen yang belum terdaftar sebelumnya. Sedangkan gap analysis dari guideline Process Trending and Robustness Analysis dengan SOP Product Review Report dan Standart Change Control in the Quality and Compliance Area serta SOP Operations Change Management dengan SOP Change Management masih memberikan hasil yang relevan walaupun pada beberapa poin memerlukan revisi.

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ABSTRAK

Pharmacists in the pharmaceutical industry has a professional responsibility to ensure that the quality of medicines produced meets the requirements and intended use by referring to the principles of Good Manufacturing Practice (GMP). Professional Pharmacist Internship is intended to provide practical experience and a real description of the role, duties and responsibilities of the pharmacist profession in the pharmaceutical industry. The internship was conducted at PT. AstraZeneca Indonesia for two months at quality assurance unit with the main activities were material induction from various departments, accomplishing Annual Product Review (APR), accomplishing Corrective Action Preventive Action (CAPA) and evidence based on self-inspection and accomplishing procedures gap analysis. The induction which was given is about description of the tasks and functions of each departemen. The APR were two packing product APR of product I MY, I TW and I AU and also one repacking product APR of Z and B. As a result, both of packing and repacking products were released. Application of CAPA and evidence based on self-inspection documentation error were done by giving the SOP to the department who have unlisted previously. Wherease gap analysis of guideline the Robustness analysis and Process Trending with SOP Product Review Report and Standart Change Control in the Quality and also Compliance Operations

Area and SOP Change Management with Change Management SOP still deliver a relevant results even if at some point require revision.