

# Praktek kerja profesi di PT Astrazeneca Indonesia Head Office periode Maret April tahun 2018 = Internship at PT Astrazeneca Indonesia Head Office period March - April 2018

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## Abstrak

### **<b>ABSTRAK</b><br>**

Praktik kerja profesi di PT AstraZeneca Indonesia Head Office Periode Bulan Maret – April Tahun 2018 bertujuan untuk mengetahui tugas dan tanggung jawab apoteker di industri farmasi dan memahami penerapan Cara Pembuatan Obat yang Baik CPOB di Industri Farmasi dan tanggung jawab di bidang regulasi dan perolehan izin edar. Selain itu calon apoteker juga dapat memiliki gambaran nyata tentang permasalahan pekerjaan kefarmasian di industri farmasi, memiliki wawasan, pengetahuan, keterampilan, dan pengalaman praktis untuk melakukan pekerjaan kefarmasian di industri farmasi. Tugas khusus yang diberikan yaitu berjudul “Pelaksanaan Inspeksi Diri Self Inspection terhadap Sistem Dokumentasi dan Pelaksanaan Standar Operasional” ;Submission of NDA New Drug Application and Managing Maintanance of Licence . Tujuan dari pelaksanaan tugas khusus di PT AstraZeneca Indonesia Head Office adalah pelaksanaan rutinitas dalam rangka evaluasi kinerja personel dan pelaksanaan Standar Operasional Prosedur dan sebagai persiapan terhadap audit internal pihak Global AstraZeneca. Secara umum, PT AstraZeneca Indonesia Head Office telah menerapkan 12 aspek CPOB dengan baik dan benar, penulis juga telah mendapatkan kemampuan untuk memahami peran, tugas, wawasan dan tanggung jawab apoteker dan memberikan solusi pada permasalahan di industri farmasi.

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### **<b>ABSTRACT</b><br>**

Internship at PT AstraZeneca Indonesia Head Office Period March -April 2018 aims to understand the duties and responsibilities of pharmacists in the pharmaceutical industry and the understanding of the application of good manufacturing practice GMP in the pharmaceutical industry and understand the responsibilities about regulatory affairs in their duties to apply the product and get approval for marketed products. In addition, the pharmacist candidate can also have the insight, knowledge, skills and practical experience to undertake pharmaceutical work in the pharmaceutical industry. The special assignment given is “Self Inspection for Implementation the SOP of” ;Submission of NDA New Drug Application and Managing and Maintenance of Licence . The purpose of this special assignment as period evaluation to personal performance and implementation of Standar Operational Procedur. In general, PT AstraZeneca Indonesia has applied 12 aspects of GMP well and correctly, the authors also have the ability to understand the roles, duties, insights and responsibilities of pharmacists and provide solutions on products in the industry pharmacy.