Laporan praktek kerja profesi apoteker di Regenic laboratory PT Bifarma Adiluhung Jl. Jendral Ahmad Yani No. 2 Pulomas, Jakarta periode 6 Januari-28 Februari 2014 = Apothecary profession internship report at Regenic laboratory PT Bifarma Adiluhung Jl. Jendral Ahmad Yani No. 2 Pulomas Jakarta on the period of januari 6th to februari 28th 2014

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Abstrak

Melalui Praktek Kerja Profesi Apoteker (PKPA) di ReGeniC Laboratory, penulis berkesempatan memperoleh ilmu dasar terkait aspek regulasi dan cGMP yang harus diterapkan sebagai tanggung jawab profesinya. Penulis juga berkesempatan memperdalam ilmu bioteknologi terkait sel punca. Aplikasi klinis sel punca di Indonesia memang sudah terrealisasi, namun dalam praktiknya, perlu dilakukan optimasi dan pemantauan terhadap proses pengolahan dan produksi produk sel punca secara kontinu. Secara keseluruhan, penerapan seluruh aspek cGMP atau CPOB di ReGeniC Laboratory telah berjalan dengan baik di semua kegiatan produksi dan pengawasan mutu. Secara khusus, penerapan beberapa aspek cGMP untuk produk sel punca perlu ditelaah kembali melalui diskusi komprehensif antara pihak regulator dan pihak ReGeniC karena beberapa aplikasi aspek cGMP untuk produk sel punca jelas berbeda dengan produk obat layaknya industri farmasi. Profesi apoteker memiliki peran vital dalam implementasi cGMP dalam suatu laboratorium pengolahan sel punca, khususnya sebagai bagian pengawasan mutu. Namun, di laboratorium pengolahan sel punca, tuntutan peran apoteker tidak hanya sebagai personil kunci layaknya industri farmasi, tetapi juga sebagai peneliti untuk riset dan pengembangan sel punca.

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Through intership in ReGeniC Laboratory the author had the opportunity to acquire the basic knowledge related to current Good Manufacturing Practices cGMP aspects that should be applied as pharmacist professional responsibility in industrial context Moreover the author also had the opportunity to deepen their knowledge of biotechnology especially stem cells Clinical applications of stem cells in Indonesia has been developed by some institution but in practice optimization and monitoring need to be done related to processing and production of stem cells continuously Overall the implementation of all aspects of cGMP in ReGeniC Laboratory has run well in all the activities of production and quality control In particular the application of some aspects of cGMP for stem cell products need to be re examined through a comprehensive discussion between regulators and ReGeniC because some aspects of cGMP applications for stem cell products are clearly differ from pharmaceutical drug products Pharmacist profession has a vital role in the implementation of cGMP in a stem cell processing laboratory particularly as part of quality control However in the stem cell processing laboratory pharmacist roles is not only its responsibility as a key personnel in pharmaceutical industry but also as a researcher and long life learner conducting research and development of stem cells.