

Penyusunan Format Laporan Hasil Audit Proses, Line Clearance, dan Produk Jadi Periode 2022 = Formatting Audit Report for Process, Line Clearance, and Finished Products for 2022 Period

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Abstrak

Calon Apoteker yang ingin berkecimpung di bidang industri farmasi tidak hanya dituntut untuk memiliki pengetahuan mengenai Cara Pembuatan Obat yang Baik, tetapi juga memerlukan keterampilan yang dapat diimplementasikan pada saat terjun langsung di ruang lingkup industri farmasi. Salah satu cara untuk memberikan bekal pengetahuan dan pengalaman kepada calon Apoteker tentang ruang lingkup industri farmasi yaitu melalui kegiatan Praktek Kerja Profesi Apoteker (PKPA). Pelaksanaan praktik kerja profesi ini berlangsung selama dua bulan dengan tugas khusus, yakni Penyusunan Format Laporan Hasil Audit Proses, Line Clearance, dan Produk Jadi Periode 2022. Data hasil temuan audit proses, line clearance, produk jadi selama satu tahun diperoleh melalui pemeriksaan dokumen dan rekaman, wawancara, serta observasi oleh tim auditor. Kemudian, data hasil temuan dianalisis dan diklasifikasikan berdasarkan tingkat risiko yang berdampak pada mutu, dan berdasarkan sumber temuannya. Selain itu, CAPA (Corrective Action and Preventive Action) diklasifikasikan berdasarkan statusnya. Penyusunan format laporan audit laporan hasil audit proses, line clearance, dan produk jadi dapat berguna sebagai standar acuan dalam penyusunan laporan hasil audit selama satu tahun. Laporan hasil audit proses, line clearance, dan produk jadi sekurang-kurangnya mencakup tujuan, ruang lingkup, latar belakang, metodologi, hasil dan pembahasan, kesimpulan, serta daftar rujukan.

.....Pharmacists who want to work in the pharmaceutical industry are not only required to have knowledge of good manufacturing practice drugs, but also need skills that can be implemented when directly involved in the pharmaceutical industry. One way to provide potential pharmacists with knowledge and experience regarding the scope of the pharmaceutical industry is through internship. The internship is for two months with a specific task, namely Formatting Audit Report Process, Line Clearance, and Finished Products for 2022 Period. The data of process audit findings, line clearance, finished products for one year were obtained through document and records inspection, interviews, and observations by the auditor team. Then, the findings data are analyzed and classified based on the level of risk that has an impact on quality, and based on the source of the findings. In addition, CAPA (Corrective Action and Preventive Action) is classified based on its status. The preparation of audit report formats for process audit results, line clearance, and finished products can be used as a reference standard in the preparation of audit reports for one year. Reports on process audit results, line clearance and finished products encompass objectives, scope, background, methodology, results and discussion, conclusions, and a list of references.