Analisis Gap terhadap Guide to Good Manufacturing Practice (GMP) = Gap Analysis Based on Guide to Good Manufacturing Practice Guideline (GMP)

Aimee Detria Arianto, author

Abstrak

PT. Kalbio Global Medika (KGM) akan memasarkan salah satu produknya ke Australia. Untuk dapat memperoleh izin edar, KGM harus menunjukkan kepatuhannya terhadap kaidah GMP yang ditetapkan oleh Therapeutic Goods Administration (TGA) sebagai badan otoritas negara yang berwenang atas pengaturan produk kesehatan di Australia. Upaya yang dilakukan mengetahui tingkat kepatuhan yang ada adalah dengan melakukan analisis gap terhadap pedoman Good Manufacturing Practice (GMP). Pedoman yang digunakan sebagai acuan diperoleh dari situs resmi TGA, antara lain Therapeutic Goods Act 1989 dan PIC/S Guide to GMP. Therapeutic Goods Act 1989 berisi tentang kewenangan menteri kesehatan serta hak dan kewajiban industri farmasi, sementara PIC/S Guide to GMP berisi tentang aspek pembuatan produk obat, zat aktif obat, produk steril, produk biologis, sistem komputer, kualifikasi, validasi, sampel, dan manajemen resiko mutu yang dibagi ke dalam bagian I, bagian II, dan beberapa annex. Analisis dilakukan dengan menentukan keterterapan klausa, kondisi sebenarnya, tingkat kekritisan dan status pemenuhan, serta solusi atas gap yang teridentifikasi. Dokumen seperti quality manual dan standar prosedur operasional digunakan sebagai sumber data untuk melakukan analisis. Berdasarkan hasil analisis terhadap pedoman mengenai manajemen resiko mutu, kegiatan alih daya, inspeksi diri, dan pengendalian perubahan, KGM memenuhi 89% dari ketentuan yang dipersyaratkan pada PIC/S Guide to GMP (PE009-016).
..... PT. Kalbio Global Medika (KGM) will market one of its products to Australia. To obtain marketing authorization, KGM must demonstrate its compliance with the GMP requirements set by the Therapeutic Goods Administration (TGA) as the state authority agency that has authority over the regulation of therapeutic goods in Australia. Conducting a gap analysis of the Good Manufacturing Practice (GMP) guidelines was done to manage compliance. The guidelines used were obtained from the official TGA website, which was the Therapeutic Goods Act 1989 and the PIC/S Guide to GMP. Therapeutic Goods Act 1989 regulates the Ministry of Health's authority and obligations of the pharmaceutical industry, while the PIC/S Guide to GMP provide guidance on manufacturing medicinal products, active drug substances, sterile products, biological products, computer systems, qualifications, validation, samples, and quality risk management which were divided into part I, part II, and several annexes. The analysis was carried out by determining the applicability of the clause, actual conditions, criticality, and fulfillment status, as well as action plans to minimize the gaps. Documents such as quality manuals and standard operating procedures were used. Based on the analysis regarding quality risk management, outsourcing activities, self-inspection, and change control, KGM complies with 89% of the requirements stated in the PIC/S Guide to GMP (PE009- 016).