Pelaksanaan Audit Internal Departemen Produksi PT. Forsta Kalmedic Global = Implementation of Internal Audit of the Production Department of PT. Forsta Kalmedic Global

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Abstrak

PT. Forsta Kalmedic Global (FORSTA) merupakan perusahaan manufaktur alat Kesehatan dan diagnostik yang menerapkan Cara Pembuatan Alat Kesehatan yang Baik (CPAKB) agar mutu produk yang dihasilkan terjaga. Forsta melakukan Audit Internal secara berkala untuk memverifikasi bahwa Departemen Produksi masih melakukan pemenuhan terhadap CPAKB dan ISO 13485:2010. Temuan audit internal dibuatkan Corrective Action Preventive Action (CAPA) sebagai tindak lanjut. Penulis dilibatkan secara aktif dalam kegiatan audit internal dan pembuatan CAPA sehingga mengangkat kegiatan tersebut sebagai pokok bahasan penelitian observasional kemudian dituangkan dalam laporan PKPA. Metode yang digunakan adalah observasi, wawancara dan studi literatur. Hasilnya, audit dilakukan oleh tim audit internal berdasarkan ”Checklist Audit Temuan” yang dirumuskan berdasarkan CPAKB dan ISO 13485: 2016. Tim terdiri dari Lead Auditor dan tim audit. Audit internal departemen produksi dilaksanakan pada 6 September 2023 dilakukan oleh tim inspektor penjamin mutu (QA) dan tim inspektor pengendali mutu (QC). Audit meliputi area produksi yaitu: gowning, janitor, staging, primary packaging, suture attaching, broth filling, petri filling, cleaning, mixing, autoclave, natural suture, weighing, koridor produksi, secondary packaging, dan ante room. Audit internal Departemen Produksi menghasilkan 21 temuan. 15 temuan tergolong dalam temuan minor, sedangkan sisanya tergolong rekomendasi. 16 memerlukan penyelesaian administrasi yaitu pemerataan SOP melalui form berita acara kepada QA sebagai CA dan PA berupa melakukan inspeksi diri secara berkala terhadap SOP alat/mesin/prosedur, data tersebut terus diperbaharui dan melakukan koordinasi dengan QA. 5 temuan lainnya memerlukan koordinasi dengan Departemen Engineering. Audit internal departemen produksi yang dilakukan oleh FORSTA dan penyelesaiannya telah sesuai dengan CPAKB dan diharapkan dapat menjaga mutu perusahaan.

..... PT. Forsta Kalmedic Global (FORSTA) is a medical and diagnostic equipment manufacturing company that applies GMP (Good Manufacturing Practice) for medical device so that the quality of the products produced is maintained. Forsta carries out regular Internal Audits to verify that the Production Department is still complying with GMP and ISO 13485:2010. Internal audit findings create Corrective Preventive Actions (CAPA) as a follow-up. Author was actively involved in internal audit and CAPA creation, thereby highlighting these activities as the subject of observational research which was then outlined in the PKPA report. The methods used are observation, interviews and literature study. As a result, the audit was carried out by an internal audit team based on the "Audit Findings Checklist" formulated based on CPAKB and ISO 13485:2016. The team were from Quality Assurance (QA) and Quality Control (QC). The internal audit of the production department was carried out on September 6 2023. The audit covers every production room. The Production Department's internal audit produced 21 findings. 15 were categorized as minor, 6 were classified as recommendations. 16 requires administrative completion, namely distributing SOPs through the minutes form to QA as CA and PA in the form of carrying out regular self-inspections of SOPs for tools/machines/procedures, this data continues to be updated and coordinated with QA. The other 5 findings

require coordination with the Engineering Department. The internal audit of the production department carried out by FORSTA and its completion is in accordance with GMP and expected to safeguard the company’s quality