

Penyusunan Risk Assessment Terkait Control Contamination Strategy (CCS) di PT Finusolprima Farma International = Preparation of Risk Assessment Related to Control Contamination Strategy (CCS) at PT Finusolprima Farma International

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Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=9999920543485&lokasi=lokal>

Abstrak

Produk steril memiliki persyaratan minimal risiko kontaminasi mikroba, partikulat, dan endotoksin/pirogen pada fasilitas, peralatan, dan proses harus dirancang, dikualifikasi, dan divalidasi dengan tepat untuk meningkatkan perlindungan produk. Strategi pengendalian kontaminasi / Contamition Control Strategy (CCS) harus diterapkan di seluruh fasilitas industri farmasi untuk menilai efektivitas seluruh rancangan, prosedur, teknis, dan organisasional serta pemantauan yang telah digunakan untuk mengelola risiko terhadap mutu produk. Penyusunan Risk Assessment Terkait Control Contamination Strategy (CCS) di PT Finusolprima Farma International dilakukan dengan melakukan studi literatur pada Prosedur Tetap, membandingkan prosedur yang telah ada dengan ketentuan EU GMP & CPOB 2018 dan menyusun hasil penerapan CCS. Dengan adanya kegiatan Penyusunan Risk Assessment Terkait Control Contamination Strategy (CCS) di PT Finusolprima Farma International diketahui elah dilakukannya analisis efektivitas Contamination Control Strategy (CCS) menggunakan prinsip manajemen risiko mutu pada PT Finusolprima Farma International namun masih terdapat prosedur pengendalian kontaminasi yang belum terdokumentasi dengan baik sehingga perlu ditambahkan untuk memudahkan personil terkait dan pencegahan kontaminasi dapat lebih dikendalikan.

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Sterile products have minimal risk requirements for microbial, particulate and endotoxin/pyrogen contamination. Facilities, equipment and processes must be appropriately designed, qualified and validated to increase product protection. Contamination control strategies (CCS) must be implemented in all pharmaceutical industry facilities to assess the effectiveness of all designs, procedures, and technical and organizational monitoring used to manage product quality risks. Preparing a Risk Assessment Related to Control Contamination Strategy (CCS) at PT Finusolprima Farma International was carried out by conducting a literature study on Standing Procedures, comparing existing procedures with the provisions of EU GMP & CPOB 2018 and compiling the results of CCS implementation. With the activity of Preparing a Risk Assessment Related to Control Contamination Strategy (CCS) at PT Finusolprima Farma International, it is known that an analysis of the effectiveness of Contamination Control Strategy (CCS) has been carried out using quality risk management principles at PT Finusolprima Farma International. However, contamination control procedures still need to be properly documented. So, it needs to be added to make it easier for related personnel and contamination prevention to be better controlled.