

INTISARI

Implementasi CDOB merupakan aspek penting dalam menjamin mutu, keamanan, dan khasiat obat selama proses distribusi. BPOM telah melakukan pengawasan terhadap fasilitas distribusi pada tahun 2024 menunjukkan fakta dari 945 PBF yang diperiksa di seluruh Indonesia, sebanyak 295 PBF (31,21%) dinyatakan Tidak Memenuhi Ketentuan (TMK) sedangkan yang Memenuhi Ketentuan (MK) sebanyak 650 PBF (68,79%). Pada tahun 2024, BBPOM mencatat dari 36 PBF yang berada di wilayah pengawasan, telah dilakukan pemeriksaan pada 16 PBF dengan hasil 2 sarana Tidak Memenuhi Ketentuan (TMK) dan 14 sarana Memenuhi Ketentuan (MK). Ketidakpatuhan ini terjadi karena masih terdapat potensi kegagalan yang dapat memengaruhi kualitas pelayanan dan kepatuhan terhadap regulasi. Penelitian ini bertujuan untuk menganalisis risiko potensi kegagalan dalam implementasi CDOB menggunakan metode FMEA.

Penelitian ini menggunakan metode kualitatif dan kuantitatif dengan desain deskriptif untuk studi kasus pada PBF X di Kota Samarinda. Pendekatan kualitatif dilaksanakan melalui *Focus Group Discussion* (FGD), wawancara mendalam dengan personel kunci PBF, dan observasi langsung. Pendekatan kuantitatif dilaksanakan dengan penentuan tingkat risiko berdasarkan nilai *Severity* (S), *Ocurrence* (O), dan *Detection* (D). Pada penelitian ini hanya mengkaji 3 aspek CDOB, yaitu aspek bangunan dan peralatan, operasional, dan keluhan, obat dan/atau bahan obat kembalian, diduga palsu, dan penarikan kembali.

Hasil penelitian ini menunjukkan nilai RPN berada pada rentang 54 – 216 dengan mayoritas risiko berada pada kategori sedang (53,2%), rendah (38,3%), dan tinggi (8,5%). Prioritas tindakan mitigasi terdapat pada aspek penarikan kembali (*recall*) (RPN = 216), aspek penyimpanan (RPN = 200), dan aspek penyaluran (RPN = 175). Tindakan perbaikan difokuskan pada pemisahan dan pengendalian status produk, melakukan *double check*, penerapan sistem pelacakan berbasis *batch number*, dan memberikan pelatihan kepada petugas gudang.

Kata Kunci: CDOB, FMEA, Distribusi Obat, Manajemen Risiko, PBF

ABSTRACT

The implementation of CDOB is a crucial aspect in ensuring the quality, safety, and efficacy of medicines throughout the distribution process. The Indonesian FDA (BPOM) conducted supervision of distribution facilities in 2024, revealing that out of 945 pharmaceutical wholesalers (PBF) inspected across Indonesia, 295 PBFs (31.21%) were classified as Non-Compliant (TMK), while 650 PBFs (68.79%) were Compliant (MK). In the same year, the Regional Office of BPOM (BBPOM) reported that, out of 36 PBFs under its supervision, 16 had been inspected, with results showing 2 facilities classified as Non-Compliant (TMK) and 14 as Compliant (MK). This non-compliance occurs due to the presence of potential failure risks that may affect service quality and regulatory compliance. This study aims to analyze the risk of potential failures in the implementation of CDOB using the FMEA method.

This study employed both qualitative and quantitative methods with a descriptive design in a case study conducted at PBF X in Samarinda City. The qualitative approach was carried out through Focus Group Discussions (FGD), in-depth interviews with key personnel, and direct observation. The quantitative approach involved determining risk levels based on Severity (S), Occurrence (O), and Detection (D) scores. This study focused on three CDOB aspects: buildings and equipment, operational processes, and complaints, returned products, suspected counterfeit products, and recall.

The results showed that the Risk Priority Number (RPN) ranged from 54 to 216, with the majority of risks categorized as moderate (53.2%), low (38.3%), and high (8.5%). The priority for mitigation actions was identified in the recall aspect (RPN = 216), storage aspect (RPN = 200), and distribution aspect (RPN = 175). Corrective actions focused on product segregation and status control, implementing double-check procedures, applying batch number-based traceability systems, and providing training for warehouse personnel.

Keywords: CDOB, FMEA, Drug Distribution, Risk Management, Pharmaceutical Wholesalers.