

**SKRIPSI**

**PENGARUH SISTEM MANAJEMEN MUTU TERHADAP  
KEPATUHAN APOTEKER PEDAGANG BESAR FARMASI  
(PBF) PADA STANDAR CARA DISTRIBUSI OBAT YANG  
BAIK (CDOB) DI KOTA BATAM**



**CHINDI KLAUDIA**

**61608100821024**

**PROGRAM STUDI SARJANA FARMASI  
INSTITUT KESEHATAN MITRA BUNDA**

**BATAM**

**2025**

**SKRIPSI**

**PENGARUH SISTEM MANAJEMEN MUTU TERHADAP  
KEPATUHAN APOTEKER PEDAGANG BESAR FARMASI  
(PBF) PADA STANDAR CARA DISTRIBUSI OBAT YANG  
BAIK (CDOB) DI KOTA BATAM**



Skripsi ini Disusun Sebagai Salah Satu Persyaratan Untuk Menyelesaikan  
Program Pendidikan Sarjana Farmasi

**CHINDI KLAUDIA**

**61608100821024**

**PROGRAM STUDI SARJANA FARMASI  
INSTITUT KESEHATAN MITRA BUNDA**

**BATAM**

**2025**

## DAFTAR ISI

	<b>Halaman</b>
<b>PERNYATAAN PERSETUJUAN</b> .....	Error! Bookmark not defined.
<b>PENGESAHAN</b> .....	Error! Bookmark not defined.
<b>KATA PENGANTAR</b> .....	Error! Bookmark not defined.
<b>ABSTRAK</b> .....	Error! Bookmark not defined.
<b>ABSTRAC</b> .....	Error! Bookmark not defined.
<b>HALAMAN PERNYATAAN PERSETUJUAN PUBLIKASI SKRIPSI UNTUK KEPENTINGAN AKADEMIS</b> .....	Error! Bookmark not defined.
<b>DAFTAR ISI</b> .....	<b>ii</b>
<b>DAFTAR GAMBAR</b> .....	<b>vi</b>
<b>DAFTAR TABEL</b> .....	<b>vii</b>
<b>DAFTAR LAMPIRAN</b> .....	<b>viii</b>
<b>BAB I PENDAHULUAN</b> .....	Error! Bookmark not defined.
1.1 Latar Belakang .....	<b>Error! Bookmark not defined.</b>
1.2 Rumusan Masalah .....	<b>Error! Bookmark not defined.</b>
1.3 Tujuan Penelitian.....	<b>Error! Bookmark not defined.</b>
1.4 Manfaat Penelitian.....	<b>Error! Bookmark not defined.</b>
1.4.1 Manfaat bagi perusahaan .....	<b>Error! Bookmark not defined.</b>
1.4.2 Manfaat bagi insitusi.....	<b>Error! Bookmark not defined.</b>
1.4.3 Manfaat bagi peneliti .....	<b>Error! Bookmark not defined.</b>
1.5 Keaslian penelitian .....	<b>Error! Bookmark not defined.</b>
<b>BAB II TINJAUAN PUSTAKA</b> .....	Error! Bookmark not defined.
2.1 Pedagang Besar Farmasi (PBF).....	<b>Error! Bookmark not defined.</b>
2.1.1 Definisi PBF .....	<b>Error! Bookmark not defined.</b>
2.1.2 Landasan Hukum PBF .....	<b>Error! Bookmark not defined.</b>
2.1.3 Tugas dan Fungsi serta kewajiban PBF .....	<b>Error! Bookmark not defined.</b>
2.1.4 Persyaratan PBF.....	<b>Error! Bookmark not defined.</b>

2.1.5	Tata cara pendirian PBF .....	<b>Error! Bookmark not defined.</b>
2.1.6	Tata Cara Pemberian Pengakuan PBF .....	<b>Error! Bookmark not defined.</b>
2.1.7	Tata Cara Pemberian Sertifikat Distribusi Cabang ....	<b>Error! Bookmark not defined.</b>
2.1.8	Masa Berlaku Izin PBF.....	<b>Error! Bookmark not defined.</b>
2.1.9	Apoteker Penanggung Jawab PBF .....	<b>Error! Bookmark not defined.</b>
2.1.10	Penyelenggaraan PBF .....	<b>Error! Bookmark not defined.</b>
2.2	Cara Distirbusi Obat Yang Baik (CDOB) .....	<b>Error! Bookmark not defined.</b>
2.2.1	Manajemen Mutu.....	<b>Error! Bookmark not defined.</b>
2.2.2	Organisasi dan Personalia.....	<b>Error! Bookmark not defined.</b>
2.2.3	Bangunan dan Peralatan.....	<b>Error! Bookmark not defined.</b>
2.2.4	Operasional .....	<b>Error! Bookmark not defined.</b>
2.2.5	Inspeksi Diri.....	<b>Error! Bookmark not defined.</b>
2.2.6	Keluhan, Obat dan/atau Bahan Obat Kembalian, Diduga, Palsu Penarikan Kembali.....	<b>Error! Bookmark not defined.</b>
2.2.7	Transportasi.....	<b>Error! Bookmark not defined.</b>
2.2.8	Fasilitas Distribusi Berdasarkan Kontrak ...	<b>Error! Bookmark not defined.</b>
2.2.9	Dokumentasi .....	<b>Error! Bookmark not defined.</b>
2.2.10	Ketentuan khusus bahan obat .....	<b>Error! Bookmark not defined.</b>
2.2.11	Ketentuan Khusus Produk Rantai ( <i>Cold Chain Product/ CPP</i> ) .....	<b>Error! Bookmark not defined.</b>
2.2.12	Ketentuan Khusus Narkotika, Psikotropika Dan Prekursor Farmasi.	<b>Error! Bookmark not defined.</b>
2.3	Kerangka Konseptual .....	<b>Error! Bookmark not defined.</b>
2.4	Hipotesis Penelitian.....	<b>Error! Bookmark not defined.</b>
<b>BAB III METODOLOGI PENELITIAN .....</b>		<b>Error! Bookmark not defined.</b>
3.1	Jenis dan Rancangan Penelitian .....	<b>Error! Bookmark not defined.</b>
3.2	Populasi dan Sampel Penelitian .....	<b>Error! Bookmark not defined.</b>
3.2.1	Populasi.....	<b>Error! Bookmark not defined.</b>
3.2.2	Sampel .....	<b>Error! Bookmark not defined.</b>
3.3	Lokasi dan Waktu Penelitian .....	<b>Error! Bookmark not defined.</b>

3.3.1 Lokasi.....	<b>Error! Bookmark not defined.</b>
3.3.2 Waktu penelitian .....	<b>Error! Bookmark not defined.</b>
3.4 Variabel Penelitian.....	<b>Error! Bookmark not defined.</b>
3.4.1 Variabel Dependen (Y) .....	<b>Error! Bookmark not defined.</b>
3.4.2 Variabel Independen (X).....	<b>Error! Bookmark not defined.</b>
3.5 Kerangka Konsep .....	<b>Error! Bookmark not defined.</b>
3.6 Prosedur Penelitian.....	<b>Error! Bookmark not defined.</b>
3.6.1 Tahap Persiapan .....	<b>Error! Bookmark not defined.</b>
3.6.2 Tahap Pelaksanaan .....	<b>Error! Bookmark not defined.</b>
3.7 Pengumpulan data .....	<b>Error! Bookmark not defined.</b>
3.8 Pengolahan Data dan Analisa Data.....	<b>Error! Bookmark not defined.</b>
3.8.1 Pengolahan Data .....	<b>Error! Bookmark not defined.</b>
3.8.2 Analisis Data .....	<b>Error! Bookmark not defined.</b>
3.9 Definisi Operasional.....	<b>Error! Bookmark not defined.</b>
3.10 Etika Penelitian.....	<b>Error! Bookmark not defined.</b>
<b>BAB IV HASIL PENELITIAN DAN PEMBAHASAN .....</b>	<b>Error! Bookmark not defined.</b>
4.1 Gambarn Umum Lokasi Penelitian .....	<b>Error! Bookmark not defined.</b>
4.1.1 Lokasi Penelitian PT A .....	<b>Error! Bookmark not defined.</b>
4.1.2 Lokasi Penelitian PT B .....	<b>Error! Bookmark not defined.</b>
4.1.3 Lokasi Penelitian PT C .....	<b>Error! Bookmark not defined.</b>
4.1.4 Lokasi Penelitian PT D .....	<b>Error! Bookmark not defined.</b>
4.1.5 Lokasi Penelitian PT E .....	<b>Error! Bookmark not defined.</b>
4.1.6 Lokasi Penelitian PT F.....	<b>Error! Bookmark not defined.</b>
4.1.7 Lokasi Penelitian PT G .....	<b>Error! Bookmark not defined.</b>
4.1.8 Lokasi Penelitian PT H.....	<b>Error! Bookmark not defined.</b>
4.1.9 Lokasi Penelitian PT I.....	<b>Error! Bookmark not defined.</b>
4.1.10 Lokasi Penelitian PT J .....	<b>Error! Bookmark not defined.</b>
4.2 Hasil Penelitian.....	<b>Error! Bookmark not defined.</b>
4.2.1 Karakteristik Responden.....	<b>Error! Bookmark not defined.</b>

4.2.2 Uji Instrumen Penelitian .....	<b>Error! Bookmark not defined.</b>
4.2.3 Analisis Bivariat.....	<b>Error! Bookmark not defined.</b>
4.3 Pembahasan .....	<b>Error! Bookmark not defined.</b>
4.4 Keterbatasan Penelitian .....	<b>Error! Bookmark not defined.</b>
<b>BAB V PENUTUP</b> .....	<b>Error! Bookmark not defined.</b>
5.1 Kesimpulan.....	<b>Error! Bookmark not defined.</b>
5.2 Saran .....	<b>Error! Bookmark not defined.</b>
<b>DAFTAR PUSTAKA</b> .....	<b>Error! Bookmark not defined.</b>
<b>LAMPIRAN</b> .....	<b>Error! Bookmark not defined.</b>

## DAFTAR GAMBAR

Gambar 3. 1 Kerangka Konsep ..... **Error! Bookmark not defined.**

## DAFTAR TABEL

Table 4. 1 Karakteristik Responden Berdasarkan Gender ..... **Error! Bookmark not defined.**

Table 4. 2 Karakteristik Responden Berdasarkan Jabatan ..... **Error! Bookmark not defined.**

Table 4. 3 Karakteristik Responden berdasarkan Lama Bekerja **Error! Bookmark not defined.**

Table 4. 4 Karakteristik Responden Berdasarkan Berdasarkan Frekuensi Terlibat Langsung Dalam CDOB ..... **Error! Bookmark not defined.**

Table 4. 5 Hasil Uji Validitas ..... **Error! Bookmark not defined.**

Table 4. 6 Hasil Uji Reliabilitas ..... **Error! Bookmark not defined.**

Table 4. 7 Hasil Uji Korelasi *Spearman Rank* ..... **Error! Bookmark not defined.**

## DAFTAR LAMPIRAN

Lampiran 1 Kerangka Kerja.....	<b>Error! Bookmark not defined.</b>
Lampiran 2 Surat Izin Penelitian.....	<b>Error! Bookmark not defined.</b>
Lampiran 3 Surat Ethical clearance .....	<b>Error! Bookmark not defined.</b>
Lampiran 4 <i>Informed Consent</i> .....	<b>Error! Bookmark not defined.</b>
Lampiran 5 Uji Validitas .....	<b>Error! Bookmark not defined.</b>
Lampiran 6 Kuesioner.....	<b>Error! Bookmark not defined.</b>
Lampiran 7 Pengisian Kuesioner .....	<b>Error! Bookmark not defined.</b>
Lampiran 8 Sertifikat CDOB .....	<b>Error! Bookmark not defined.</b>
Lampiran 9 Surat Pesanan Produk .....	<b>Error! Bookmark not defined.</b>
Lampiran 10 Surat Pesanan Obat Mengandung Obat-obatan Tertentu.....	<b>Error! Bookmark not defined.</b>
<b>Bookmark not defined.</b>	
Lampiran 11 Surat Penolakan Pesanan Obat-Obatan Tertentu ..	<b>Error! Bookmark not defined.</b>
<b>defined.</b>	

