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Analisis Kendala Proses Produksi Pada Perusahaan XYZ Farmasi Menggunakan Overall Equipment Effectiveness (OEE) dan Failure Mode and Effect Analysis (FMEA)
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Universitas Gadjah Mada, 2026 | Diunduh dari http://etd.repository.ugm.ac.id/

INTISARI

Industri vaksin dituntut untuk menjaga efisiensi dan kualitas produksi guna memenuhi peningkatan permintaan global. Proses produksi yang berbasis mesin dan terotomatisasi menuntut optimasi kinerja mesin secara berkelanjutan. Penelitian ini bertujuan untuk menganalisis kinerja mesin serta mengidentifikasi kendala proses produksi pada *filling line* vaksin di Perusahaan XYZ Farmasi, dengan fokus pada *Filling Machine* dan *Capping Machine*.

Analisis kinerja mesin dilakukan menggunakan metode *Overall Equipment Effectiveness* (OEE), sedangkan identifikasi losses menggunakan *Six Big Losses* yang diprioritaskan dengan Diagram *Pareto*. Akar penyebab permasalahan dianalisis menggunakan Diagram Ishikawa *(Fishbone Diagram)* berbasis 5M, serta prioritas tindakan perbaikan ditentukan melalui *Failure Mode and Effect Analysis* (FMEA).

Hasil penelitian menunjukkan bahwa rata-rata nilai OEE *Filling Machine* sebesar 60,82% dan *Capping Machine* sebesar 54,38%, yang masih berada di bawah standar *world class* sebesar 85%. *Breakdown Losses* merupakan losses terbesar pada *Filling Machine*, sementara *Idling and Minor Stoppages* mendominasi pada *Capping Machine*. Faktor utama penyebab *losses* meliputi keterbatasan sistem deteksi dini, ketidaktepatan pemeliharaan mesin, rendahnya *awareness* operator, variasi keahlian operator, serta ketidakkonsistenan pada bahan kemas primer. Berdasarkan analisis FMEA, tiga kode risiko dengan nilai RPN di atas ambang batas *acceptable* diprioritaskan sebagai fokus perbaikan.

Kata Kunci : Produksi Vaksin, *Overall Equipment Effectiveness*, *Six Big Losses,* Diagram Ishikawa *(Fishbone Diagram)*, *Failure Mode and Effect Analysis*

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ABSTRACT

The vaccine industry is required to maintain production efficiency and quality in order to meet increasing global demand. Machine-based and automated production processes require continuous optimization of machine performance. This study aims to analyze machine performance and identify production process constraints on the vaccine filling line at XYZ Pharmaceuticals, with a focus on the Filling Machine and Capping Machine.

Machine performance analysis was conducted using the Overall Equipment Effectiveness (OEE) method, while losses were identified using the Six Big Losses prioritized with a Pareto diagram. The root causes of problems were analyzed using a 5M-based Ishikawa Diagram (Fishbone Diagram), and improvement action priorities were determined through Failure Mode and Effect Analysis (FMEA).

The results of the study show that the average OEE value of the Filling Machine is 60.82% and the Capping Machine is 54.38%, which is still below the world-class standard of 85%. Breakdown losses are the largest losses on the Filling Machine, while Idling and Minor Stoppages dominate on the Capping Machine. The main factors causing losses include limitations in the early detection system, inaccurate machine maintenance, low operator awareness, variations in operator skills, and inconsistent primary packaging materials. Based on the FMEA analysis FMEA analysis, the three risk code with RPN values above the acceptable threshold are prioritized as the focus of improvement.

Keywords: *Vaccine Production, Overall Equipment Effectiveness, Six Big Losses, Ishikawa Diagram (Fishbone Diagram), Failure Mode and Effect Analysis*