

ABSTRAK

Nama : Fitria Febri Sahara
NIM : 41619110045
Program Studi : Teknik Industri
Judul Laporan Skripsi : Analisis *Lean Manufacturing* Dengan Metode *Value Stream Mapping* Untuk Mengurangi *Waste* Pada Sistem *Management Corrective Action and Preventive* Di PT Brightgene Biomedical Indonesia
Pembimbing : Selamat Riadi, ST, MT

Compliance merupakan suatu proses yang dimana memastikan bahwa proses, operasi dan praktik yang dijalankan didalam suatu perusahaan berjalan dengan regulasi yang telah ditetapkan, salah satu nya melalui management *Corrective and Preventive Action (CAPA)*. Dalam proses CAPA pada PT Brightgene Biomedical Indonesia dinilai masih belum optimal terbukti dengan leadtime proses yang dinilai terlalu lama. Tujuan dari penelitian ini adalah menghilangkan waste yang terjadi didalam sistem management CAPA dengan menggunakan metode Value Stream Mapping. Metode Value Stream Mapping merupakan metode untuk dapat melihat aktivitas yang bernilai tambah dengan yang tidak, menggunakan pemetaan visual. Jenis penelitian yang digunakan ialah deskriptif kuantitatif, data primer didapatkan dari proses observasi dan wawancara serta leadtime dari setiap proses yang berlangsung. Setelah dilakukan improvement menggunakan value stream mapping dan diagram fishbone dan FMEA didapatkan bahwa leadtime untuk sistem management CAPA mengalami penurunan yaitu mulai dari pendaftaran sampe penutupan proses normal sebesar 53 %, apabila terdapat perubahan, pembatalan dan perpanjangan CAPA sebesar 91 %, apabila kekurangan bukti 53 % dan apabila ada penilaian efektivitas 50 %.

Kata Kunci: Lean Manufacturing, VSM, Compliance, CAPA.

ABSTRACT

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Compliance is a process that ensures that processes, operations and practices carried out within a company run according to established regulations, one of which is through Management Corrective and Preventive Action (CAPA). In the CAPA process at PT Brightgene Biomedical Indonesia it is considered to be still not optimal as evidenced by the process lead time which is considered too long. The purpose of this research is to eliminate the waste that occurs in the CAPA management system using the Value Stream Mapping method. The Value Stream Mapping method is a method to be able to see activities that are plus and minus, using visual capture. The type of research used is quantitative descriptive, primary data obtained from observation and interviews as well as the lead time of each process that takes place. After improvements were made using value stream mapping and fishbone diagrams and FMEA, it was found that the lead time for the CAPA management system had decreased, starting from registration to closing the normal process by 53%, if there were changes, cancellations, and extensions of CAPA by 91%, if there was a lack of evidence 53% and if there is an effectiveness assessment of 50%.

Keywords: *Lean Manufacturing, VSM, Compliance, CAPA.*