

Assessment of the Risks for Workers Using FMEA: A Case Study in a Pharmaceutical Industry

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Abstract

Safety is a relative quantity that is a function of the situation in which it is measured. This research was conducted in a well established pharmaceutical company in Bangladesh practicing GMP (Good Manufacturing Practice), which has a tablet manufacturing facility. Tablet manufacturing comprises a number of manufacturing activities and machineries. Each of these activities, requiring amalgamated interaction of man, machine, equipment and environment has the potential of producing unforeseen hazards. Therefore, analysis of risk is not only necessary here, it is also important to use an appropriate tool that can incorporate all the risk- producing parameters. The research work conducted here using a very effective tool named Failure Mode and Effect Analysis (FMEA), consisted of observing the works at different sections, breaking them down into sequential steps, noting the surrounding variables of each task, and using these data to perform risk analysis to find out the most hazardous works for the workers.

Keywords: Failure Mode and Effect Analysis (FMEA), Good Manufacturing Practice (GMP), Risk Analysis, Risk Matrix, Tablet Manufacturing