

Abstract

PT. Phapros Tbk is a pharmaceutical company under the PT. Kimia Farma, which has a vision and several missions based on the fundamental pillars of trust, and holds firmly to the core value of *AKHLAK*. This company produces OTC medications, generic drugs, prescription drugs, and medical devices. Thus, in producing various pharmaceutical products, specifically the Quality Assurance (QA) department, plays a crucial role in ensuring the quality of raw materials supplied by monitor actively their active suppliers. To ensure the supplier's credibility, efficient inspection schedules, and response to the misuse case of DEG and EG in drugs, the QA department is encouraged to create and compose a supplier qualification document based on the ICH Q9 Guidelines about Integrated Quality Management. Supplier qualification is a risk assessment tool to ensure the quality of supplied products before production. In composing supplier qualification document, data suppliers gathered are assessed based on the factors of severity, availability, probability, and detectability, and calculated using the Risk Priority Number (RPN formula). The calculation results will then be implemented in a risk assessment category to determine further actions for inspection. According to the obtained results from the internship, 122 suppliers are categorized as a high to very high-risk category, in which further actions of inspection are needed. Hence to maintain consumer safety and efficacy, the QA department is encouraged to plan an inspection schedule based on the results of the supplier qualification document, update the supplier's data regularly for data maintenance, and monitor audit frequency.

Keywords: PT. Phapros Tbk, Quality Assurance, ICH Q9, Supplier Qualification, Inspection