

ABSTRACT

CV. XYZ is a manufacturing company that produces spare parts for motor vehicles. As an organization of supplier spare parts, CV. XYZ important to determining quality of the product and develop product design. To improve the quality of their products and services, CV. XYZ who have a QMS (Quality Management System) ISO 9001: 2008 need to update to ISO 9001: 2015. In this standard was conducted of risk based thinking to anticipate the risks that might happen. Risk registers is documented information required as validation that the organization has been doing risk-based thinking.

This research focuses on the design of the Standard Operating Procedure (SOP) for the design and development of products by clause 8.3 of ISO 9001: 2015. The data collected in this research are potential data risks, profile and corporate structure, vision and mission of the company, the requirement clause 8.3 of ISO 9001: 2015, and the existing condition of the company. These data are then processed to produce the identification of gaps and the activity list. The activity list is used as input to the assessment process were then to be a risk register. Risk register as validation that the organization has implemented risk-based thinking. At the risk register contains information such as the results of risk identification, risk analysis how severe these risks occur, risks evaluation and treatment of selected risks. The results of the identification of gaps and the risk register as a design input in the form of draft procedure. Furthermore, the draft procedure to be improved by using Business Process Improvement (BPI) to obtain simplification process.

This research resulted procedure Product Design and Development of Product. In this procedure cover all stages of design process from the determination of the design input, design control in the form of review, verification and validation, as well as a review of the design output if compliance with the specified design inputs. Then, this research produce the addition of unit at the structure of organization to implement quality assurance systems.

Keyword : ISO 9001:2015, Risk Based Thinking, Standard Operating Procedure, Business Process Improvement