SUMMARY

AHMAD SENJAYA. Deviation Handling Model in the Production of Pharmaceutical Industry (Study case: PT XYZ). Supervised by ARIEF DARYANTO and SETIADI DJOHAR.

The pharmaceutical industry in Indonesia, has enormous potential in the next 10 years. The large number of people as the increasing awareness of public health and supported by the government’s program on national health insurance is a factor driving the growth of the pharmaceutical industry in Indonesia.

This study aims to develop an effective and efficient deviation handling model that used in the pharmaceutical industry (case study at PT XYZ). The AHP method is used to analyze the priority of deviation categories, which is used as the pilot for modelling. The period of data analyzed is data deviation of 2015 and 2016. Analysis of important factors in handling deviations is analyzed through in-depth interviews with stakeholders (Production manager, QA Manager and Head Quality).

The novelty of this research is the availability of technical and applicative model to handling deviation in the production of pharmaceutical industry. Today’s there is no pharmaceutical authority regulating technical guidelines for dealing with deviation in the production of pharmaceutical industry, currently available guidance is only general and non-applicable.

The AHP analysis identifies eight categories of deviations that are prioritized in construct a deviation handling model. The deviation handling model has been verified to provide more effective and efficient results in addressing the risks involved in an aberration.

Keywords: AHP, deviation handling model, pharmaceutical industry, risk management