Abstract

The release of drugs, narcotics, psychotropics, and precursors to the market should be controlled. The manufacturing process and distribution need to be supervised to ensure the safety and the quality of the product that is going to be marketed. Each country has authority bodies that are specifically formed to supervise and control the drug related product before and after it is marketed. Indonesia has Badan Pengawas Obat dan Makanan (BPOM) that released good manufacturing practice (GMP) as a regulation system for the release of drug related products. Growth of the drug industry in Indonesia always occurs, therefore, updates on GMP are occasionally needed. The materials for updates can be obtained by benchmarking more advanced countries as an insight. Additionally, comparison and review are made to manage the insights. As for the results, there are 5 points that differ between Indonesian current GMP and pharmaceutical inspection co-operation scheme (PIC/S) newly revised GMP. Furthermore, specific standards and radioisotope handling requirements need to be added to current Indonesian radiopharmaceutical GMP. Lastly, real-time release testing (RTRT) methods are beneficial methods that can be used to test product quality, however, information and requirements of their usage is still limited.

Keywords: BPOM, Benchmarking, Comparison and Review