Chapter 1

Introduction

1.1 Host Institution Description

Kalbio Global Medika (KGM) is a current Good Manufacturing Practice (cGMP) contract development manufacturing company that is located in Delta Silicon 3 Cikarang Industrial Estate. It is one of Indonesia's first and leading producers of biopharmaceuticals which was established in 2014 and officially inaugurated in 2018 by the President of the Republic of Indonesia, Ir. Joko Widodo. KGM is a division of PT Kalbe Farma, Tbk., the top healthcare company in Southeast Asia and Indonesia, and a part of the PT Kalbe-Genexine Biologics (KGbio) Group, a clinical-stage biotechnology company focused on providing biologics medical innovation to markets outside of the US or Canada, Western Europe, and China. With a focus on quality, innovation, and operational excellence, the vision of PT KGM is to be the best contract manufacturing organization (CMO) and contract development manufacturing organization (CDMO) in the region. The mission of PT KGM is to provide high-quality and easily accessible biopharmaceutical products in order to promote health for a better quality of life (KGM, n.d.).

KGM is an innovative CDMO that places a major focus on manufacturing or supplying medical raw materials and biological pharmaceutical products to both domestic and foreign markets. KGM provides the following services, including process development and optimisation for mammalian cell culture; production of protein and monoclonal antibodies for pre-clinical and phase I–III studies to commercial supply; a full range of support services from cell storage to full release; fill and finish with isolator technology for vial, pre–filled syringes, and cartridge including disposable pen assembly, blister packing through the final packaging; and quality control to ensure product safety. The organizational structure in KGM consists of a President Director, Research and Development Manager, Plant General Manager, Quality General Manager, Production Planning and Inventory Control Manager, Production

Drug Substance Manager, Production Drug Product Manager, Quality Control Manager, Quality Assurance Manager, Quality System and Compliance Manager, Engineering Manager, Purchasing Manager, and Human Resources General Affair Manager (KGM, n.d.).

1.1 Department Description

In the pharmaceutical manufacturing industry, the department responsible for carrying out quality control is the Quality Control (QC) department. The responsibilities of the QC Department are carried out at each stage of production, from raw materials, to final products including packaging material and intermediate products, in order to produce good-quality products (Yuwono & Widyastuti, 2016).

In PT KGM, there are 5 sub-division for the QC department, including: 1) Test Item Control and Project (TICO) division which is responsible for sample availability for testing conducted by the QC Department, 2) Raw Materials and Packaging Material (RMPM) division which responsible to check the quality of raw materials and packaging materials used in the production process, 3) Microbiology division which responsible to check the quality of products and materials for microbiological parameters, 4) Compliance division which responsible for product inspection process during the production process or to monitor product conformity with specifications and identify possible product deviations, 5) Finished Goods (FG) division which responsible to check the quality of intermediate products or materials and finished products that are obtained or will be used in the production process, by performing a physicochemical or biochemical assay and recording the result in a testing form. The work cycle in the FG division is divided into two shifts, which are morning shift and afternoon shift. The testing depends on the schedule and sample availability, but it is frequently that there are two or more testing in a day and for one testing there are at least three or more batches tested. In addition, the QC department is led by a manager who has responsibility for approving specifications, test methods, and quality control procedures. Each division is led by a supervisor who supervises the scientists and lab assistants.