Chapter 1

Introduction

1.1 Host Institution Description

Kalbio Global Medika (KGM) is one of Indonesia's pioneers of biopharmaceuticals that is a subsidiary of PT Kalbe Farma, Tbk. that drives healthcare suppliers in Indonesia and Southeast Asia, and part of PT Kalbe-Genexine Biologics Group, a clinical-stage biotechnology company dedicated to delivering biologics medical innovation. KGM is a current Good Manufacturing Practice (cGMP) biomanufacturing company with its current pipeline includes several biosimilars and novel biologics. Founded in 2014 and inaugurated officially in 2018 by the President of the Republic of Indonesia, Ir. Joko Widodo, PT KGM focuses on operational excellence, quality, and innovation to support the Indonesian government program for improving health by offering high-quality and accessible biopharmaceutical products. KGM is a Contract Development and Manufacturing Organization (CDMO) company that consists of several departments, including but not limited to Quality Control (QC), Quality Assurance (QA), Quality System and Compliance (QSC), Production (PD), Research and Development (R&D), Warehouse, and Engineering.

KGM offers a wide range of support services, starting from cell storage until the complete release. Moreover, KGM provides process development and optimization for mammalian cell culture, as well as the synthesis of proteins and monoclonal antibodies for pre-clinical and phase I to phase III clinical studies up till commercial supply. Fill and finish of packaging (e.g. cartridge, vial, prefilled syringe, disposable pen assembly, and blister packing) are also conducted in KGM by utilizing isolator technology. Furthermore, KGM offers QC toll-in service for biologics that are performed by qualified scientists to control and ensure the quality of the products fulfills all requirements.

1.2 Department Description

QC is a crucial operation in the pharmaceutical industry as it ensures drug safety, efficacy, and quality. It covers all phases of pharmaceutical production, starting from the inspection of raw materials up until the release of the drug product must meet the proper specifications. QC also applies proper documentation to support the conclusion of the final result and help in the identification of out-of-specification (OOS) results (FDA, 2014; Dispas et al., 2022).

The QC department of PT KGM is led by a manager and consists of five divisions with specific responsibilities that are led by supervisors. The Raw Material and Packaging Material (RMPM) division is responsible for inspecting the raw material that will affect the quality of the drug product. The microbiology division deals with testing that needs to be done using microbiological parameters (e.g. bioburden, endotoxin, and sterility tests). The Intermediates and Finished Goods (FG) division is in charge of testing the quality of intermediate and finished products, including stability study. In the case of OOS, the compliance division is responsible for coordinating the investigation of the root cause and the CAPA (Corrective Action and Preventive Action) identification with related personnel. All of the schedules related to the QC department are handled by the Test Item Control (TICO) and Project division. TICO is responsible for monitoring and distributing all of the received samples in QC to each division, including coordinating the project and commercial samples between QC and other departments, as well as outsourcing sample testing. TICO division also handles the schedule of routine sampling of raw materials, packaging material, water, pure steam, and compressed air which are crucial to ensure all production processes run smoothly. Moreover, TICO is in charge of managing the storage capacity of both routine and stability samples. After all of the required testing is completed, the TICO division is responsible for generating the final report in accordance with Good Documentation Practice (GDocP) and archiving it properly. The job desk of TICO also involves administrative tasks including, but not limited to preparing all forms needed in QC, registering the Request for Analysis (RFA) sent by the requestor, and performing the handover of closed Quality Control Analysis Report (QAR) to the related department.