

UNIVERSITI TEKNOLOGI MARA

**DEVELOPMENT OF DESIGN ADVISOR TOOLS
FOR SEPARATION PROCESS OF
BIOPHARMACEUTICAL PRODUCTION**

NURULHUDA BINTI ABDUL LATIF

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ABSTRACT

As for this research of designing advisor tool for the separation process of biopharmaceutical products, the software tool is programmed in MATLAB and the user interacts by means of a GUI which allows editing the parameters used for simulations in a friendly way. It is well known that the use of software simulators allows economizing time and money to evaluate the behaviour of systems. In this sense, we show a software tool using MATLAB that allows numerical values to be obtained displaying advises or options for the separation of the biopharmaceutical products. Plus, the use of this software tool allows qualitative comparison between the advisor tool of the Matlab and the simulation from SuperPro designer. The development of this inexpensive yet a big help that include the scope of ability to evaluate development options in terms of cost, yield and risk. Effective manufacturing productions are crucial as the demand of biopharmaceutical products are high and in need of scale up from laboratory based to financially feasible processes. The purpose are to develop a decision support tools should provide a user friendly interface between the user and the tool platform. The tool aids should help the user in visualising the simulation platform and facilitates the separation processes outlook. This computer aided should be able to help achieving the goal of changing in process capacity and formulate the models at different scale thus able to reduce the time involve in the process separation

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Biopharmaceuticals make up something like one-third about medications right now. Any therapeutically functional pill fabricated includes the uses of microorganisms by the bioprocessing skills are the biopharmaceutical products. In the manufacture of these biopharmaceutical products, multiple skills, and expertise as well as improvement and development of vaccines by means of biopharmaceutical require focused deliberations on many levels. The separation and purification of biopharmaceuticals are the ones with high cost and time consuming downstream processes. (Sekhon, 2010) For manufacture of high-volume, low value bulk pharmaceutical and biopharmaceutical- such as vitamins and antibiotics, bioseparation are essential to be used but the genetically engineered therapeutics products are extremely high in value though at very small scale. Both field require the same requirement where a large number of bioseparations needed to isolate the product to certain requirement and level of purity. This is important in the pharmaceutical industry that the product manufacturing is well regulated and observed. With the development of design advisor tool, the process in completing all the stages in ensuring that the products produces are effective and safe to use while avoiding the trial and error method is one great effort. (Bowles, 2000)

In the downstream processing of biopharmaceutical production, the separation process involves separation of biomass which is separating the biomass basically by centrifugation and ultrafiltration. In obtaining the highest yield of the product in the bioseparations, the parameters to consider and very important are the solubility, thermal stability and the separation thermodynamic. (Geankoplis, 2003) An advisor tool that can provide the outlook or the simulation of the process of the separation itself is very important to be able to choose the best ways and less costly productions. The advisor tools can be a simulation that can provide an evaluation of process and options from the process perspective and the cost by revealing and revise the process data thus helps the department that making the decisions in the manufacturing.