TAGUCHI METHOD IN BIOPROCESS ENGINEERING: *Case Studies*

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Case Study 5: Analysis of Process Capability and Quality of Monoclonal Antibody Production in Bioreactor

Maizirwan Mel, Mohd Ismail Abdul Karim, Faridah Yusof

1. Introduction

Since the advent of monoclonal antibodies (MAbs) from hybridoma cells in 1975, hybridoma technology has had a major impact on the scientific and research world. The demand for MAbs has increased considerably in recent years. MAbs are being used in in-vitro diagnostics, immunoaffinity chromatography, in vivo imaging and immunotherapy (Jackson, 1999; Freshney, 2000). While the demand for MAbs will remain primarily stable in other areas, it is projected that human therapy (primarily the treatment of cancer) will require large quantities of highly pure monoclonal antibodies, which can be conservatively estimated at 50 kilograms/year for each therapeutic MAb. The excessive costs of producing sufficient quantities of MAbs and the small yields from conventional technology are important factors in making research and development of cost effective large scale MAb production essential (Stoll et al, 1996; Zola, 2000; Mel and Yumi, 2004).