Characterization Services for Biopharmaceutical-producing Cell Line in Compliance with ICH Q5

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The cell substrates used in the production of biopharmaceuticals are defined as cell lines derived from microorganisms, humans, or animals. The validation of these cell lines is carried out in accordance with the Quality Q5 (Quality of Biotechnological/Biological Products) guidelines recommended by the International Committee on Harmonization (ICH). Despite the rapid progress in biopharmaceutical development developers face challenges due to the complexity of cell line characterization and the specialized nature of testing environments. However there is limited availability of characterizing services for cell substrates domestically, leading to dependence on foreign services. Consequently, there is an increasing need for the expansion of information and services related to cell line characterization. Therefore, our research institution aims to establish cell line analysis technologies for production cell lines and contribute to providing these services.

We conducted an evaluation of the cell substrate characteristics of biopharmaceutical production cell lines, assessing factors related to the mixing of different cell lines, foreign contamination, intrinsic factors, and molecular contaminants. Additionally, we confirmed the cell substrate characteristics of production cell lines and established a methodology for testing foreign contamination factors. Based on this foundation, we have established comprehensive empirical services to support international-level characterization of cell lines used in biopharmaceutical production.

Our research institute offers a distinctive service in Korea, providing cell line characterization without relying on foreign sources. This service enables time and cost savings, enhances stability and quality, strengthens international competitiveness, and ensures compliance with ICH regulations. Furthermore, by addressing the technological gaps in domestic biopharmaceutical development companies, our institution fosters the growth of the domestic biopharmaceutical industry. As a result, it enhances the competitiveness of domestic companies in the biopharmaceutical field and safeguards the sovereignty of the domestic biopharmaceutical industry.