生物製劑先導工廠潔淨室環境管理之研究

許榮炳,鄭美鈴,蕭炎泉
營建管理學系
建築與規劃學院
ycshiau@chu.edu.tw

摘要

Establishing a pilot plant for biological products must comply with all the relevant latest enactments proclaimed by the Department of Health, including Standards for the Establishment of Pharmaceutical Factory, Good Manufacturing Practice (GMP), GMP Validation Operation Standards, and Quality Control Regulations for the Bio-safety Level 3 Laboratories, etc. The establishment must meanwhile refer to the U.S. or EU regulations relevant to cGMP. It must also pass validations and factory inspections.Although the industry of biomedical sciences is characterized by high investment and high risk, it is currently one of the competiveness focuses of the technological developments in advanced countries. One after another, many countries have established organizations dealing with relevant policies and paid great attention to it.
This investigation takes advantage of the opportunity of building a pilot plant for biological products by the government to probe into the environment control operations in the clean rooms of the pilot plants for biological products. This piece of research is expected to make up for the information shortage as well as be the reference for the workers related to building the factories for biological products in

order to benefit the improvements of the control measures for the factory construction.
It is also expected to enhance the domestic understanding on the operations relevant to
the establishment of the factories for biological products.

關鍵字：Biological Products Factory, Clean Room