





第**44**回

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演題

Recent advances in the Safety Evaluation of Influenza Vaccine by Multiplex Gene Detection System in a Preclinical Study and Lot Release Test

バイオマーカーを用いた 次世代ワクチン安全性評価法の開発

演者

水上 拓郎 先生

国立感染症研究所 血液·安全性研究部

National Institute of Infectious Diseases

日時

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場所

札幌コンベンションセンター Room C (中ホール B)

要旨

accines are one of the most beneficial and universal tools for prevention of infectious disease. Unlike other pharmaceutical products most of the vaccines were mainly derived from pathogen itself, thus the safety and quality of vaccines is strictly evaluated in the preclinical phase of trials. In addition, after the marketing authorization, every vaccine lot must be tested by the National Control Laboratories (NCL) according to the guidelines published by each country and WHO. In this seminar, we will focus on the development process and quality control of vaccines. In addition, we will introduce the recent advances in the vaccine platform and new method for evaluating vaccine safety using toxicogenomic approaches. We recently developed a systems biological approach to vaccine safety evaluation where identification of specific biomarkers in a rat pre-clinical study evaluated the safety of influenza vaccines. Our identified 20 biomarkers could evaluate the safety, batch-to-batch and manufacturer-to-manufacturer consistency of seasonal trivalent influenza vaccine using a multiplex gene detection system (Quanti Gene Plex). These biomarkers will facilitate the future development of new influenza vaccines.

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