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Consideration on non-clinical studies required for therapeutic peptide vaccines

Mineo Matsumoto

Pharmaceutical and Medical Devices Agency (PMDA), Japan

While the guideline of non-clinical studies for prophylactic vaccines against infectious diseases was publicized in 2010, the one for therapeutic vaccines has yet to be established in Japan. The concept of the non-clinical studies that are required for therapeutic vaccines differs from that for prophylactic vaccines, due to the differences in the risk-benefit balance as well as the mechanisms of actions between them. Among the therapeutic vaccines, the development of the vaccines that make use of peptides as the active ingredients has been the most conspicuous in our country thus far. We consider the necessary non-clinical studies for therapeutic peptide vaccines as follows. 1) The main safety concern is related to the immunity response that might exert its effect on normal sites that express the target antigens. Therefore, the identification of those possible target sites with use of in silico data, etc., is important. 2) Due to the strong dependence on HLA, it is very unfeasible to replicate the immunity responses in animals. Therefore, the required animal studies are characterized as those detecting 'off-target-', not on-target toxicity. 3) Considering the higher number of administration than prophylactic vaccines, the concern for local toxicity, especially for the cases where plural administrations are conducted onto a single site, is considered high. The off-target toxicity studies need to be designed from the aspect of detecting this 'accumulative local toxicity'. This work was conducted by the research group aiming at international harmonization of non-clinical guidelines for vaccines, funded by Ministry of Health, Labour and Welfare.

Biography

M. Matsumoto has completed his Ph.D at the age of 29 years from Tokyo University and postdoctoral studies from University of California Irvine and Mitsubishi Kagaku Institute of Life Sciences. He has been a toxicological reviewer (principal reviewer) of pharmaceuticals including vaccines in PMDA, the Japanese regulatory agency, since 2008

matsumoto-mineo@pa.go.jp