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Analytical methods and biological products

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There is a gap in the knowledge of analytical methods and validation. Many researchers (in particular academic groups) focus on discovery of new biological products without considering the relevant compliance and regulatory guidelines. Therefore, the potential candidate leads nowhere pass the lab bench! Validation of methods is one of the major GMP compliance required by regulatory agencies. Validation of analytical methods during and after process development is necessary to demonstrate that the analytical methods are fit for their intended purpose. All relevant data obtained during validation should be included in the Investigational New Drug (IND) application for clinical trials. One of the main guideline for validation is the International Council for Harmonization (ICH Q2A) which discusses the characteristics that should be considered during validation. This workshop will review and discuss the specific recommendations for validation of analytical procedures.

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Vaccination with self-adjuvanted protein nanoparticles provides protection against lethal influenza challenge

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Subunit vaccines are generally less immunogenic than whole organism vaccines. One approach to reduce this deficiency is the development of repetitive antigen displays. One of the most promising repetitive antigen displays is our Self-Assembling Protein Nanoparticle (SAPN). Based off of coiled-coil oligomerization domains our SAPNs can self-assemble into spherical particles that mimic the size and shape of small viruses and are decorated on their surface with antigens. We have applied the SAPN technology to the development of a universal influenza virus vaccine. By incorporating two conserved antigens (M2e and Helix C) we aimed to generate a vaccine candidate that is broadly protective not only through different seasons but also against different subtypes. One of the most important considerations in vaccine development is adjuvant formulation. We have designed and implemented a new technology that incorporates the TLR5 agonist flagellin into the SAPN. Flagellin is an established adjuvant that is known to induce increased antigen processing as well as increased humoral and cellular immune responses. By adding flagellin to our SAPNs we have generated Self-Adjuvanted SAPNs. We have applied this technology to the development of universal influenza vaccine. In this study we demonstrate that addition of flagellin does not affect the ability of SAPNs to self-assemble, nor does it change the size or shape of the SAPNs. Self-Adjuvanted SAPNs are able to stimulate TLR5 in vitro in a dose dependent manner. Specific Pathogen-Free Chickens vaccinated with the Self-Adjuvanted-SAPN induce significantly higher levels of antibodies than unadjuvanted-SAPNs. Antibodies from chickens vaccinated with the Self-Adjuvanted-SAPNs are cross-neutralizing towards group-1 influenza strains in the in vitro experiments. Upon immunization with Self-Adjuvanted-SAPN mice were completely protected against a lethal challenge with A/human/Puerto Rico/8/1934 (H1N1). Our data indicate that we have generated a Self-Adjuvanted-SAPN that has a great potential as a universal influenza vaccine.

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