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Novel quadrivalent influenza vaccine produced in *E. coli* elicits protective HAI titers in healthy adults

We have produced a novel, quadrivalent influenza vaccine candidate comprising the globular head domain of the HA antigen fused to *S. typhimurium* flagellin. Vaccine fusion proteins can be produced quickly and with high yields in standard production strains of E. coli. Due to the presence of flagellin, which serves as an innate immune stimulator via TLR5, the seasonal vaccine does not require exogenous adjuvant. Optimal formats of HA globular head length and insertion sites within flagellin were selected by a panel of *in vitro* and *in vivo* methods, including the generation of HAI titers in multiple animal species. As the product consists of soluble monomeric proteins, we have also developed a suite of novel potency methods. The release and stability assay package measures the concentration of the vaccine components by reversed phase UPLC, the biological activity of both HA and flagellin moieties by Capture ELISA and the presence of neutralizing epitopes by a Neutralization Inhibition Assay (NIA). A rabbit model of toxicology has been developed which is sensitive to the innate stimulation of flagellin and generally predictive of the appearance of clinical symptoms by vaccine format and dose. A prototype quadrivalent vaccine was tested in young healthy adults. Total dose levels of 8-12 mcg (2-3 mcg per component) were found to be safe and immunogenic. Seroprotection levels varied from 91-100% across the 4 strains. Serocoversion rates ranged from 71-100% for subjects with starting titers <40.

Biography

Scott Umlauf has completed his PhD from the University of Wisconsin-Madison and carried out Postdoctoral studies at the National Institutes of Health in the lab of Ronald Schwartz. He is currently the Senior Director of Product Development at VaxInnate Corporation, a biotechnology company which combines innate immune stimulation with disease antigens to generate novel fusion protein vaccines.

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