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Stabilization and drying of vaccines for novel delivery

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Abstract

Stabilizing, gently drying, and individually packaging microparticles of vaccines offers important advantages in terms of efficacy and safety of vaccine administration. For example, aqueous suspensions of Edmonston-Zagreb measles vaccine stabilized with myo-inositol, then gently dried at 50 – 60 ºC by Carbon Dioxide Assisted Nebulization with a Bubble Dryer® (CAN-BD), yields microparticles with 1-5 microns aerodynamic diameter. These are then effectively delivered from individually sealed blister packs into aerosol bags, the aerosol of which can be delivered throughout respiratory tracts without reconstitution in water. The microparticles deposit on the moist surfaces and are rapidly dissolved to initiate development of a mucosal immune response. Within a few days, after inhalation of the dry powder aerosol vaccine by rhesus macaques, measles virus-specific antibodies were detected, and after 13 months the macaques receiving aerosols from reservoirs attached to masks were fully protected when challenged with wild-type measles virus. The immune response was at least as robust as that from subcutaneous injection of liquid vaccine into non-human primates. Phase I clinical trials in 60 adult human volunteers were started in March 2012 and no serious adverse events have been observed to date (March 2013). The delivery of dry powder aerosols eliminates the need for water for reconstitution to be supplied or carried to the field as is necessary for conventional reconstitution of freeze-dried vaccines. Contamination of multi-dose vaccine vials is avoided and the hazards of accidental needle sticks and dirty needles are avoided by mucosal aerosol administration. Other novel dry vaccines, e.g., HepB are being developed

Biography

Prof. Robert Sievers, at the University of Colorado Boulder Department of Chemistry and Biochemistry and CIRES, and affiliate of the Biofrontiers Institute, has co-authored approximately 200 publications, which have been cited in more than 5,000 publications by other groups. He has been awarded 41 U.S. and foreign patents. In 2002, he founded Aktiv-Dry LLC, a spin-out company from CU developing needle-free vaccine delivery systems, DPIs, and new formulations of stable vaccines, anti-virals, and antibiotics. He also co-founded Sievers Instruments, Inc. in 1984, which was acquired by Ionics, and subsequently by GE Analytical. He has mentored 40 Ph.D. students.