Viral diseases offer a major challenge to vaccine development because of the complex nature of virus structures and the large size of the virus particle needed to generate an effective immune response. Classical approaches to develop antiviral vaccines have required the use of attenuated (or inactivated) live viruses produced in cell culture. Although this approach has been widely successful and is still in practice, not all viruses are amenable to replication in cell culture, particularly at commercial scale. In appropriate expression systems, recombinant viral proteins of modest size (≥24 kDa) have been produced that self-assemble into icosahedral virus-like particles (VLPs) whose surface is immunochemically comparable to that of the actual virus – this has been a major success story in contemporary vaccines. This talk reviews the scientific challenges in the production and characterization of VLP vaccines, and the data necessary to provide assurance of comparability for manufacturing changes.

Michael W Washabaugh, MedImmune, USA

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wshabaughm@MedImmune.com