Mark Reid, J Vaccines Vaccin 2015, 6:3
http://dx.doi.org/10.4172/2157-7560.S1.024

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5th Asia Pacific Global Summit and Expo on
Vaccines & Vaccination

July 27-29, 2015 Brisbane, Australia

Key steps in moving a vaccine from proof of concept in mice to human clinical trials

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Key practical steps for moving a vaccine candidate from laboratory grade research material and animal proof of concept data to human clinical trials is discussed. Key considerations include manufacturing considerations (to Good Manufacturing Practice, GMP) and the capacity to make the vaccine at industrial scale with long stability periods; Good Laboratory Practice (GLP) toxicology studies, species selection and study types will be discussed in addition to the design of First in Human studies to demonstrate safety, tolerability and immunogenicity of early vaccine candidates. Key business considerations for the investigator "pitch deck" are also reviewed as the first question asked by large, vaccine companies when considering a new vaccine is: "can this vaccine be sold".

Biography

Mark Reid is the Director of BioDesk and Regulatory Affairs at Clinical Network Services (CNS) Pty Ltd and has a broad background in Regulatory Affairs with his main area of interest being anti-infective drugs and vaccines. Mark is a virologist by training and has worked on nine anti-infective drug programmes and 12 vaccine programmes including genetically modified organism (GMO) vaccines. One vaccine is now registered in Australia, India and Thailand. Prior to working in the pharmaceutical industry, Mark setup a virological laboratory under ISO 17025 (1999) and ISO 9001.

Mark has a BSc (hons), MMedSci (drug dev) and MBA. Mark is also a certified member (by examination) of the Regulatory Affairs Professionals Society for both European and US filings.

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