Veterinary Vaccine R&D – A commercial Perspective

Dr Michael.J Francis,
MSD Animal Health.

Brief synopsis of a presentation given at the First UK Veterinary Vaccinology Forum Confreence, ICC, Birmingham on the 16th Feb 2015

In 2013 the total Animal Health Market was worth $23 billion globally with a modest growth rate of 2%. This was segmented by vaccines (26%), pharmaceuticals (62%) and medicinal feed additives (12%), and the species division was split between food animals (59%) and companion animals (41%) (Data from Vetniosis, see http://www.ifahsec.org/our-industry/). A number of market trends (including an increasing global demand for safe food sources, increased global mobility, growing consumer interest in the environment and "green" approaches, enhanced regulatory standards, need for greater customer convenience and enhanced value, and new emerging diseases with zoonotic potential) has led to an increased focus on biological control measure utilising vaccination. Such vaccines will have to address improvements in safety, efficacy and stability, along with novel delivery, ease of administration and cost efficient manufacture.

The commercial product development process is dependent on good communication and input from the target markets. This ensures that unmet needs can be identified and that vaccines can be designed with the end user in mind. A new development project requires a clear Product Profile or Summary of Product Characteristics. This enables the R&D Project Leader to develop a plan for the duration of the project with associated milestones and timelines. The new product development process can be divided into clear phases such as Discovery, Feasibility, Development, Registration, Launch and Post-launch support. Discovery often occurs within an academic environment but as a project moves into feasibility and on into full development a commercial organisation will be required to take on a leading role. It is important to involve experts with a knowledge of commercial regulatory requirements very early in a vaccine's development, since this will avoid the possibility of encountering pitfalls which can render the vaccine unfit for registration. An example of this would be the use of components of animal origin such as bovine serum without having extensive knowledge of their origin, associated full documentation and certification for freedom from Transmissible Spongiform Encephalopathies (TSEs).

The development process for a veterinary vaccine typically takes between 3 to 6 years in total depending on the country in which the product is being registered, the technology being used and the target species. The regulatory data package generally focuses on aspects of the product's Quality, Safety and Efficacy, and the detail will depend on the regulatory authority involved in the registration. It is important to consider the recommended dose and recommended route of administration for each species and category of animal in which the vaccine is intended for use, including animals of minimum age. In Europe the process is governed by the European Medicines Agency (EMA) (http://www.ema.europa.eu/ema/) and in the US veterinary vaccines are regulated by the USDA Centre for Veterinary Biologics (CVB) (http://www.usda.gov/wps/portal/usda/usdahome). Another valuable source of product testing requirements are pharmacopeia monographs and within Europe these would be found within European Pharmacopoeia (https://www.edqm.eu/en/european-pharmacopoeia-8th-edition-1563.html). Other authorities across the world have the own regulatory bodies and specific testing requirements.

New vaccine technologies often find their first application within veterinary vaccines. They might include novel delivery systems, novel adjuvants/immunostimulants and recombinant technologies. The EMA has regulatory guidelines specifically directed at Live Recombinant Vaccines and DNA veterinary vaccines (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000374.jsp&mid=WC0b01ac058002ddc5). There are now many examples of registered commercial Veterinary Vaccines derived though biotechnology from the early 1980's onwards, involving prokaryotic and eukaryotic antigen expression, sub-unit delivery, viral vectors, chimeric antigens, virus like particles (VLPs), genetic attenuation, DNA delivery, and plant expression. However, in spite of this significant degree of innovation, the majority of new vaccines are still based on conventional inactivated and attenuated approaches.

In conclusion, when developing a new vaccine it is important to consider the market needs, carefully define the product profile and obtain commercial input throughout a vaccine's development. One should also consider incorporating novel features to provide added value, end user benefits and customer convenience. Finally it is necessary to be adaptable and quick to respond to change through the development process.