

**DuPont Pioneer innovationLEADER of the Year Award
Application**

Harrisvaccines

1. Originality of the innovation(s): Is this a completely new concept/idea/process or the re-imagining of an existing one? Was it developed independently or in cooperation with others?

Ames, Iowa-based Harrisvaccines is unlike any other animal vaccine producer in existence today. Its vaccine production method is unique in its development, its scientific foundation, and its future application in the fight to protect the United States from the impact of economically devastating animal diseases. The Harrisvaccines method makes the development of vaccines safer, vastly more efficient, quicker, and more efficacious.

Harrisvaccines employs exclusive SirraVax RNA Particle Platform technology that utilizes the genetic sequence of a virus, in an electronic state (series of As, Cs, Ts, and Gs), to create vaccines. No live pathogen (viral or bacterial) is needed for this process – an extremely unique production characteristic and a major biosecurity benefit. Its custom vaccines are also tailored to be farm or region-specific – dramatically improving the effectiveness of the vaccine, as many viruses mutate or emerge into tens or hundreds of different variant strains. Harrisvaccines' technology also reduces the time needed to produce a vaccine, creating it in just four weeks as opposed to the 10 – 12 months it often takes using traditional methods. As diseases are constantly evolving, this is crucial to containment and eradication efforts.

Harrisvaccines scientists, led by Founder and President Dr. Hank Harris, were the first to apply the SirraVax RNA technology to animal vaccine manufacturing in this way and Harrisvaccines holds exclusive rights to the platform for livestock and companion animal products, worldwide.

2. Impact of the innovation(s): Did this innovation meet an unmet need? How has it affected a specific industry and/or the public at large? If internal, what impact has it had on the processes and efficiencies of your organization?

The United States is under constant threat of the introduction of foreign animal diseases by emergence as natural phenomenon, contamination of imported products, or by agro-bioterrorism. Few dynamics pose a larger threat to the country's agricultural economy and food supply, and therefore, national security.

Harrisvaccines is producing solutions for some of the most economically devastating foreign animal diseases in the world. These diseases include: Foot and Mouth Disease, Swine Influenza, Porcine Epidemic Diarrhea Virus, Porcine Reproductive and Respiratory Syndrome Virus, Rotavirus, and Classical Swine Fever.

Harrisvaccines was the first to produce an H1N1 vaccine for pigs in the face of the 2009 pandemic outbreak that swept across the nation. Then, in 2014, Harrisvaccines became the first company in the United States to receive a conditional U.S. Department of Agriculture (USDA) license for a Porcine Epidemic Diarrhea Virus (PEDv) vaccine. PEDv causes diarrhea, vomiting, and dehydration in hogs, and significant (nearly 100 percent) mortality in baby pigs whose immune systems are weak. Although PEDv has been present in Europe and Asia for many years, 2013 marked the first time PEDv entered the United States. By 2014, outbreaks had occurred in more than 30 states, resulting in the death of more than 8 million piglets. Without a doubt, this is the most impactful livestock disease in recent decades – causing pork prices to soar and supply to be short.

Regulatory agencies, industry officials, and farmers nationwide were not prepared for a PEDv outbreak of this magnitude. Harrisvaccines was at the forefront of the fight to halt the spread of the disease, thanks to their rapid-response technology.

Beyond PEDv, Harrisvaccines is working to develop solutions for additional diseases that traditional vaccines have been unable to adequately tackle. Harrisvaccines has worked with the Department of Homeland Security on Foot and Mouth Disease (FMD) in swine and cattle and Classical Swine Fever (Hog Cholera) in swine. These vaccines are currently being tested at Plum Island. Preliminary efficacy data show significant protection – in some cases, 100% protection.

3. Commercial impact of the innovation(s): Has the innovation gone to market? What financial evidence or market acceptance information does the innovation have to support new value for the end user? What is the quantifiable evidence of success?

While Harrisvaccines has several vaccines on the market for various diseases and animal species, their PEDv vaccine – *Porcine Epidemic Diarrhea Vaccine, RNA* – has certainly been the most impactful. Harrisvaccines' PEDv vaccine has become a cornerstone of its business. In just the first three quarters of 2014, Harrisvaccines sold over 1.8 MM doses – a sum amounting to half of the company's total doses sold and around 60 percent of revenue over that time period.

Impressively, nine of the top ten swine producers in the country are now utilizing Harrisvaccines product to control PEDv outbreaks in their operations. The product has also been shipped to five Canadian provinces, Mexico, and the Philippines, while other countries continue to work with Harrisvaccines to get the PEDv and other vaccines exported across the globe.

Harrisvaccines has also expanded by doubling in personnel (from 20 full-time equivalents in 2013 to 45 in 2014). Additionally, we are in the process of adding several thousand square feet to our USDA manufacturing facility by early 2015.

4. Culture of innovation: Does the individual or company promote an atmosphere conducive to innovation? Have they consistently been a leader in their field when it comes to innovation?

Harrisvaccines' SirraVax platform is more than the disruptive RNA Platform technology; it is a disruptive business model because we can rapidly develop and commercialize custom-tailored, 100 percent matched vaccines for livestock producers at a competitive economic price. This increases producers' bottom line, improves herd immunity, and safeguards human health from emerging zoonotic diseases.

Furthermore, company founder Dr. Hank Harris' impact on the global biosciences industry extends beyond his work with Harrisvaccines. Throughout his career, Dr. Harris has focused on issues that pose a threat to food security, animal health, and biosecurity around the world. For example, in the 1980s, Dr. Harris hypothesized and developed protocol for multi-site pig production. This practice was adopted worldwide within years of its introduction, and continues to save producers and consumers billions of dollars each year.

Harrisvaccines also promotes innovation in a unique way via their company culture and atmosphere. Harrisvaccines truly believes in young talent and fresh ideas and employs dozens of recent graduates from Iowa State University, among others. They have created an open office environment that fosters creativity and allows employees to reach their full potential.