

O14 was a very rough year for the swine community with the outbreak of Porcine Epidemic Diarrhea – a deadly virus that took the lives of 8 million piglets across the United States and devastated the pork industry. The epidemic hit virtually overnight, and with vaccines taking months or even years to develop, the outlook appeared grim – to most. Harrisvaccines responded immediately, and using its patented SirraVaxSM technology to analyze the gene sequences of PED, the company was able to commercialize a vaccine (via veterinary prescription) in just four months. Then, nine months later, it became the first company in the U.S. to gain conditional licensure from the USDA. USDA-licensed *Porcine Epidemic Diarrhea Vaccine, RNA* was administered to female pigs right before they gave birth, and provided essential protection to the piglets.

PHASE III SUCCESS

Went from selling 1 million doses of vaccines in 2012 to selling 5-7 million doses a year currently.

AGENCIES

SNAPSHOT

lowa-based Harrisvaccines rapidly responds to new diseases as they emerge - developing and manufacturing custom, life-saving vaccines for livestock

HARRISVACCINES

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"We are unique in that we can develop new vaccines and we only need about 4-6 weeks production time, which is unheard of in this industry," explains Joel Harris, Head of Sales & Marketing for Harrisvaccines. "All we need is the genetic code of the virus to start vaccine production; it is similar to binary code – all viruses have an RNA code that we dissect and analyze and that allows us to start production."

Perhaps what paved the way for a swift U.S. Department of Agriculture (USDA) conditional approval was the success Harrisvaccines had in protecting against the Swine Influenza Virus (SIV) five years earlier. The vaccine developed was initially designed to combat H1N1, but has been continually altered due to the fact the virus is constantly mutating. In September 2012, Harrisvaccines was granted a full USDA license for its *Swine Influenza Vaccine, RNA*, marking the first time its SirraVaxSM RNA Particle technology had received a full USDA license.

To produce any of their vaccines, the company collects saliva, blood, or tissue samples from animals, which are then sent to state or private diagnostic labs to extract gene sequences. The lab sends gene-sequencing codes electronically to Harrisvaccines, providing the company with the blueprint for the pathogen strain on that particular farm. These sequences are then "plugged in" to the platform to rapidly develop customized herd-specific vaccines. Disease pathogens, or live viruses, never enter Harrisvaccines' facility, so safety and regulatory issues faced by its competitors are avoided.

Once an animal is injected with the vaccine, the RNA particles target the dendritic cells, which are involved in stimulating immunity. Each RNA particle enters one cell in the animal and then produces the protein encoded by the Gene of Interest. The immune system of the animal recognizes the protein and develops a protective response against the real pathogen.

The company's technology extends from pigs and poultry to dogs, horses, shrimp, and more. Avian Influenza (H5N1) has been a hot topic in the agriculture realm as of late, killing more than 45 million birds all across the United States since spring of 2015. Harrisvaccines is one of only a few companies that have developed a vaccine, which is currently awaiting approval from the USDA for licensing and stockpile funding. Canine Influenza (H3N2) is another disease of note – a highly contagious form of influenza that infects nearly every dog that is exposed to the pathogen and causes respiratory issues, pneumonia, and even death. A recent outbreak occurred in April 2015, and has consequentially spread to multiple states throughout the nation. Harrisvaccines used its cutting edge SirraVaxSM RNA Particle technology to create a Canine Influenza vaccine within weeks of the outbreak. This vaccine is also currently awaiting USDA approval.

Harrisvaccines' relationship with USDA started back in 2008 with its participation in the SBIR program. With a business model that was truly unique, agencies didn't have a "box" to put the company in, but completing the SBIR program was a way to show government officials the potential of the company.

"SBIR provides the opportunity for unique technologies to get a footing," says Harris. "It is very hard to pitch an idea to angel investors and convince them that this complex system has everyday applications. So when you have SBIR projects that are reviewed by scientists and researchers in your field, they get it, and you can develop a commercialization plan."

Another advantage is being located in the state of lowa. The founder of Harrisvaccines, Dr. Hank Harris, D.V.M., is an emeritus professor of Animal Science and Veterinary Medicine at lowa State University, and the company's headquarters are located right in the college's research park. The University has been key in supporting the company and as such, Harrisvaccines hires a steady pipeline of talent from the institution. Harrisvaccines has also received lowa Economic Development Authority support and the lowa Farm Bureau is a lead investor in the company. Additionally, the USDA regulation headquarters are located 10 minutes away, providing easy access for government officials to tour the facilities or attend in-person meetings.

With several more vaccines underway, and demand for its patented technology creating buzz in the heartland, Harrisvaccines is proving that life-saving innovations can be developed quickly, and on-demand.





LEFT Harrisvaccines manufactures every innovation in the state of Iowa, within its USDA-licensed facility. **RIGHT** Harrisvaccines' *Porcine Epidemic Diarrhea Vaccine, RNA* was administered to female pigs right before they gave birth, and provided essential protection to piglets during the outbreak of PED.