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Schering-Plough Animal Health
EXPERTISE...COMMITMENT...VALUE

GETTING IT RIGHT

Millsboro's experience, investment and technology set new industry standards for quality coccidiosis vaccines

The soaring demand for coccidiosis vaccine in recent years has pushed manufacture of the product to a new level of sophistication.

"The heat's been on to meet the increased demand for Coccivac products," says Larry Manogue, site manager at the Millsboro, Del., plant where Schering-Plough Animal Health Corporation manufactures the live coccidiosis vaccine.

"Our challenge has been to produce more vaccine while continuing to provide poultry producers with a pure, safe, high-quality and efficacious product. It's been a welcome challenge that we've been able to meet, though, due to support from corporate headquarters and a strong foundation of experience here at the plant," he says.

Major expansion

In 2000 and 2001, Schering-Plough Animal Health initiated a \$2 million upgrade at Millsboro. It is now in the planning stages for an additional investment in Coccivac production.

"We needed to expand our production capacity. We increased the square footage and renovated to improve efficiency as well as biosecurity. New equipment — some of it customized — was purchased. Meticulous planning and procedures were a long time in the making," Manogue says.

The physical improvements are many within this USDA-approved facility dedicated to antigen production, and include custom-designed bird cages and physical segregation of critical production stages, he says.

Experience counts

"We also have huge experience and that counts for a lot," he says. Over 25%



Each coccidia species used in coccidiosis vaccines is grown in a separate group of birds. Birds are housed within a facility dedicated to antigen production and each group has its own room.

of the Millsboro plant employees have more than 25 years experience in poultry vaccine production. The average staff person has nearly 18 years experience in the field.

"There's no question that we have the most experience in the industry producing coccidiosis vaccines, and that translates into a more reliable product for end users," Manogue says. "That's made it easier to move forward."

Additional expertise comes from Graham Knight, the production supervisor at Millsboro. He transferred from Schering-Plough Animal Health's plant in Harefield, UK, where he worked with the Paracox line of coccidiosis vaccines, which are approved for use in Europe, the Middle East and parts of Latin America. Knight also underscores the importance of experience coupled with modern technology.

"The product concept for coccidiosis vaccination isn't new — coccidiosis vaccination is about 50 years old — but experienced technicians bring continu-

Photos by Lisa Helfert

Technicians Sue Toomey (front) and Elsie Alexander prepare to treat harvested oocysts with an inactivant, one of several steps taken to ensure the purity of coccidiosis vaccines made at the Millsboro plant.



ity and consistency to the final product,” he says. “Our coccidiosis vaccines are up-to-date due to all the knowledge we’ve accumulated about coccidia over the years coupled with modern approaches to manufacturing.”

As an example, he cites mechanization of the process used to harvest oocysts — the infective stage of *Eimeria* organisms contained in Coccivac that

stimulate the natural immune system of birds. Mechanization has helped standardize procedures and enhanced the yield and quality of oocysts, he says.

“The experience and judgment of technicians remain important, but mechanization makes the process more reproducible,” Knight says. “Reproducibility helps ensure that the results will be consistent from batch to batch.”

Coccivac production

Experience and technology set the stage for the real work at Millsboro — the tedious day-to-day task of producing coccidiosis vaccines — and enable the production team to accommodate complications that are inherent to coccidiosis vaccine production, Knight says.

One challenge is the nature of various coccidial oocysts of *Eimeria* species, which each reproduce at a different rate and time. “Theoretically, you could inoculate a bird with different components, but you could not accurately tell how many oocysts of each will be there for harvesting later.” This means that to produce one dose of finished vaccine, each vaccine component has to be produced separately because of variations from species to species, he continues.

“Similarly, the different species of coccidial oocysts that must go into coccidiosis vaccines to ensure that birds in the field are protected cannot be easily differentiated under the microscope, even by experienced technicians. “Once blended, you can’t tell precisely one species from another, which complicates quality control testing,” he says. If you don’t get the right balance, the final product will be compromised and vaccinated birds may not be completely immunized against one or more *Eimeria* species,” according to Knight.

To solve this problem, each species is grown in a separate group of birds housed in the antigen-production facility. Each group has its own dedicated room, Knight says. “With dedicated



Production Supervisor Graham Knight checks oocyst antigens, which are stored in a walk-in cooler before blending.

rooms and GMP controls we can guarantee the purity of each species.

“We inoculate one group of birds with one coccidia species. The resulting output is collected, then we recover the parasites from the feces of infected birds,” he explains. “We want different numbers of oocysts for each species to make Coccivac. Ultimately, the oocysts are blended, but we grow them individually.”

After blending, each serial of a Coccivac vaccine has the exact same number of infective oocysts for each species. Different species of coccidia have different life cycles and varying levels of shedding, and the balance of the various species must be just right to enable effective coccidiosis control with vaccination, Knight says.

In fact, the USDA, which regulates vaccines, has approved the Coccivac formulation based on the results of extensive testing and field trial data. However, the actual concentration of oocysts of each blended lot may differ, which is why the color of the coccidiosis vaccines may differ among lots, he notes.

Quality assurance and control

Manufacture of quality coccidiosis vaccine requires not only a commitment to well-designed production procedures, but to a rigorous quality assurance and control program, which, for Schering-Plough Animal Health’s Millsboro products, is managed by Mr. Ed Walczak.

“Quality *assurance* is a wide-ranging concept that covers all matters that affect the quality of the vaccines from production to labeling and includes extensive documentation,” he explains. “Quality *control* is part of quality assurance and is concerned with sampling, testing and generally making sure that the vaccines fulfill all quality requirements.

“We have always had stringent written procedures for ensuring quality. Testing is conducted at every step of the production process. Harvested bulk



Cleanliness at every step is crucial to production of high-quality coccidiosis vaccines. Here employee Lenny Jenkins thoroughly hoses down chicken coups before sterilization.

material is tested for purity and sterility; individual materials that go into the vaccines are controlled, and every completed batch of vaccine is thoroughly tested before it goes out the door, Walczak says.

“In fact, every single completed batch of vaccine is tested for potency and purity. Each is also safety tested in birds at an increased dose level,” he



Coccidiosis vaccines are tested for sterility after they are formulated and bottled. Technician Lori McKamey rehydrates coccidiosis vaccines to field strength and uses them to inoculate plates to test for bacteria and fungi.

An Inevitable Change

Coccidiosis vaccination is on the upswing because the poultry industry is ready for a change in the way it controls coccidiosis, says Dr. Rick Phillips, director of poultry technical services for Schering-Plough Animal Health.

Several emerging factors have primed the poultry industry for change, he says. One is the growing resistance of coccidial organisms to the in-feed anticoccidials traditionally used to control coccidiosis. In addition, studies have emerged demonstrating that coccidiosis vaccination yields equal or better results than birds receiving traditional in-feed anticoccidials when a severe or drug-resistant field challenge is present.

“In other words, coccidiosis vaccines have proved to be a viable alternative to conventional in-feed anticoccidials,” Phillips says.

More poultry producers are turning to coccidiosis vaccination due to public demand and the so-called green movement; more consumers want birds raised as naturally as possible with fewer drugs, a trend that took hold in Europe a few years ago and is now emerging in the United States. Vaccination enables producers to control coccidiosis by initiating natural immunity instead of by using drugs, he says.

Spray Cabinet

The advent of the spray cabinet also has played a role in the proliferation of coccidiosis vaccination, Phillips continues. The device enables 100 chicks at a time to be vaccinated, which has made administration of coccidiosis vaccines easier and faster than eye administration. The cabinet ensures a more efficacious outcome than water administration or administering the vaccine on feed because it provides uniform distribution, he says.

The result of increased use of coccidiosis vaccination has been a five-fold increase in coccidiosis vaccine sales for Schering-Plough Animal Health between 1998 and 2001 and further growth is occurring, he says.

Coccivac vaccines include Coccivac-B for broilers and Coccivac-D for breeders and layers.



Technician Stacy Clavette checks coccidiosis vaccines for mycoplasma, which is not a government-required test but one that the Millsboro plant conducts anyway for added insurance that the product is pure.

says. “Our customers should be confident that the product they buy is effective, safe and consistent from batch to batch. The last thing they need to be worried about is vaccine quality.”

Extra testing

Although Millsboro strictly adheres to USDA testing requirements, it goes the extra mile, Walczak says.

For instance, Coccivac is checked for mycoplasma, which is required by the USDA for some poultry vaccines though not coccidiosis. Millsboro nevertheless conducts controlled 24-day mycoplasma tests on its Coccivac products.

Testing also is conducted when special concerns arise. In 1999, when poul-

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try producers were worried about the J virus — a new avian leukosis virus subgroup — the Millsboro plant enlisted the help of the University of Delaware poultry division to conduct a study.

“We deliberately spiked coccidiosis vaccine components with J virus in the laboratory. We demonstrated that our production process would inactivate it if any were there,” Walczak says. “In fact, we used the J virus to spike vaccine components at three different stages of production, and discovered that the virus was wiped out every time — at each stage of production tested,” he says.

“Later, we also conducted a similar study with the University of Delaware to show our procedures eliminated chick anemia virus.”

“It’s for our own peace of mind to ensure that the vaccines are safe and efficacious in every way,” he says. Since the vaccine is produced with live birds, we must be sure the end product is not contaminated in any way.

“We are dedicated to producing very high quality vaccines that are going to perform well in the field. We just aren’t going to put something out there that doesn’t meet our own high standards for quality and that won’t perform well in the field,” he adds.

Tech services

Site manager Manogue says one other factor crucial to successful use of Coccivac vaccines is Schering-Plough Animal Health’s strong technical services department.

“For poultry producers to have an effective coccidiosis vaccination program, it’s imperative that the vaccines be used properly. That’s why the presence of our technical service veterinarians in the field is crucial. They back up our work here by working with poultry producers,” he says.

“Overall,” Manogue says, “the more efficient production that has resulted



Manogue: ‘...the more efficient production that has resulted from improvements at the plant these past few years has offset the pressure to produce more vaccine.’



Rigorous QA/QC programs at the Millsboro plant are managed by Ed Walczak, shown here with technician Stacy Clavette.

from improvements at the plant these past few years has offset the pressure to produce more vaccine. The pressure hasn’t affected quality. We planned it that way.”

Now the Millsboro team is looking ahead again. “During the last expansion, we built an infrastructure so we could expand in the future. Because we anticipate even further growth in the use of coccidiosis vaccination, plans for the next expansion are on the drawing board,” Manogue says.



By the time it’s ready to send to producers, every batch of coccidiosis vaccine has been thoroughly tested for potency, purity and safety.

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