Weleda plays pioneering role as first to use Conferma’s rapid sterility test

In the following interview, Ms. Nelly Segur explains why Weleda sought an alternative to the 14-day waiting period for conventional sterility testing of its products. Her team is the first to use a rapid sterility test developed by Conferma, part of the Solvias Group. Conferma’s rapid sterility test, based on the Milliflex® system, takes only five days – almost three times faster than conventional methods – and can identify the relevant microorganisms in the event of contamination.

In brief, how would describe Weleda and the philosophy behind your products?

Weleda produces classic homeopathic medicines and anthroposophic medicines in the tradition of Rudolf Stein — a holistic approach that encompasses the individual, society and nature. All our products are based on natural and biological substances and environmentally friendly manufacturing practices.

What is your professional background and current position at Weleda?

I have a degree as a pharmacist and a QP certification. I began working at Weleda 16 years ago in regulatory affairs. Today, I am responsible for everything around quality: quality control, quality assurance and validation as well as pharmacovigilence.

What type of sterility tests have you used in the past for batch release of your products?

For the batch release of our pharmaceutical products, we have used conventional sterility tests that take 14 days. Conferma performs all of these tests, which were previously done in house at Weleda.

What is still needed to complete QP 2-2, a head-to-head comparison between the rapid sterility test and the conventional sterility test on your first six products?

We are currently working with Conferma to write a detailed protocol for QP 2-2, including the number of batches, microorganisms and test replications. Our goal is to finish the final stage of quality validation for the first six products in 2015.

What is the attitude of the French National Agency for the Safety of Medicine and Health Products (ANSM) toward Conferma’s rapid sterility test?

Conferma developed its rapid sterility test after discussions with the authorities and has given them updates about the process of quality validation. According to the specific guidelines at present, the feedback has been positive. French regulatory authorities and other regulatory authorities around the world recognize the future potential of rapid sterility tests. Weleda has full confidence in the quality of the work performed by Conferma and their ability to pass regulatory inspections or audits.

Is cost a factor in switching to rapid sterility testing?

We don’t anticipate a significant difference in the cost compared to conventional sterility testing. For us, the main advantages in switching are speed, precision and benefits to the image of Weleda.

How will the faster turnaround on sterility testing directly benefit your business?

At Weleda, we produce frequently in small quantities — on average, three batches per day. Faster batch release will help us be more flexible in delivering customized products to pharmacies, reduce the amount of inventory in the warehouse and help us to avoid stock-outs.

Do you have plans to start using the rapid sterility test for additional Weleda products?

The six products that we are evaluating now are representative of the full range of our pharmaceutical products. If the QP 2-2 validations are successful, we could envision switching our entire range of injectable preparations — over 300 products — to Conferma’s rapid sterility test.

Will you continue to use the conventional testing method for some products?

We would no longer see the need for conventional testing. An exception would be when there is a doubt about the results of a rapid sterility test for a particular batch, or when the product is not suitable for the rapid sterility test (e.g. non-filterable).

What would you describe the overall collaboration with Conferma?

After 16 years of working with Conferma, I can highly recommend them. We have a collegial partnership that goes beyond the business relationship. If there is a contamination problem in production, for example, I can just pick up the phone and Conferma sends an expert to our site. They always help us to find solutions.