Kelly McGuill

Microbiology Analyst IV
Agawam, MA, USA

HIGHLIGHTS

Biology degree from Westfield State University with a concentration in ecological sciences

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Environmental monitoring, safety and testing expert transitioned to Microbiology

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Radiation Safety Officer for Cambrex (Agawam, MA)

Teaches STEM Microbiology to inspire the next generation of scientists

SUMMARY

Kelly oversees the planning and testing schedule for the sterility department, and trains other sites on sterility testing and gowning qualifications.

AREAS OF EXPERTISE

- Sterility testing
- Environmental monitoring
- Microbial enumeration testing
- Preventative maintenance

LINKEDIN

Kelly McGuill

"If you have quality from the start, you have a very good chance of making it to—and through—the filing process. That's why clients come back to us, they can rely on us to keep them compliant and focused on the next phase."

How does this work inspire you?

I have a lot of family members that have gone through cancer treatments and have replacement bones that we test, including hips and knees. I think about the patients that will take the drugs and use the medical devices that I'm testing—and they could be my family members.

What type of testing do you work on?

We offer a wide range of testing, including compendium, release, and sterility testing, disinfectant qualifications, microbial limits testing for USP 60, 61, and 62, endotoxin testing, mycoplasma, and daily water testing for pharma companies in New England.

Why is the work you do so critical?

We have to be very observant with the products that we test. Contamination issues can arise in the lab or even from the packaging, like a blister pack. Our job is to ensure we avoid contamination or false positives — both are costly and impact timelines. So, every test is treated as if the future of the molecule depends on it.

What is your role in working with other sites?

A lot of the Cambrex sites send their products to Agawam for testing so there's non-stop collaboration. The non-sterile drug products they manufacture at all the other sites are sent to us for testing. The whole company truly depends on us, and we embrace that role.

What is the best part of working at Cambrex?

The people. I really enjoy working with the team in Agawam and our other sites. We also never have a day that's the same. You never know what you're going to walk into. You can have your day planned out, and then you open the incubator, and your day just transforms into something else, which keeps things interesting!

How has your career evolved at Cambrex?

I joined Cambrex in an entry-level position and was so excited about the opportunity. I was hired for a special project to help a client certify a new lab and get it into a state of control. It was a special opportunity to be able to travel to all the other labs while we were waiting for this project to start around New England to gather best practices. Shortly after, I transitioned to the microbiology department, which is a lot different than environmental monitoring. You have to work with a lot more organisms and live bugs.

What are some of the challenges you face day-to-day?

A lot of the challenges simply come down to science. Organisms just sometimes don't want to do what they're supposed to do. Microorganisms have bad days too. A lot of the time we run into failed suitability, and then we'll have to ask for more product, which is not great for a lot of our clients or sister sites, but we manage to get it done.

How does your expertise benefit clients?

Many of our clients don't have a microbiology background, and that's why they come to us. We give them the USP chapters if they're filing in the U.S. We'll also suggest things, or if they're doing too much, we'll help guide them through the whole process to ensure they're maintaining efficiency and compliance.

What type of requests do you get from clients?

We'll have a client say they need compendium testing. We'll get a feel for what kind of testing they're considering by sending them a questionnaire about their drug product. It will answer all the pertinent questions we'll need on the technical side to create a protocol for validation. And then, we will set up a meeting with the client and talk them through exactly what we're going to be doing. If they're okay with the way we're going to test it with the protocol, we'll answer any of their questions about any other testing they might need to do. Basically, it depends on the route of administration, how we decide what we're going to test, and how we're going to test it.

For example, parenteral that are injectables always need sterility testing and endotoxin testing. Right off the bat, we know that we will need our sterility SMEs and endotoxin SMEs ready for the call. We also ask if they want to do any in-process testing, which will involve microbial limits testing, just to make sure that down the line, they're not having any contamination issues.

What happens when you have contamination?

We initiate an immediate investigation on our side. If there are no lab errors, we will let the client know. They always get the investigation document, and then if they're still having issues after their own investigation, we meet to explore their manufacturing process step-by-step to see if we can maybe pinpoint where the contamination is coming from. A lot of the time, the clients don't test their raw materials, so the problem is there from the start.

In some cases, the client doesn't know much about their product, so we do a lot of method development to see if it'll be soluble or filtered. And then, basically, we'll have to work with the drug product before we test it to figure out how we will test it.

What sets Cambrex apart from the competition?

We focus on quality from the start and never waive. This ensures you have a very good chance of making it through the filing process. Whether developing, manufacturing or testing the drug, we take quality very seriously across our sites and teams.

I feel personally responsible for ensuring that the client will stay in compliance with their testing. We make sure that the FDA will be happy with the way the product was tested. The FDA also looks for raw data and real-time documentation, along with any kind of deviations that were missed, so we are methodical about delivering these details.

How do you determine testing methods for any given project or sterility testing?

It depends on the drug product type and the way it's delivered. If it's in a powder or liquid already in a vial, we'll do steritest. If it's a med device, we do direct immersion.

The testing of non-steroidal drug products is based on the solubility of the drug product, which is very nice to know ahead of time. If we don't know that, that's when the method development comes in. And then the only issue we will run into is if it's inhibitory and then we can't grow the organism in the product we'll have to change the method, redo the protocol, and then execute again in hopes of good results.

What role does the environmental monitoring team play?

We have a great environmental monitoring program, and the team works very hard internally and externally for our clients. They take a lot of samples at the client's facilities and bring them back to our lab for testing. They also do a very great job of internal monitoring and staying out of the analyst's way, which is a challenge scheduling-wise!

It's a very cool department to be in! You get to see a lot and work with clients who are starting up labs to build them and complete risk assessments to help plan environmental monitoring programs. It's really cool to see from start to finish and then go in and do the static and dynamic testing. The dynamic testing is with all of their employees working, and it's fun to interact with people from other companies.

Given your involvement with STEM, what message do you typically share with students?

I have a lot of friends who are teachers, so I do a lot of career days for younger kids. A lot of the aren't familiar with microbiology, but by the end of my sessions, they have a clear understanding, and hopefully, I've piqued their interest in some way.