

Operator Training Programs Improve Data Quality

Implementing a standardized training program yields more consistent results

Thought Leadership

Dr. Nathaniel Hentz, director, scientific market development, Artel, worked for more than 10 years at the BTEC Analytical Lab at NC State University, teaching graduates topics that focused on biopharmaceutical assay development and validation. Before his tenure at NC State, Dr. Hentz worked at Bristol-Myers Squibb for two years supporting automation screening systems within the Lead Discovery group and seven years developing screens at the RPT Laboratories for Eli Lilly.

Doreen Rumery, MLT, laboratory director at Artel, is a certified medical laboratory technologist and ASQ certified manager of quality/organizational excellence with more than 40 years in the clinical laboratory and manufacturing industries. Doreen oversees all laboratory activities at Artel, including technical operations, method validation, technician training, and conformance with current regulatory standards.

Q: FROM YOUR EXPERIENCE, WHY DO YOU THINK IT IS IMPORTANT TO INSTITUTE A TRAINING PROGRAM?

NH: It is important—specifically the pipetting training program—because it is a foundation for assays. When most people start with a new company, it's critical that they go through a training program to bring everyone to the same level and to standardize pipetting performance.



▲ Dr. Nathaniel Hentz



▲ Doreen Rumery, MLT

DR: Whether it is a pharmaceutical, clinical or academic lab, I feel that without laying down the foundation for the basic skills, you're going to eventually encounter problems. That's why we begin with training on pipetting technique, operating our laboratory instrumentation and other basic laboratory equipment, before we even move into more of the advanced science of the testing we perform.

Q: WHAT RECOMMENDATIONS DO YOU HAVE FOR LAB MANAGERS FOR NOT ONLY IMPLEMENTING A TRAINING PROGRAM, BUT ALSO FOR CONDUCTING ONGOING OPERATOR TRAINING AND MAINTAINING ASSESSMENT RECORDS?

NH: Essentially, you need to have a training program, and I think assessment records are

equally important. I have seen all too often that people treat training programs as a box on a checklist, and when it's complete, nobody revisits it until there is a problem. With the assessments and records, you can go back and review and intervene as appropriate to help personnel maintain consistency over a long period of time.

I'd also add that it's all about analyzing the data. When we think about longevity and looking at an individual's performance you have to collect the data and have pass/fail criteria. It can help people see how they are performing, and it's not to make them feel bad, it's about understanding that we all let our performance slip sometimes, and regular assessment just serves as a reminder. Otherwise, without this data, it almost becomes pointless to have an ongoing training program.

DR: I would also add that I thought we had a good training process in place, and then this past year we ran into an issue where our two "trainers," the ones who had previously provided all the trainings, were both out of office at the same time. This left a relatively new team in charge of training the new hires on their own. So, a training program is critical, and we really learned a valuable lesson.

Like I said, we already had a training process, but we decided to standardize it and set very tight tolerances so proper expectations and protocols were set from the very beginning. For every method that people are learning, there is a lot of intra-laboratory comparison where we compare to each other, as well as other laboratories. It is not necessarily easy, but it is really important and has helped us ensure technical competence. Our lab has been expanding, and we have been onboarding new employees and having a standardized training program in place has made it much easier. The new hires knew exactly what they would be doing week-to-week, and they felt good about the progress they were making. It's also really important to have a program for consistency, and to be able to trust your results.

Q: DO YOU SEE A TREND IN THE MARKET WHERE LABS ARE INVESTING THEIR RESOURCES IN TRAINING?

NH: I've definitely seen an upward trend and interest in training. I think COVID-19 forced people out of the laboratory and there were a lot of opportunities for training outside the lab, because people had more time. Also, for the staff working around the clock, performing tests or working in a manufacturing facility, there was an investment in training because these organizations—pharmaceutical companies and contract research organizations, for example—realized the importance of quality. I think quality was always recognized, but this year its importance really came to light.

DR: I have found an increase in the training options available. People used to travel to shows and conferences to see new lab equipment and attend workshops, but when travel stopped, people looked for other options. There are so many videos and resources, and many of them are free. I have found this is especially the case for lab equipment. I asked one of our new technicians to become a subject matter expert on automated liquid handling instruments, and she was able to find hours of online videos to educate herself on the different models. A lot of companies are putting more effort into training for their products, which really helps the end users who are trying to learn. So, I think there is a big market trend for training, not necessarily for paid training, but for creating assets and putting them out there.

Q: HOW DOES A LAB GET STARTED SETTING UP A TRAINING AND OPERATOR ASSESSMENT PROGRAM?

DR: I will speak to this as we have just done it. The first thing we did when we set this up was to base all the testing on orders of complexity. The simplest methods—pipetting, for example—received a lot of focus at the start because they are fundamentals. Then, we add more complex training as individuals master the first test to build on these skills. Once we get to a certain point, I like to immerse them in that testing. So, I may

have them do a full week of testing to really get the muscle memory, and so they know they are doing it well before we move on to more complex methods.

We also keep detailed records because people struggle with different methods. The records help us identify why it may have posed a challenge for them, and then we can communicate expectations clearly. We can also plan a schedule for monitoring compliance so that everyone goes through the same competence training on a yearly basis.

As a laboratory director, I am in the lab with everyone else doing the same testing, and I think it shows that if it's important for me to do something correctly, then it is important for everyone else to make sure they are doing it correctly as well.

Finally, if training is not effective, we try to figure out why. Was the instructor not effective? Were the expectations unclear? Maybe the instructions were too vague. Often, we find the instructions need to be reworked to be very clear, because what makes sense to one person may not resonate with someone else. It is also important to eliminate language barriers, like abbreviations. Too often it is assumed that everyone knows what the abbreviations stand for. It's really about getting all of that put together and documented so people can make progress and be successful. Most people want to learn more and want to make sure they are doing things right. Implementing a training program is one way to demonstrate to them that you are investing in them, so that they can be successful.

Q: PIPETTES AND AUTOMATED LIQUID HANDLERS ARE USED TO PERFORM ASSAYS IN LABORATORIES. HOW DO YOU THINK PIPETTING IMPACTS ASSAYS AND TEST RESULTS? WHAT KIND OF IMPACT DOES LACK OF PROPER TRAINING HAVE ON ASSAY OR TEST RESULTS?

NH: This is the foundation, whether you are using a handheld pipette or an automated liquid handler. With a handheld pipette, error is often attributed to the lack of training, and with an automated system, it is often improper setup. With either, as you start adding multiple steps or you have multiple liquid handling components, you are going to propagate error. This can mean having to repeat a test, and if you are working with patient samples, there is only a finite amount of sample available, and sample loss can be catastrophic. It is the expense, as well as the availability of materials, that are both affected.

DR: In my time in the lab, I witnessed an issue with method transfer. We had designed the method using air displacement pipettes and transferred the method to another lab using positive displacement pipettes. We were seeing very different results, and it wasn't until I went into the other lab to observe that I realized they weren't doing anything wrong, they were just using a different tool. At the very beginning, you need to set those standards and train people properly. Pipette tips matter, solutions matter, pipetting technique matters. It's really looking at all those different components and making sure they are addressed. In this case, the method transferred accurately when we standardized pipettes. Who would think something that simple would have such a huge effect? Still, we see it time and time again with our customers.