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Podcast: Modernize Your Food Safety Lab with NSI CRMs (transcript)

Paul (Host): Hello and welcome to the Rapid Microbiology podcast. I'm your host, Paul Carton. Today's topic will interest laboratories that test foods for contaminants, be they pathogens, allergens, or chemicals. With the introduction of the Food Safety Modernization Act in the US, the food safety system has shifted focus from responding to foodborne illness to preventing it.

With this transformation comes greater responsibilities for food producers and food testing labs, but how can labs be sure they're performing tests correctly? How can they be absolutely sure without using certified reference materials as positive controls that the food they've cleared for consumption is void of contamination? To remove this doubt and prepare your lab for the dreaded audit, I'm pleased to have Lauren Stainback of NSI Solutions, a brand of ZeptoMetrix, as our guest today. She's global product manager application specialist based in North Carolina. Hello, Lauren, and welcome to our podcast.

Lauren (Guest): Thank you so much, Paul. It's a pleasure to be here.

Paul : Great to have you, Lauren. First, can you tell me what NSI do?

Lauren : Certainly. We manufacture reference materials. We are experts in making products for other scientists to use in their labs to validate their test methods, prove their proficiency, and QC instruments. It's essentially a chemical standard or a microbiological standard used like a consumable, but it's got a certificate of analysis that's provided with it. It's not just the material that we're providing, we're also providing data that the lab will try to replicate in their own lab by testing the materials in the same way that we've certified it to be used.

Paul : When you say the data, does that correspond with growth patterns on media and also molecular information as well?

Lauren : Yes. It depends very much on the brand that the customer is buying from. We're a part of a family of other brands under the ZeptoMetrix parent company. The products that we manufacture are chemical reference materials, so they would be like something for gas chromatography or it would be something like a total petroleum hydrocarbon standard that they'd use in a wet chemistry lab. Environmental testing uses that a lot. Then we also make microbiological controls. Yes, they would plate them on media and observe the growth, and they could count the colonies as well.

Paul : What about the molecular confirmation that's needed?

Lauren : Yes, so we do have some customers that use our live bacteria that are certified to deliver a certain amount of colony-forming units. With the emergence of new molecular assays, customers are buying our products and using them on quantitative PCR, QPCR. They're also using them for lateral flow tests or ELISA, so we do see the emergence of that. ZeptoMetrix is globally known for molecular assay controls and standards.

Paul : If someone buys a CRM pack from you, could they simply grow up that strain again?

Lauren : Yes, certainly.

Paul : Is that how it works? They buy a pack off you and then they're able to use that as a stock and work off that stock, or do they have to keep on coming back to you and ordering each pack?

Lauren : There's such a thing as propagating the cultures, and so there's some limits on how many times you can produce new propagated cultures off of a reference material culture. It's called passaging, and the more that you do it, the more the culture can diverge from the original parental cell line behaviour. They call them isolates when they get so different from the original source material that they misbehave because bacteria mutate quite an awful lot. What we sell are reference materials that are not passaged or passaged minimally, and so they behave as they should, as the parental cell line would be expected to behave. They exhibit normal growth behavior on media, and they would buy a 10-pack or a 20-pack of these bacterial pellets from us, and then they could hydrate one pellet and immediately plate on media instead of having to buy a source strain, propagating it, quantitating it, and then trying to stock it or bank it at a certain concentration level. Ours are basically hydrated and pre-certified to deliver a certain concentration of bacterial colonies.

Paul : Are all food testing labs, apart from using it to validate rapid methods, are food testing labs using CRMs on a daily basis?

Lauren : Oh, yes. You'll find them even using things to calibrate measurements, such as UV-vis or turbidity or Brix for quantitating the amount of sugar in something. They're not just using microbiological controls, they're using quite a lot of different reference materials on a daily basis. That's what suggested for them to basically batch a bunch of unknown samples with a known control, like a certified reference material to basically QC the results they got from the unknown samples because of the known sample tests well, and it's what they call an acceptance limit. Then they know that the unknown samples were also tested properly, so the results can be relied upon. That's how reference materials used is like it's a positive control and it can be quantitative or qualitative, so it depends on what they buy.

Paul : I would've expected most testing labs or every testing lab to be using a positive control. Is there labs that aren't using CRMs?

Lauren : Yes, there are some labs that try to use their own. They'll try to make their own positive controls. It could be for a variety of reasons. It's not like it's a lazy thing to

do. Sometimes reference materials simply don't exist for that particular application, or it could be a material that's proprietary to the laboratory or the manufacturer that has the laboratory attached to it. That's often the case in pharma as well as food.

Paul : Can you give me an example in terms of food?

Lauren : Sure. There are a lot of different flours and a lot of different grains, and there's not a certified reference material for every single type of grain or type of flour that's in existence. We have a lot of requests for gluten to be an analyte in a very obscure mixture of grain flours, for example. It's just not simply something that was necessarily lucrative for us to commercialize and develop. We do make custom reference materials for situations such as that. Then another example would be lactic acid bacteria in different types of dairy products. We just make a generic skim milk that we sell alongside our lactic acid bacterial certified reference materials. But, an ice cream manufacturer could come along and say, "Well, we need a high cream dairy or we need a yogurt dairy." Well, we simply don't have that. We just have a skim milk matrix. We try to make it work for the largest variety of customers, but there are those instances where something may not exist and we may have to create it as a custom product.

Paul : Customization comes in there. Okay, very good.

Lauren : I will just say that the biggest issue that the food industry has is that the food matrices and how they're tested, they're very intertwined. We don't see the same thing with drinking water or wastewater or processed water. Food matrices are vastly different. They'll have different acidity levels, moisture content. They can even have bactericidal terpenes or things in the food, like limonene is common in citrus products. Bacteria, for instance, if you were to take a reference material and spike it into some of these different food matrices, the amount you spike in is not the amount you recover. It's very dependent on the food matrix that you're working with. It's very difficult to figure out analytical methods for all these varieties of different food matrices. I think that's one of the biggest challenges our customers have, as well as what we have being a reference material producer.

Paul : With different strains that are out there, there's some *Salmonella* strains that are coming now and again. They have a resurgence after a couple of years. With those specific strains, and someone has used one of your CRMs for a *Salmonella*, but the strain itself is different in a way biochemically perhaps, and your client comes back to you to say, "Your reference material did not pick up on this."

Lauren : It definitely happens in the wild type strains that are out there. Bacteria are constantly swapping DNA prolifically just so that they can evolve quickly and thrive in whatever environment they find themselves in. *Salmonella* is one that appears over and over again in food recalls and in foodborne disease outbreaks. It's because it's so successful at being able to colonize different parts of the body, different matrices. You find it in soil, you can find it in the plant itself as an endophyte inside the plant's vascular system. *Salmonella* can just grow just about anywhere. There are pathogenic *Salmonella* strains, and then there are non-pathogenic *Salmonella*

strains. What a customer of ours is doing is typically QC-ing their media. They'll have media that will specifically indicate if *Salmonella* has been detected as present. It'll either be a chromogenic media, so *Salmonella enterica* will turn a color. Then a non-pathogenic *Salmonella*, like *Salmonella salford* wouldn't turn a color on the media. They would be buying our CRMs, our *Salmonella salford* or *Salmonella enterica* certified reference materials to QC the media they've prepared, so its capable of detecting the pathogen, should it be present in an unknown sample.

Paul : You obviously consult with auditors a good bit considering the proficiency testing scheme. Are auditors sometimes finding that clients do not have CRMs or haven't adequately used them in practice?

Lauren : Yes. They're finding a lot of times that the certified reference material word itself is foreign to a lot of microbiologists in industry labs. I think it's just a nomenclature issue. You say positive control, and any scientist in the lab is going to know what you're talking about. A certified reference material just means that it's been manufactured under an accreditation. It's been certified for its intended application, its intended testing application by a laboratory that's capable of producing credible data with their reference materials that they're manufacturing. ISO 17034 is the accreditation that we have to be reference material producers, and we undergo audits, numerous audits in order to be a certified reference material producer.

It's not dissimilar from the testing lab accreditation. They have to have ISO 17025 if they're an accredited testing or calibration lab. What we're finding is that being an accredited lab wasn't something that was required to be in the food testing arena. .Now, with FSMA, FSMA wants to align the laboratories that are performing testing for the food industry. They need to have some sort of quality system that's consistent across the board. They're getting them in this position to be accredited to some type of guide standard. That's where it's all headed.

Paul : Sorry. For our EU listeners, FSMA, it's the Food Safety Modernization Act. People may not be familiar with it as abbreviated that way.

Lauren : That's correct. Yeah, so that Food Safety Modernization Act was established to get a framework together for laboratories to work within. The FDA specifically established a laboratory accreditation for the analysis of foods program, that's abbreviated L-A-A-F, LAAF, which I think is funny. They've implemented this new LAAF program with the intention of improving accuracy and reliability of food testing throughout applying uniform standards of data quality and also, FDA oversight, which again, is that audit portion that everyone is so afraid of, or I guess respectful of, not necessarily afraid of.

Paul : Has FISMA had an effect on the number of recalls in your opinion?

Lauren : Yes. I think now that there's an official framework, I think the budget has been there for more surveillance testing, and I think the surveillance testing has led to picking up on more, either potential contamination risks or in fact, yes, food contamination, so I have seen an increase. Again, it's one of those things of where I think it was

because of more surveillance. I think these things were out there, but we just didn't know they were out there.

Paul : What shape or form does this surveillance come in?

Lauren : Surveillance, meaning that products that are on the shelves are picked at random, and they are tested within accredited laboratories all over the United States. That data is shared in a public database, I'm sorry, it's not public. It's publicly funded, but it is a database that the FDA uses and watches. If there is something negative or if there's a contaminant found or if there's a potential contamination risk discovered, then a recall notice can be issued rather quickly, and that information is shared across the network.

Paul : In the EU, we have a rapid alert system, RASFF, which is public, and it can show you the country was found in a description of its severity in terms of health and its origin. Does the US have something similar to that? I know there's FSIS, but it's more of a list of your recalls.

Lauren : Yes. I think after the recalls issued, that's when it becomes public. I think that you've been the model over in Europe and in the UK with your systems and your notification systems, and I think we're trying to emulate that, but we're a bit behind. We haven't had this level of surveillance and this level of testing being done in our food network before. It's all just trying to get ahead of foodborne diseases to prevent it, not after it's happened. I think it's all a matter of shifting things so that we have an earlier warning system and we can get things off the shelves or keep things from getting on the shelves in the first place.

Paul : Here in Ireland, there's labs who give bonuses for food microbiologist who streak more plates every day. If you hit the target of streaking or going through so many samples, you get a 10% bonus added onto your payslip. I was going to say to you, if you're going into a lab and advising them on using more CRMs in their batch testing, do you experience any of that in the US?

Lauren : It's more about trying to sample a representative amount for the batch size that you're testing. It's more in line with: do enough that you're going to be able to see something. If there's a problem, you want to be able to see it, but they don't necessarily incentivize scale. It's more so just about balancing the amount of samples you're taking from the batch of a prepared food or a raw material to ensure that enough of it was sampled, but if anything adverse was there, you would've been able to see it.

Paul : Sure.

Lauren : That's very interesting, I had no idea they did that. That's really cool.

Paul : I think even rapid tests have not been adopted that much. Lab managers are still using traditional methods in food testing laboratories. I'm not sure the reasons for that. I think the food technicians here are working long hours, a lot of overtime

hours. There's not that many food testing laboratories in Ireland. For some reasons, they're not using the rapid test, and I have no idea why.

Lauren : I just think it's new, and scientists are, while we love new and we love exciting, we also love things that we know work and we know they work well, and we've been using them for decades. There's that, I don't know, that scientific method where you just keep going back to the same old, same old because you know it works and it's comfortable. You could push the envelope a little bit. I think I see a lot more of the molecular tests being used to screen, but not to confirm a positive. If you were to, let's say, let's just use E. coli for example, you could screen all the incoming raw materials into your plant. If you detected E. coli in something, then you could send that to the QC lab and have them retesting things with the traditional plate, the samples on media. I see that a lot.

Paul : It is being used. Yeah. You've probably touched on it a little bit there. There is new risks, as you say, there's new products, new matrices and new ingredients that you don't have CRMs designed for. Is there any risks you are seeing coming to the market due to a reliance on importation and globalization?

Lauren : Well, for sure. Especially, just talking about microbiological specimens. I mean, you have so many exotic bacteria in these different types of foods that I've never seen before, and they're just naturally evolving. It's not until we start DNA sequencing that you really can confirm what family or genus they're a part of. I think that the growth of globalization has just led to an exponential increase in the amount of importing and exporting that's going on.

I think industry-wide, testing has tried to catch up with that, but it's just takes time to test for these things. We want to trade and we want to sell, and we want to produce products and release them as quickly as possible and get them on shelves. It's just a tit-for-tat, really. I think it's just, that we want to spend time and look at these different cultures, look at these different crops and what grows in the soil, what grows in the plants or on the surface of the foods. We just simply don't have time to really enjoy that aspect of food science. We're so busy just keeping up with the commercial demands of the lab that we don't have a lot of time to do the R&D.

Paul : I think that's the responsibility of Codex really to be looking into the international standards. In your experience, what are some of the most recent food recalls and how can they be avoided, please?

Lauren : Well, I know last summer it was tragic the amount of ice cream that got yanked from shelves because we had some outbreaks of listeria and salmonella in some of the dairy materials that I think it was in powdered milk and some other things, and they must have gotten cross contaminated. There were so many different producers using some of the same raw materials that its really difficult to pinpoint which batches. Several brands got recalled, and it was evident because freezer aisles were empty of ice cream for quite a while, several weeks. You know in the summer, there's nothing better than having some nice cold ice cream.

That was one example. More commonly, you see salads being pulled because of just how they're processed and handled. There's really no cooking that goes into salads. They're cut, washed and served. It's really easy for bacteria to still be there. There's normal bacteria that aren't pathogenic, they aren't harmful. We need them in our gut health, but then there are these problem children out there, the salmonellas and the *E. coli* and *Listeria* and *Clostridium* that shouldn't be there. When they're detected, you have these big recalls and it tends to be lettuces, tomatoes, and then ice cream is the most recent, and I think the biggest that I've seen in a while.

Paul : What would you say the maximum time before a product is released onto the shelves before the food testing lab catches it?

Lauren : I think the laboratory has results when the food products are being moved from a cold chain logistics to being stopped. I think a lot of times, you'll see the recall notice posted before the lot's even been released, but it's just a matter of prevention or trying to get ahead of it. You'll see them post them actually in the grocery stores. If you have this lot or that lot, come for a refund or throw it away, don't use it. I'd rather them be ahead of it than risk waiting and seeing, "Oh, did we in fact put this out on the shelf?" I think it's been released from the factory, obviously, and it's in the cold chain logistics process of being stopped at the local level that it's being caught.

Paul : Correct me if I'm wrong, the FSMA was back in the start of the last decade, 2011, is that right?

Lauren : Yes, that's correct. There was a lot of time from when they proposed what they wanted to do and they had to gather feedback from the industry to find out who is this going to hurt? Who is this going to help? What kind of economic burden is this going to put on the companies that make our food or process our food or grow our food? Then how much of that is going to be borne by the consumers? Food is something the US is really conscientious of. We've subsidized food costs since the 1920s, so it's definitely something they wanted to enter into very thoughtfully and not be aggressive or heavy-handed and just demand all these new regulations on this industry.

I think they really took their time. Some people might say too long, but they did take quite a long time to gather feedback from the industry. I think they've done a nice job rolling it out and making sure, like they still haven't gotten enough accredited laboratories. They're still asking for laboratories to voluntarily become part of this. The Food Safety Modernization Act established the Laboratory Accreditation for Analysis of Foods program, the LAAF program, and they've allowed time for laboratories to get voluntarily accredited in that program.

Paul : Would there be some states that wouldn't have accredited labs at all?

Lauren : That's correct.

Lauren : They don't feel they have enough accredited labs to meet the demand.

Paul : Since FSMA came into operation, has NSI seen an increase in inquiries for your CRMs?

Lauren : Absolutely, yes. We've also been asked, could we help train labs on how would they get accredited or what steps do they need to go through in order to comply? Of course, that's not really our realm. We're not consultants. Given that we are ISO 17025 accredited testing laboratory, and we produce reference materials out of that accredited testing laboratory, so we've got these dual ISO accreditations that fit into one another. We are able to also leverage our third accreditation, which is ISO 17043, which is the ISO accreditation for proficiency testing providers. We have an accredited testing lab, we manufacture certified reference materials, and we provide proficiency tests. Proficiency tests are the route that we suggest most to laboratories that are looking to get an accredited status because it's an independent third-party test that they have to perform and pass. Then all of that is reviewed by an auditor who would then audit the laboratory itself and credit them.

Paul : I was glancing through FSMA, and I notice a new defense section of FSMA that I haven't really seen in such legislation before. It mentions the risk regarding intentional contamination or an adulteration event, possibly bio-terrorism that could cause great harm to the public and food chain. Has that always been there?

Lauren : It has. America is a global superpower, and like the other global superpowers, there are domestic terrorist acts and there are foreign terrorist attacks. I think that's always, ever since 9/11, I think that conversation has to unfortunately be woven into just about every aspect of our government, and especially regarding public safety. Yes, I do think that, that has always been part of it, and it's not just, we're a global economy, so threats can arise from just about anywhere.

Paul : Sure.

Lauren : The ones you least expect, so you just go ahead and build that defense into it and have that perspective when you're working on any of these regulations. You're trying to protect the public from all types of threats, and that's one of them, unfortunately.

Paul : You did mention you do work with your clients in regards to audits, and obviously, it's a daunting prospect. How can NSI make it less so daunting for labs?

Lauren : Having been a lab director myself and having to supervise and go through audits for my own lab that I worked in, I think the best thing is an ounce of prevention is better than a pound of cure. I always suggest that where there's a reference material, it's bought and used, and that just ensures that everything in the laboratory is constantly being monitored. You're looking at that certificate of analysis for that reference material, and you're reviewing your own laboratory-generated data, and you're ensuring that those certified reference materials are matching acceptance limits that you've established. That's like a routine check. then I always enroll all of my analysts in proficiency testing programs that are relevant for the testing activities of the lab.

For food industry, it would be participating in the NSI food science PT studies, so that would be a proficiency test that they could get once a quar once every six months, and it would be an independent third party sending them samples that the laboratory would treat as routine samples and test them, report the results, and then be graded. They'll either get an acceptable result or a non-acceptable result. If you get a non-acceptable result, you know you have to do some evaluation and figure out what went wrong. It does greatly narrow the amount of things that can go wrong if you're constantly monitoring everything by doing the reference materials [00:31:00] and also routinely participating in proficiency tests, at least annually.

Paul : Ready-to-eat products seem to be always in the recalls list. Is it because food producers are not doing hurdle technology adequately, or what do you think is happening there? Is the shelf-life information incorrect?

Lauren : I honestly think it's just the amount of touch points that processed foods go through. If you think about it this way, contamination can occur at the farm, it can occur at harvest. It occurs during processing or during preparation. A ready-to-eat food has been through all of that. I think it's just a matter of the touch points of making a ready-to-eat foods, the risk of contamination goes up with each step. If I'm just getting something that's just been plucked from a field and not even washed or anything, just dusted off like a potato, it's less likely to get contaminated in the process of something other than like a ready-to-eat, bagged, pre-made chef salad or something like that.

Paul : Of course. There's several companies that provide certified reference materials. Why should labs choose NSI?

Lauren : For the same reason I did back in the day when I was just a customer. The level of technical support that you get from having the reference material produced all at the same site that it's produced, it's packaged, it's tested all at the same site in Raleigh, North Carolina. I think that the technical support you get, you get it quickly, you get it just with every single lot being consistent, being made by the same people, and the level of technical support being given throughout. I think that's really our strength is that we are still putting the customer first. We will drop what we need to do and retest something. If there's something weird that's occurring at the customer's lab, we'll literally try to get to the bottom of it with the customer. You just don't have that same level of customer interaction with these other companies simply because of scale or maybe where they're located, there's a language barrier or something like that. Certainly, in North America, our strength has been that technical support and that customer service.

Paul : Excellent. Thanks, Lauren, for sharing your expertise today.

Lauren : You're so welcome, and thank you for the great conversation and interesting questions.

Paul : With a shortage of qualified food microbiologists in the Labor Market and a reluctance of food testing labs to adopt rapid methods, food microbiologists are

sometimes having to work long hours to keep up with samples for the growing population. Under stress, mistakes can happen. We've learned today how certified reference materials are essential in managing the food testing lab for audits, and to be sure that a recall is legitimate and important to catch that batch before it causes foodborne illness. Thank you for listening today. Catch you next time.