This month's topic is the use of templates for swab sampling in cleaning validation protocol execution (as well as in recovery studies). A template is usually a sheet of inert material, such as PTFE, within a "window frame" cut out to the same size as the desired swabbed area. If the sampling area is to be 100 cm2, then a 10 cm by 10 cm "window" is cut out in the template. If the sampling area is to 25 cm2, then a 5 cm by 5 cm "window" is cut out in the template. The template is held in place on the surface to be sampled, and the swabbing pattern (swabbing motion) is performed on the surface within the open "window" of the template. Needless to say, a template is generally only used for swab sampling (although there may be rare situations where a separate rinse sample is used on only part of the equipment surface, and then a template might be used to control the area rinsed).

Why is a template used? First, let me say that my experience has been that roughly 80-90% of the people who do swab sampling do not use a template; they use the "eyeball" method. For clarification, the "eyeball" method means training your samplers to swab approximately the desired surface area. Only about 10-20% will use a template. Now the main reason for using a template is to control more carefully the area sampled. If I use a template, I can sample exactly 100 cm2, with a variation of perhaps only 2%. On the other hand, with the "eyeball" method, I can expect a variation of as much as 10% in the sampled surface area.

If that is the case, why doesn't everyone use a template? Well, there are some concerns with the use of a template. The first concern is that it is preferable to use a new template for every sampled site. If I have 15 swab sampling locations, that means I need to have 15 clean templates, one for each site. The reason for a new, clean template for each site is that in the sampling process I will definitely contact the edge of the template, and possibly carry a low level of a contaminant into the result for the next sample. The same template could be used again and again for each of the 15 sites. Providing all sites have passing results, I am less concerned about possible carryover to the next site. However, if I do have a failing result for a swab sample, I would like to know where (in what location) that failure occurred. That could be important for taking appropriate action to improve my cleaning process. If sampled location #3 fails, it may also cause a "false" failure in sampled locations #4 and #5 (for example). While I might suspect that the failures in #4 and #5 were caused by contamination from the template used on #3, I have no way of verifying that.

One possible way to get around that problem is to use a template that is larger than my desired sampled area, and only swab in a designated area inside the template. For example, if the desired sampled area is 100 cm2, then I could use a template that is 11 cm by 11 cm. I would then train my samplers to swab 1 cm inside the "window" all around. In that way, I would not "contaminate" the template between samples. However, the issue with such an approach is that it negates to a good extent the main advantage of a template. I no longer have precise control of the swabbed area, and am depending to a great extent on "eyeballing" that I am 1 cm inside the window frame. In other words, such a modified approach to use of a template may solve one problem, but it sacrifices quite a bit in terms of accuracy.

Another issue with the use of a template is that, while it does control the swabbed area precisely, it does so in a highly variable process. What do I mean? Well, I mean that the swabbing process itself is a highly variable process, regardless of the control of the surface area. There is a relatively entrenched belief in the cleaning

validation community that swab sampling is wonderful and that rinse sampling is highly problematic. However, in my view swab sampling is a type of manual cleaning, and like manual cleaning it is inherently variable. I have heard some people, who claim that manual cleaning cannot be validated because of its inherent variability, extol the virtues of swab sampling. However, having done swab sampling recovery studies, look at the differences between several different trained samplers. If one person gets 75% recovery and another gets 90% recovery, is my immediate reaction that the person with the lower recovery has poorer technique? No, my immediate reaction is "Okay, we know that swab sampling is variable; what's new?" Now don't get me wrong here; I will set some kind of limits at to acceptable variability, but those limits will be closer to a 20% or less difference being acceptable, as opposed to only a 5% or less difference.

A possible analogy to using a template to get the exact area in a highly variable process is in cutting lumber for building a house. If I were using a chain saw to cut the lumber, would it add any value to use a precise laser marking system to mark the lumber before I cut it with the chain saw? Probably not. The inexactness from using the chain saw to cut the lumber means that I could probably mark the wood with a tape measure and still get the same results. Like all analogies, this one falls apart if you take it too far. In the case of cutting lumber for building a house, I have other options than using a chain saw; I could use table saw for example, and in that case a laser measuring system may make a difference. In swab sampling for cleaning validation protocols in pharmaceutical manufacturing, we don't have a better option that the current practice for swabbing. Perhaps in the future someone will invent an automated swab sampling apparatus to more precisely control pressure and sampled surface area. However, such a device is not currently available.

A third issue in the use of templates is that a template can be used on flat (or slightly concave or convex surfaces). However, for many of the sampling locations that are the worst cases, I may not be able to sample using a template because those worst case locations are not flat. In other words, for the most critical locations, I am essentially falling back on the precision of the eyeball method. What this also means is that I will train my samplers to swab with a template and also train them to swab using the "eyeball" method. Here again, I would prefer to spend more time training on the eyeball method than on spending the same overall time training on two methods.

Just for clarification, I'm not saying that there is no value in using a template. It certainly can be used. However, I am not convinced (and if my observation as to the percent of people using a template is reasonably close, industry appears not be convinced) that use of a template offers such vastly superior advantages that it should be used by all.