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Surface Roughness and Cleaning

This month's Cleaning Memo relates to a paper that was just published in the PDA Journal of Pharmaceutical Science and Technology, entitled "Bacterial Adhesion to Surfaces: The Influence of Surface Roughness" (Volume 60, No. 3, pages 164-171), by Frank Reidewald. While the title refers to bacterial adhesion, there is an emphasis in a portion of the paper on cleaning, and the effect of surface roughness on the difficulty of cleaning. Let me say upfront that focus is on cleaning biofilms from water systems. However, I believe it is possible to make analogies with cleaning in product manufacture (indeed the author brings up the example of cleaning a fermentor), so it is worth taking a look at what the author has to say.

The suggestion in the paper is that the "current practice of using highly polished stainless steel surfaces" may be a misconception, and the insistence on such electropolished surfaces is not necessary for good cleanability. The author points out that there are limited technical papers based on laboratory studies to demonstrate the effect of surface roughness on bacterial adhesion and/or cleaning, and that those papers generally support the idea of no significant difference in cleanability based on surface roughness.

One analogy emphasized in the paper is the so-called "Lotus-Effect". The surface of the lotus plant remains free of particles and microorganisms precisely because of the rougher surface morphology (compared to other plants). The surface of the lotus plant is covered with "spikey structures", which are in turn covered with "waxy crystals". This combination (of roughness and waxiness) is thought to prevent adhesion and allow water to easily pick up particles and roll them off the surface of the plant.

The author asks the question of whether stainless steel surfaces in pharmaceutical manufacturing are "so different ... that the principles of resisting bacterial colonization should be so different?" At this point the author discusses prior publications on biofilm formation and removal. I would suggest reading the original paper for more detail.

However, the question remains -- what is the implication of this for surface roughness and cleanability for process equipment? The main benefit of this paper is to point out that what we think we know for sure may not necessarily be the case. Furthermore, we implicitly believe that minor changes in the surface roughness of stainless steel are not significant in terms of cleanability (otherwise we would repeat our cleaning validation on a regular basis as the surface itself changed).

In evaluating this issue, we should be careful about applying analogies that may not be fully comparable. For example, is there a difference between preventing soiling of surfaces and cleaning a soiled surface? I would argue that there is a difference, and the lotus plant analogy may apply to preventing soiling, but not to cleaning (at least in the context of pharmaceutical process cleaning). Furthermore, is there a difference between the case of bacterial adhesion and the case of biofilm removal? I would argue that there is, since one is a soiling process and one is cleaning process. Lab studies to demonstrate effects with one case do not necessarily apply to the other case. Another question to ask is whether there is an analogy between biofilm removal and pharmaceutical product removal? If biofilm removal is usually done with an oxidizing biocide (such as peracetic acid), then clearly the mechanism is different unless I am also using an oxidizing cleaning agent for pharmaceutical equipment cleaning.

I also believe the lotus plant analogy can be carried too far in extending it to stainless steel, because it appears that it is the combination of the "spikey structures" and the "waxy coating" that provides the mechanism to preventing soiling of surfaces. Clearly the waxy coating is not a current possibility with stainless steel surfaces.

While I do have some concerns about the specific arguments made, the overall conclusion of the author, that cleanability of stainless steel surfaces within the range of a Ra (roughness average) value of 0.01 μm to 3.3 μm may have little effect on the cleanability of a stainless steel surface, may be true. In one sense this is comforting in that I should be less concerned about changes in cleanability over time as a surface potentially deteriorates. Does this mean I will change my specification for the surface finish of stainless steel equipment? Probably not. After all, if I have lived with a certain specification, and if I have generally found it acceptable throughout its life (with the usually derouging and passivation preventative maintenance that may be necessary), I probably don't want to loosen my requirements just based on the fact that there is no defining lab study (or series of studies) that clearly specifies a looser requirement.

Furthermore, I doubt that any lab study could overcome the track record of the acceptability of current requirements based on its history of use. After all, the issue with any lab study is whether the conditions in the lab adequately represent conditions of real use. A second issue with lab studies concerns the tools available to measure effectiveness of cleaning. The tools used have to be good indicators of real differences. I can run lab studies that show no difference in cleanability between surfaces with Ra values of 0.2μm to 3.0 μm; however, I would also like to use a measurement tool that would indicate when a cleaning process is ineffective. In such studies, I may have to extend the range of Ra values for surfaces or I may have to change the measuring tool. In other words, the measurement tool should, at some point in increasing surface roughness, be able to distinguish difficulty of cleaning.

The author of the paper discussed should be commended for pointing out areas where more studies could be helpful. However, the result of his investigation should not be a wholesale change in standards, but a call to better research. It should also remind us to be open to change our minds on what "everyone knows to be true".