Why Sampling Is Important

By: Dr. Teri C. "TC" Soli, SoliPharma Solutions

The maintenance and control of a water system to provide and distribute water of acceptable chemical and microbiological quality is undoubtedly the most important set of operations for a water system. A close second is sampling. So, why is sampling so important? Anyone involved in testing those samples knows the answer. If the water sample is not reflective of the "true" water quality, "bad data" is the result. When decisions or further actions are based on "bad data", inappropriate or needless decisions, consequences, or actions are the result. Therefore, the message is simple: When collecting samples, collect them well.

Sampling can be done from sampling valves or use point valves. If sampling is done through use point valves used in manufacturing and you are part of an FDA-regulated industry, then you MUST sample the water exactly the same way that the water is used from that outlet – same hose, same outlet flushing procedure, same everything, nothing different. The rationale is simple: The water sample is usually intended to reflect the quality of water being used. Since the chemical and microbiological condition of the hose and the effectiveness of any flushing procedure have a great influence on most of the quality attributes, you have to mimic those flushing procedures and hose conditions to get a true picture of the quality of water of the water being used.

Sampling done from sampling valves is usually for a different purpose. These outlets are not manufacturing use points, and the samples collected from them are typically intended to reflect the quality of water inside the pipes. Therefore, anything that can be done to eliminate "external influences" that may degrade the water quality during its collection process is fully allowed. This includes using sterile hoses, inordinately long flushing procedures, extreme valve sanitization procedures, specially designed valves, etc. After all, the purpose of this sampling is to get an accurate indication of the water quality inside the system without the possible negative influences from the valve and hose (if used) as it leaves the system into your sampling container.

Valve design greatly influences the quality of a water sample. Ball valves are often used in water systems. These valves have wet surfaces that encourage microbial biofilm growth and are isolated from the water flow until the valve is opened for sampling. As the water flows across these potentially biofilm colonized surfaces, the bacteria in the biofilm can be sloughed into the water stream. There may be no bacteria in the water system, but as the water flows through the valve, it picks up lots of bacteria in the valve. You might think that sufficient flushing would shear off all these valve-surface bacteria, but chances are it will not. The ball portion of the ball valve is colonized not only through the channel but also around the ball. O-ring seals on the ball are no match for a decent biofilm, and they slide effortlessly past them, so no matter how long you flush or how you "work the valve", bacteria will continue to be sheared off into what may have been otherwise sterile water as it exits the valve.

Needle valves are also usually big offenders, with a singular exception. Typically, needle valves have a large downstream surface within the valve that remains wet after the last sampling use. That surface can grow biofilm like crazy. When a sample is collected, the water flows past this colonized surface as it exits the valve, picking up all manor of biofilm bacteria on the way out.

The exception I mentioned is the so-called sanitary sampling valve. Its internal downstream surfaces are designed to be continuously flooded with a sanitizer after the valve is used in sampling so that those surfaces are hostile to microbial colonization. Furthermore, the upstream surface of the valve has the appearance of a

very large hypodermic needle sticking into the middle of the fluid stream in the pipe and is designed to avoid sloughing off the biofilm that may be colonizing the pipe wall near the fluid path as water exits during sampling. Whether this "hypodermic" design actually reduces microbial contamination of the sampled water is still questionable in my mind, but the hostility of the downstream surfaces of the valve DOES have a great advantage.

This sanitary valve design brings up an important point. Not all samples collected from a valve are for microbial testing. Other tests such as for endotoxin, TOC, conductivity, or even particulates could be performed on those samples, perhaps in addition to microbial testing. Be absolutely certain that what you do to prepare the valve for sample collection does not compromise ANY of the other test attributes that may also be assessed. For example, it is not wise to use alcohol in the sanitary valve or as an external valve sanitizer if you plan to collect samples for TOC as well as microbial testing. If you have no choice, then the order of samples collected (e.g. TOC first [before valve sanitization] then microbial) is important. Also bear in mind that for some tests in addition to microbial, the chemical quality of the hose may also be important. A brand new flexible plastic or rubber hose may actually be chemically very dirty, not from extraneous matter, but from the plasticizers and other organics in and on the hose itself.

And that brings up my final point – flushing. Be vigorous, VERY vigorous. It is the RATE of flow across a surface that removes contaminants, including biofilm, not just the volume or duration of flow. So whenever you specify valve flushing as a mechanism to remove these external contaminants, make certain the flow rate is somehow inferred. For instance, specifying that the valve be fully opened for X seconds or Y volume is far preferable to merely specifying flushing for X seconds or Y volume. Also remember that if you then reduce the flow for sample collection, changes in the hydraulics within the valve may cause the sloughing of more biofilm not removed in the fully opened flush. Therefore, you should continue to flush at that reduced flow rate for some period of time or volume (which you must determine) before actually grabbing the sample.

So again, why again is all this so important? You must get accurate test results to make accurate decisions. I dare say that in the pharmaceutical industry today, AT LEAST 50% (and probably closer to 90%) of all microbial test results are erroneously high or highly variable due to inadequate or inconsistent flushing. Don't let erroneously bad test results force you into bad decisions. And if you find you need to flush better to get a good sample, you probably need to flush better before using the water too.

Dr. Teri C. "T.C." Soli is the principal consultant for Soli Pharma Solutions. He has 28 years of pharmaceutical industry experience. He holds B.S and M.S. Degrees in Microbiology and Immunology from the University of Arizona. He served 18 years on PhRMA's Water Quality Committee and is currently a member of the USP Pharmaceutical Waters Expert Committee.

T. C. has authored and co-authored numerous papers and lectured extensively on various aspects of pharmaceutical water chemistry and microbiology. He has been a featured PFI Conference speaker.