FEATURE FOCUS BIOENGINEERING

ture rise a little bit or allow the pH to drop, and instead sometimes have minuscule tolerances. Let the tempera-
ditions change, bioprocesses—industrial-scale procedures or micromachines which, for all their complexity, have sensitive in all of manufacturing. Unlike pressure vessels manufacturing to burgeoning fields such as bio-fuel becomes a larger industry, ranging from pharmaceutical to the bookshelves, it’s fair to say that the bio-
processing equipment standard is changing as fast as pos-
sible. And that’s a good thing, according to Gonzalez.

The BPE is now on a two-year cycle to keep up with an
guide manufacturers to the best available practices.

To get an edge on costs, for instance, manufacturers are looking to new suppliers, especially those in Asia, for various fittings. And with the cost of a material such as tita-
nium up by a factor of 10, according to some estimates, that’s not an insignificant issue. But when material is

Japanese supplier—it’s aircraft grade—you could build a nuclear reactor with it.”

Also, suppliers can deliver widely different materials, all with the same name. “You buy a material such as EPDM and there can be 20 different varieties all with the same name,” Ankers said. “Forget China and India. There are 20 different kinds just within the U.S. No one’s going to standardize unless the end user demands it.”

Such concerns are beginning to make their way into the BPE standard, as committee members push for a higher level of material purity. “It’s better, after all, to have 20 potential suppliers producing identical parts that can meet your need than to have just one or two. But setting a high standard is no guarantee that you’ll be getting what you’ve ordered.” Gonzalez said.

“We can bury ourselves with paper,” Gonzalez said. “But that by itself won’t keep fraud from occurring.”

BEST POSSIBLE PRACTICES

Gonzalez thinks that it’s more important to incorporate the best possible practices into the standard, ones that are backed by science, not custom. One instance where best practices don’t match with science, Gonzalez said, is in the treatment of rust, also known as “rouge.”

“People make a great deal of anxiety when they see rust in stainless steel,” Gonzalez said. “It’s just iron, and nobody has died of an overdose of iron, unless you are hit over the head with a bar.”

“Except in cases where cosmetics are being produced, she added, there’s likely no reason to be overly concerned with a patina of rust on stainless steel parts.

More threatening, given the nature of bioprocessing, is the presence of a layer of bacteria on equipment. Gonzalez said a new task group was recently created to look at how the standard ought to deal with biofilms such as these. “People don’t see it,” she said. “You could have a very shiny surface with a thick coating of biofilm.”

One reason why the standard up to now has not dealt with bacteria is that the focus has been on new systems. “Once you have a new system on line, it’s no longer new,” Gonzalez said. “We need to start addressing maintenance in more depth.”

Another area the standard has begun to address is that of legacy standards—instances in which common prac-
tices have been included in the standard, even though they may not be the best way to do it. Gonzalez said one such issue being addressed in the standard is that of clean-in-place processes, which enable equipment to be flushed out automatically between batches. More than 40 years ago, Gonzalez said, a rule of thumb for the min-
um flow needed to do this was agreed to: five feet per second. That’s been the flow most manufacturers have adhered to since.

“But that’s nonsense,” Gonzalez said. “Flows change due to viscosity, temperature, pressure—a whole number of factors.” Instead, Gonzalez feels a standard based on hydrodynamics, which could better anticipate the way a swirling turbulence could be induced in the flowing li-
uid, would be more useful in ensuring that machinery gets properly cleaned.

Another issue is adding design data to the standard, says Gerhard Kröhnert, a Germany-based consultant former-
ly with Dockweiler AG. Kröhnert said certain types of clamps were being produced with widely varying de-
signs. “Nearly every manufacturer kept design data a se-
cret,” Kröhnert said. “The products weren’t meeting the proper dimensions. At the end, it was obvious that sys-
tems were not interchangeable between manufacturers.”

An obvious solution, Kröhnert said, would be to adopt existing standards into the BPE, but that effort met resistance from American manufacturers. Instead, the various proprietary data was compiled into a table that was added into the 2005 standard. That solution, Kröhnert said, turned out to not go far enough. “It was just a compromise,” he said. The sub-committee tasked with looking into the problem is moving toward a fully inter-
changeable standard—the first ever for clamps.

It’s likely we are still far from the end of this era of rapid changes in the bioprocessing equipment standard. “Once you address and standardize something like tubing fit-
tings,” Ankers said, “the focus changes to the next thing that’s causing problems.”

And there’s not a little altruism driving the process. “Our mission is thinking about how to make life better for the population of the world,” Gonzalez said. ■