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CONVEYING NEWS BUILDING RELATIONSHIPS DEFINING

INDUSTRY STANDARDS MORE THAN JUST A "HOW TO"

Remember the tough professor that said, "Look to your left. Look to your right. One of those individuals will not be here at the conclusion of this course!"

Well, to put a positive spin on those words, if you look to your left or your right, one of your colleagues is probably involved in the development of one of our industry's important standards or guidelines.

For the purpose of this article, we will limit the discussion to two of these groups: the ASME Bioprocessing Equipment Standard (ASME-BPE) and the 3-A/P3-A Standards. Both of these documents are Voluntary Consensus Standards and have unique features that are common between them such as: their technical content, as well as the way they are written, approved and published. Because of these similarities, the two groups maintain communications to assure the important topics are covered and that there is not too much overlap in what is covered by each.

A Little Background on ASME-BPE and 3-A/P3-A

The ASME-BPE, published by the American Society of Mechanical Engineers, is a standard that was conceived in 1989 to fill a gap between the well-known ASTM material standards, ANSI/AWS Welding standards and the guidelines for dairy and food. The BPE began to address the unique designs of devices (equipment, fittings and valves) that are prevalent in our bioprocessing facilities.

Standards and guidelines are not intended to be "how to" books for engineers and designers to learn all the aspects of what they need to design.

During the last century, well-known codes for pressure vessels and process piping were written for safety reasons to protect the operators and anyone working near the systems. However, it was evident that there were unique requirements of bioprocessing equipment and piping; and, those requirements needed to be standardized to help protect the patient from drugs that might be manufactured in poorly designed and fabricated systems. Features of the piping systems, vessels and seals needed to be standardized to help assure they were cleanable and sanitizable to levels required for safe manufacturing of injectable and oral dosage pharmaceuticals.

Before the ASME-BPE was developed, our industry relied on the devices and designs of the food and dairy industry to build our systems in a cleanable and drainable fashion. The 3-A Sanitary Standards were developed by a consortium of food and dairy groups (including the FDA and USDA), in a non-profit company named 3-A Sanitary Standards, Inc.

With the growing need for specialized equipment for the pharmaceutical industries, a new 3-A group was formed: P3-A Council. P3-A has taken the responsibility for providing a standard for equipment used for active pharmaceutical

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What's Inside

INDUSTRY STANDARDS MORE THAN JUST A "HOW TO" (continued)

ingredients, intermediates, fill & finish, and packaging industries.

Coordination Between Standards

The potential for overlap in what these two publications covered was guaranteed. So the two groups, the P3-A Council and the executive committee of the ASME-BPE, met in 2005 to discuss and agree on their respective scope of work.

P3-A Council, who hosted the meeting, created a diagram (Fig. 1) that does a great job depicting what each standard covers and how they relate. The foundation of this division of responsibilities between BPE and P3-A is the molecule being processed and the unique requirements for each. BPE covers large molecule or protein processing where the aqueous solutions are typically pH neutral, ambient and can support the microbial growth. P3-A covers the small molecule or synthetic products that are typically developed in acids, bases and solvents and might be heated then cooled to precipitate or dry a solid product.

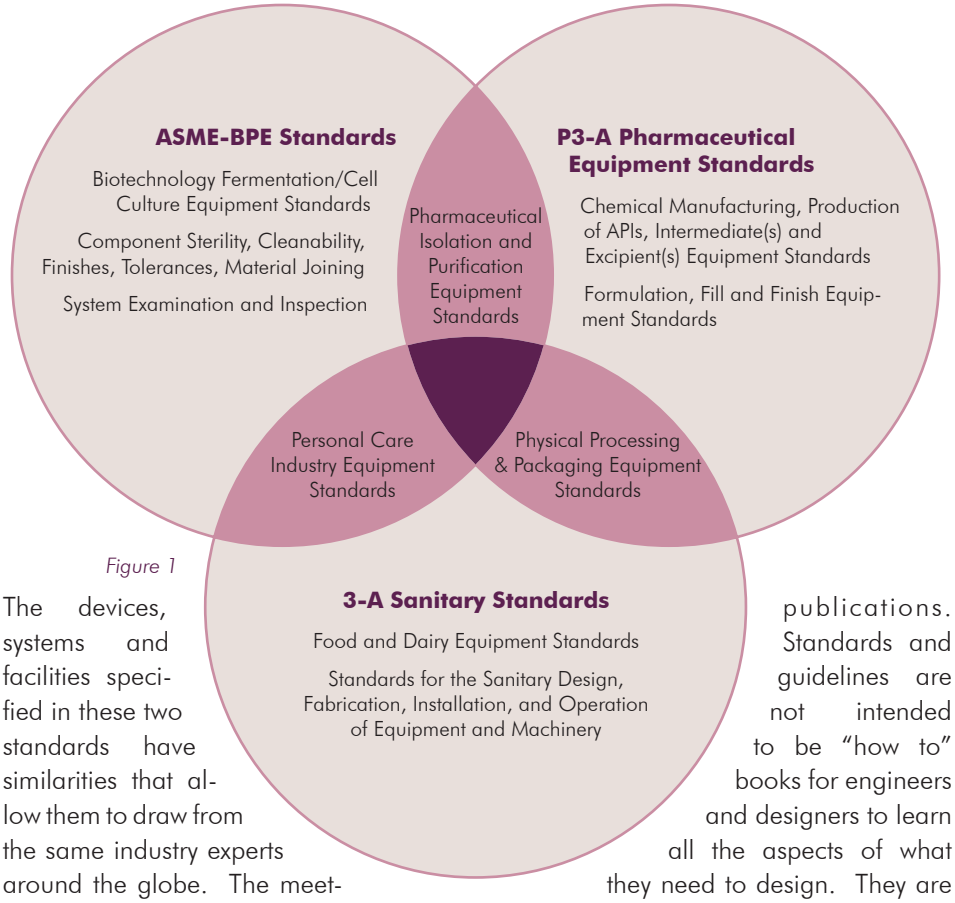

Figure 1

The devices, systems and facilities specified in these two standards have similarities that allow them to draw from the same industry experts around the globe. The meetings are informative to the participants as well as useful in creating these technical publications. Standards and guidelines are not intended to be "how to" books for engineers and designers to learn all the aspects of what they need to design. They are an organized grouping of the items that leaders in the industry agree, by voluntary consensus, are the features of successful designs or important acceptance criteria when inspecting those designs.

When you look to your left and right, are you the person that is involved in a standard or guideline? If not, you might be missing out on one of the best continuing education opportunities that exist. Working with the people that are involved with the ASME-BPE and P3-A Council will certainly make you a better designer or end-user of processing equipment.

CSI has demonstrated a long-term commitment to the development of BPE guidelines and the 3A standards through participation in task groups and committees. This commitment is a part of the investment that CSI is continually making in its industry and for its own sustainability. The industry experience and knowledge gained in these efforts is a part of why CSI is a partner on which you can rely.

About the Author: Jay Ankers

Jay Ankers is Director, Process Mechanical for LifeTek Solutions, Inc., a design and consulting group that helps biopharmaceutical companies develop processes, build manufacturing capacity and establish and maintain compliance.

Jay has over eighteen years of experience in biotech and pharmaceutical projects, including project management, construction management, facility turnover/commissioning, plant engineering, and CIP/SIP testing. He is an expert in management of overall facility and process design and layout, as well as process/utility equipment, piping, instrumentation, control systems, electrical, HVAC, civil engineering, and permitting. Jay also offers experience related to solid oral dosage, potent compounding, food-grade fermentation, drying, dust collection, and powders handling.

Jay is also heavily involved in the development of new process technologies, is actively involved in the ASME BioProcessing Equipment Standard (BPE) and chairs the Subcommittee on Design. He holds a B.S. in Building Science & Construction Management from Clemson University-College of Architecture.

Visit www.lifeteksolutions.com for more information about LifeTek Solutions, or call 267.460.0550.

Upcoming Events

CSI will be attending the following events in the coming months:

Wine & Grape Symposium
Booth #2207
Sacramento, CA
January 30-31, 2008

World Ag Expo
Pavilion D #4002
Tulare, CA
February 12-14, 2008

San Francisco Bay Area Chapter Vendor Night
South San Francisco, CA
February 28, 2008

Carolina-South Atlantic Chapter Technology Show
Raleigh, NC
March 8, 2008

Interphex 2008
Booth #1633
Philadelphia, PA
March 26-28, 2008

Alloys Seminar
Northern California
Coming Spring 2008

For more information about CSI's upcoming news and events, visit us online at www.csidesigns.com or call **800.654.5635**.

PRODUCT SPOTLIGHT:
ACE MANUFACTURING HOSE

CSI is proud to announce the addition of another quality manufacturer to our growing family of suppliers that help us provide products and services to the sanitary and high purity industries. CSI has partnered with **Ace Manufacturing Company** to represent their Flex-Rite™ line of rubber, silicone, PVC and Teflon hoses, as well as their industrial-grade hoses for washdown and steam applications.

An ISO 9001 registered company, Ace Manufacturing has consistently maintained a strong commitment to excellence throughout its 40 years of service to a wide variety of industries and business segments.

This commitment is evidenced by their development of the innovative Seal-Rite™ radial crimp couplers used on their hose assemblies. Seal-Rite™ fittings utilize the exclusive TwistLOC™ technology to provide an inseparable 360° fixed seal between the coupler stem and hose.

Unlike internal expansion methods which can deform metal and leave die impressions, the Seal-Rite™ radial crimp process will not interfere with the internal surface of the coupling stem. A full flow smooth bore transition is created after fabrication that eliminates ledges or crevices that can collect bacteria.

In addition to stocking a generous inventory of bulk hose and a wide variety of fittings, CSI is also a factory certified assembly center offering complete assembly services using our state-of-the-art crimping machine with computerized controls. The ultra-precise controller module utilizes sensors that measure and integrate both die position and required crimp force, automatically compensating for tolerance variations in the hose and fitting combination. This ensures that every hose assembly is crimped right every time.

Our assembly capabilities, located in CSI's Fowler, CA facility, give us the ability to provide all CSI customers with quick turnaround on a wide selection of hose and fitting combinations ranging from ½ to 4" diameter and in virtually any length you need.

Call CSI today at **800.654.5635**, and let one of our knowledgeable customer service representatives show you why CSI is the place to go for help with your hose and hose assembly needs.

Michael Louck Is Building Relationships with CSI Customers

Prior to building solid relationships with CSI's customers, **Michael Louck** spent his time actually building. "I have a background in construction and love working on my house," Michael said.

Now, however, Michael Louck is enjoying his new role as Customer Service Representative at CSI. Before joining CSI, Michael worked at McLeod USA in the repair/customer service department. This opportunity provided him with a lot of experience that he now applies to his job at Central States.

"Following up with a customer was always a big part of my job," he said.

On the job at CSI, Michael is taking calls and helping customers by providing accurate prices and part numbers, entering quotes and focusing on customers in CSI's California area.

Excited about his future at CSI, Michael said, "I am constantly training to become more knowledgeable so I can better assist our customers."

When asked what a customer might call him about, Michael was quick to reply, "Honestly, a customer can call me for just about anything, because if I don't have the answer I will find the answer."

Currently, Michael is also completing his degree in business at Evangel University.

If you need assistance, or have a question that needs an answer, give Michael Louck a call at **800.654.5635** extension 182.

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Visit us online at www.csidesigns.com

AA (ACRONYM AWARENESS)

All industries utilize an abundance of industry-related acronyms, but how many of them do you actually know? At CSI, we specialize in sanitary and high purity processes; so, we put together a list of acronyms used in engineering systems for food, beverage, bio tech, and pharmaceutical processes.

Test your skills with this second installment of "AA," and see how well you fare by checking your answers online at www.csidesigns.com/quiz.php. Then, check the next Transfer for the final segment of Acronym Awareness.

(1) B31 _____
(2) B31.1 _____
(3) B31.3 _____
(4) B31.5 _____
(5) B31.9 _____
(6) AWS _____
(7) GTAW _____
(8) NIH _____
(9) BSL _____
(10) CDC _____
(11) BPVC _____
(12) MSDS _____
(13) PTFE _____
(14) FSIS _____
(15) OSHA _____
(16) USDA _____
(17) CGMP _____
(18) PFD _____
(19) P&ID _____
(20) ASTM _____
(21) ASME _____
(22) ANSI _____
(23) IBC _____
(24) NEMA _____
(25) NIST _____
(26) EHEDG _____