

July 2007

What's in this Issue?Message from the BPE
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UPCOMING EVENTS Learn
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New in
May 2006
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19th Annual
Bioprocess
Technology
Seminars
October 23-27, 2006
Montreal, Canada**MESSAGE FROM THE BPE CHAIR***- Anthony P. Cirillo*

CONSISTENCY AND UNIFORMITY: Without these, discipline, productivity, and progress suffer, which ultimately leads to lack of communication, confusion, and liability issues.

The Bioprocess Equipment (BPE) Standard offers the mechanism that allows us, the Biopharm community, the ability to share in the numerous design and installation methods and philosophies that have been kept as privileged information for so long. The Standard is very succinct and definitive in its statements as is apparent by its measurable performance requirements. With the Standard, manufacturers, end users, and engineers have a single language and a common understanding, facilitating consistency and uniformity.

Our most recent meeting, held in Basel, Switzerland, included a training seminar on "Metallic Materials of Construction for Hygienic Services." The seminar addressed critical details of materials selection and fabrication techniques for hygienic systems. This session was conducted by ASME's Bioprocess Technology Seminar Group. The combination of these two teaching and sharing sectors within ASME resulted in a pleasant and positive learning experience for all in attendance.

The BPE Standards Committee and the Bioprocess Technology Seminar Group are currently working together on an ASME International Bioprocess Equipment Conference - including training seminars - to be held in Europe in June 2007. Together, both sectors will carry on the true spirit of the BPE Standard, which is to share our knowledge and experience with all members of the community around the world.

To this end, we are continuously seeking individuals who are willing to commit themselves to further advance and enhance the Standard and the knowledge of the worldwide Biopharm community.

LEARN AND GET INVOLVED

The BPE Committee, with its 9 subcommittees and numerous task groups, are meeting in San Diego on October 9-12, 2006.

Current activities of the BPE Subcommittees include:

- [Dimensions and Tolerances](#)
- [Design for Sterility and Cleanability](#)
- [Seals and Gaskets](#)
- [Polymer-based Materials](#)

Plus more. Visit the BPE website at www.asme.org/communities/technical/bpe

UPCOMING EVENTS

October 9-12, 2006: BPE Committee Meetings at the Sheraton Suites, 701 A Street, in San Diego. All meetings are open to the public as space will allow. For more details, please contact Paul Stumpf at 212-591-8536 or stumpfpa@asme.org

October 23-27, 2006: ASME 19th Annual Bioprocess Technology Seminars at the Hyatt Regency Montreal. This event offers 11 concurrent technical seminars covering a broad range of bioprocessing topics, each presented by an influential lineup of speakers. The event also includes tabletop exhibits, plant tours, and networking functions. For more details, visit the website at www.asmeconferences.org/bioprocess06 or contact Jennifer Delda at 212-591-7108 or e-mail deldaj@asme.org

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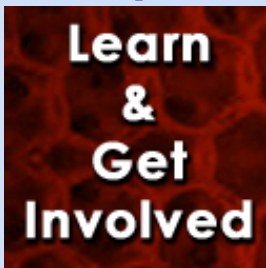
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Upcoming Events



Dimensions & Tolerances (DT) Subcommittee News

Chair: Frank Manning, Biopharm USA, VNE Corporation

Vice Chair: Dan Mathien, Industry Consultant

The Dimensions & Tolerances (DT) Subcommittee - a group of professionals actively involved in creating dimensions, tolerances and marking of stainless steel automatic weld, hygienic clamp tube fittings and all process components - is looking for new active members. If you're interested in becoming a member, make sure to come to the Subcommittee's meetings; the next to be held in San Diego the week of Oct. 9, 2006.

The Subcommittee currently has 19 active members, and each of its last three meetings has drawn between 14 and 27 visitors from industry worldwide. Since its major focus is stainless steel automatic weld, hygienic clamp tube fittings and all process components, the DT Subcommittee continually looks for opportunities to better use the fittings in the ever-changing technologies available - which is happening right now with concentric and eccentric reducer type fittings. As members of the Subcommittee, our challenge is to cut out dead leg areas out of fittings wherever possible.

Because today's acceptable fittings are much longer than necessary for new weld technologies and system designs, the Subcommittee at its recent meeting in Basel, Switzerland, has completed a draft proposal to shorten concentric fittings by 50 percent in most cases. The proposal, which is ready to go to main committee, was based on conclusions reached by the Subcommittee's "fittings task group." This task group will next address eccentric fittings.

The DT Subcommittee has tested the proposed fitting designs with actual sample fittings (done by Advance) for weld ability (done by CSI) with standard automatic weld heads and found them to be acceptable. Dr. Gad Elkabir, formerly with EGMO, also tested the new fittings for turbulence and flow characteristics and found them acceptable. The Subcommittee hopes to introduce the new concentric fittings in the 2007 edition of the BPE International Standard. The Subcommittee is currently at work on the proposal for eccentric fittings, and we will keep you updated on our progress.

Another considerable undertaking for the Subcommittee is the dimensioning of the hygienic ferrule faces. In the past, each manufacturer had its own dimensions and none matched each other. Today in the new 2005 edition of the BPE Standard, you have a table that calls out nominal dimensions that all manufacturers agreed to and currently adhere to as well. Members of the Subcommittee are right now looking at hygienic clamps for critical dimensioning at designed pressure points to ensure acceptable gasket seating with no intrusion or unacceptable crevice - an endeavor that our "clamp task group" is working on and is being coordinated with the Seals (SG) Subcommittee.

If you are interested in joining us in this important work, please join us at the DT Subcommittee meetings in San Diego this October.

Frank J. Manning (Chip)



Sales Director, BioPharm USA
VNE Corporation
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BPE News

Newsletter of the ASME BioProcessing Equipment (BPE) International Standard

www.asme.org/communities/technical/bpe

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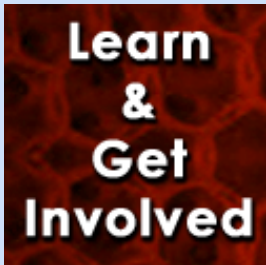
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UPCOMING EVENTS



Subcommittee on Design for Sterility and Cleanability (SD)

Chair: Jay Ankers, LifeTek Solutions

Vice Chair: David Marks, DME Alliance

The Design (SD) Subcommittee of the ASME BPE focuses on the design of bioprocessing equipment as it relates to cleanability and sterility.

There are three levels that SD addresses: Device, System, and Facility. During the first two decades leading up to this year, the subcommittee built SD Part on the design of devices such as vessels, agitators, transfer panels, hygienic unions, and instruments as well as facility level design elements that contributed to their cleanability and sterility. The next decade will see the development of the system elements such as CIP Systems, Clean Steam Systems, Compendial Water Systems, Bioreactors, Autoclaves, and Glasswashers.

New members and visitors have challenged the BPE to investigate what contributes to a system's drainability and ability to minimize microbial growth between cleaning and steaming cycles. The SD subcommittee is now supporting investigation taskgroups looking closer at what makes devices and systems even more cleanable for aseptic or sterile processes. Another investigation taskgroup has been formed to determine the minimum turbulence or Reynolds number required to clean during CIP or minimize biofilm in recirculated systems.

SD is the largest subcommittee with over a dozen active taskgroups working on the changes and updates for the next couple of BPE editions. The groups are organized to address the latest design challenges that face our fast-paced industry.

Learn and Get Involved. Join us at the next BPE meeting to be held on October 9-12, 2006, in San Diego. All meetings are open to the public as space will allow.

For more information on SD activities, contact:

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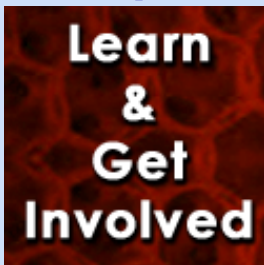
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Subcommittee on Seals and Gaskets (SG)

Chair: Cal Brown, Swagelok Co.

Vice-Chair: Marc Pelletier, MPP Biodesigns

The SG Subcommittee is currently focusing on seal performance in a variety of situations including hygienic gasket seals, diaphragm valve seals, and mechanical pump seals. With regard to mechanical pump seals, the specific focus is on pumps for compendial water systems.

For hygienic fitting seals, items currently under review include seal intrusion, leakage criteria, material formulation and absorption, and dimensional criteria.

Under review for diaphragm valve seals are the performance characteristics and applications.

One of the major focuses of the SG Subcommittee is mechanical pump seals for compendial water systems. The taskgroups under this Subcommittee are considering leakage testing, materials of construction and consideration of compliance including biocompatibility, material traceability requirements, design considerations and seal arrangement, particle generation considerations, and acceptable lubrication methods for these types of mechanical pump seals.

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For more information on SG activities, contact:

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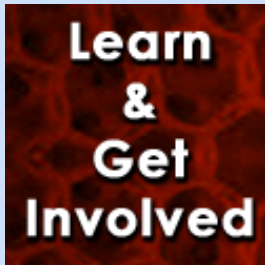
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Polymer-based Materials (PM) Subcommittee

Chair: Ted Hutton, Arkema Inc.

Vice-Chair: Reinhard Hanselka, IES Inc.

This Subcommittee establishes requirements that are applicable and unique to the use of polymer-based materials used in bioprocessing equipment, components, assemblies, and bioprocessing systems. Polymer-based materials include thermoplastics and thermosetting materials both virgin and composite forms.

At its recent meeting in Basel, Switzerland, the PM Subcommittee added a brief statement about extractants for inclusion in the 2007 edition of the BPE Standard. The Task Group on Elastomers Materials of Construction is actively working on defining measurable criteria for elastomers. Other task groups, including Filters, are working on input for the 2009 edition.

The PM Subcommittee will have a joint meeting with the Seals & Gaskets (SG) Subcommittee in San Diego at the October 9-12, 2006 meeting. During this time, a follow-up presentation for the AMGEN testing program given at the January 2006 San Juan meeting will be presented.

This Subcommittee welcomes input from interested parties. For more details regarding participation, please contact:

Ted Hutton

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