



ITT chromatography valve assembly connecting the chromatography column to the process piping



Letter from Bill

Bill Taylor, President
Industrial & BioPharm Group

Included in this issue of Solutions is the Oct. 5, 2005 press release announcing the closure of the Pure-Flo Precision operation in Springfield, MO and move of Precision products to the Pure-Flo facility in Kenosha, WI. At this time we are completing open orders in Springfield, while a cross-functional team of coworkers from Springfield and Kenosha carry out the transfer of Precision designs, processes and products. I want to recognize and thank the Pure-Flo Precision coworkers, who continue to focus on customers and quality during this extremely difficult time. Our pledge to customers is to carry this Pure-Flo Precision tradition forward in our reconfigured operation.

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Diaphragm Development

Diaphragm development is a significant part of ITT Pure-Flo's Research and Development activities. We are continuously advancing the state of the art with respect to diaphragm technology.

Pure-Flo diaphragm recipes must comply with FDA regulations and with USP Class VI. The applicable FDA regulations are provided in 21CFR177, *Indirect Food Additives: Polymers*. In the case of EPDM, the specific requirements are provided in 21CFR177.2600, *Rubber Articles Intended for Repeated Use*. These regulations limit the EPDM polymer types which may be used, as well as type and quantity of vulcanization agents, accelerants, plasticizers, fillers, etc. In addition, these regulations require that samples be subjected to extraction testing in distilled water at reflux temperature. The purpose of extraction testing is to ensure that elastomers do not give off materials to an extent that would affect food or drug purity. It's important to note that FDA does not "approve" specific recipes; rather, it limits the ingredients and specifies testing criteria as noted above.

USP Class VI refers to testing outlined in United States Pharmacopeia, Sections 87 and 88. In these tests, living organisms are exposed to samples of the elastomer or plastic material, in order to evaluate the toxicity of the material. Class VI refers to the highest possible classification; that is, the least apparent toxicity to the organisms. Testing is conducted by independent third party labs.

Diaphragm manufacturing is a complex process. In addition to the elastomer ingredients, major considerations include the mixing and calendaring (sheet-making) process, assembly of the uncured diaphragm, fabric selection and placement, stud



placement, and vulcanization process parameters. Vulcanization is the process of 'curing' the material and relies on appropriate application of heat, pressure, and a curing agent such as sulfur or peroxide. Prior to vulcanization, elastomers flow and resemble thick liquids. Vulcanization results in the cross-linking of the polymer chains, thus giving elastomers their familiar toughness and elastic characteristics.

At ITT Pure-Flo, diaphragm recipes and manufacturing process variables are selected and evaluated using advanced statistical techniques, including Taguchi parameter design and Weibull statistics. These methods are used to minimize the number of tests required, while ensuring meaningful results.

Cover story - continued on page 3



Gary Soucy



Greg Newcomb



Dana Brown

SHOP TALK: e²TOP™ Documentation

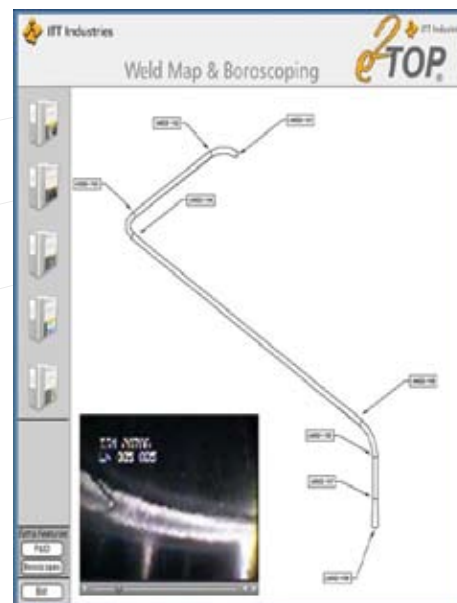
e²TOP isn't just for documentation anymore ...

The Pure-Flo facilities in Kenosha, WI and Danvers, MA implemented eTOP as a work flow process, database driven project management and turnover package in 2002. e²TOP was launched in 2005 at the Kenosha, WI facility as a nearly paperless process that facilitates the automated compiling of a "Turn Over Package". Now, in keeping with our goal of 100% on-time performance, e²TOP is used to track our progress to schedule and to reduce rework.

Complex project schedules are developed to manage the hundreds of tasks required in the manufacture of 'engineered to order' skids and modules for the BioPharm industry. One of the tasks with the longest duration and greatest impact to schedule involves the welding and inspection of process piping. A typical skid or module could have hundreds or even thousands of welds. It is critical to project timing that this work is completed on-time. This is where e²TOP helps out.

Once weld maps are completed, the numbered welds for each process line are put into the e²TOP database. At this point, we know how many welds need to be made and inspected to complete the overall task. Together with the project schedule, we can track in "real time" our progress at achieving the welds per day required to meet our customer's schedule.

An added benefit of this process has been the drastic elimination of weld documentation errors. Because the required weld documentation information (material tag numbers, line numbers, heat numbers, machine identification number, etc.) is pre-populated in the database, the possibility for keyboard entry errors by welding technicians is eliminated. All selections are made using the 'drop-down' menu features of e²TOP and technicians simply select the correct information from the database.



INDUSTRY INSIGHT: Process Analytical Technology (PAT) – an FDA initiative for the 21st Century

In 2002 the FDA launched a new initiative entitled, "Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach." The purpose of this initiative was to encourage biopharmaceutical manufacturers to use the most current concepts of risk management with the latest scientific advances in pharmaceutical manufacturing and technology to improve both drug product quality and manufacturing efficiencies.

As part of this program the FDA published its "Guidance for Industry" PAT- A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, in September of 2004. The purpose was to describe a regulatory framework for PAT that would encourage the voluntary use by the industry to encourage innovative product development, manufacturing and quality assurance.

The manufacture of pharmaceuticals is most commonly accomplished using batch processing backed by laboratory testing conducted on samples to assure quality. It is the contention of the FDA, however, that there exists a significant

opportunity today to improve pharmaceutical development, manufacturing efficiencies and quality assurance through process analysis and control.

PAT as outlined by the FDA consists of At-Line, On-Line or In-Line process monitoring that will rapidly measure a process critical control parameter (PCCP). Process control parameters are identified and selected due to their critical impact on producing a consistent quality product. It is believed that these rapid measurements of PCCPs will streamline Biopharmaceutical manufacturing, increasing efficiencies and improve product quality.

Sources:

- 1.) [Strategies for Successful Implementation of PAT in Pharmaceutical Manufacturing](#), Pharmaceutical Review, Volume 6, Issue 3. Fall 2003
- 2.) [PAT- A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance](#), Guidance for Industry, FDA, Pharmaceutical CGMP's September 2004



Denis Gauthier



Colin Harrington



Chuck Soletto

PURE-FLO UPDATE: Precision

As a result of continued economic softness in the global biopharmaceutical marketplace, ITT made the strategic decision to evaluate its manufacturing capacity across the business. As a result, the Springfield, MO facility will be closed and the work transferred to Pure-Flo in Kenosha, WI. Other factors leading to this decision include increasing segment competition, commoditization of the market, excess capacity and general business consolidation.

"This decision is not a reflection of the efforts and commitment of the employees here at the organization," said Bill Taylor, President of Industrial & BioPharm Group. "Like those at our other Pure-Flo facilities, the employees here have continually delivered the highest quality products to our customers. Unfortunately, continued economic softness and excess capacity have made necessary our strategic decision to close this facility and transfer the business to Kenosha, Wisconsin."

We will continue to quote customer needs for vessels and certain components. The production of those products will continue in the Kenosha, WI facility. The Kenosha facility has the production space, expertise and ability to meet all customer needs. The facility also has experience manufacturing overflow for Precision in the past. Design standards and critical manufacturing processes will be transferred to Kenosha. By the end of the year 2005, manufacturing will be transferred from Springfield, MO to the Kenosha, WI facility.

We are committed to maintaining our focus on customer service and to continue providing you with high-quality products, on time and within specification. We value your business and are committed to ensuring that there are no disruptions as a result of the production transfer to Kenosha.

INTRODUCING: Edgar Marino, Pure-Flo Product Manager

On October 10, 2005, Edgar Marino began working at ITT Pure-Flo as the Product Manager for Electrical Components. Edgar provides Bus Network Technology training and technical support for Pure-Flo TSR's and customers. In his new position, Edgar enjoys meeting with current and prospective customers in order to understand what will be needed for the next generation of Pure-Flo products.

Edgar received a BS in Electrical Engineering from the New Jersey Institute of Technology (NJIT). He first chose his line of work when he was exposed to network technology and control theory in college. Before coming to ITT, Edgar was a Marketing Engineer for different industrial bus networks.

Edgar is an active member of ISA (Instrumentation Society of America), PTO (Profibus Trade Organization), ATO (ASI Trade Organization), ODVA (Open DeviceNet Vendors Association of America). He periodically assists with technical seminars and certification classes from all the associations mentioned above.

In the future Edgar would like to combine his technical background with a management career. His parent's professional example and dedication motivate him to put forth his best effort. About his experience at ITT Edgar says, "People at ITT have made me feel very welcome during this new phase in my career."

Outside of work, Edgar practices sports such as judo and basketball. He also enjoys learning new languages. Since Edgar is from New Jersey, he is getting acquainted with Lancaster, PA and will eventually re-locate to the area.



Diaphragm Development (cont. from pg. 1)

Diaphragm qualification testing includes both shutoff and cycle testing while exposed to vacuum, hot water, and steam conditions. For example, sample diaphragms must survive 30,000 cycles in 45 psi saturated steam to be considered acceptable.

All of ITT Pure-Flo's experience and expertise have gone into the development of our new compound, Grade 17HP EPDM. This compound exhibits a cycle life improvement

of more than 60% over the current standard Grade 17 EPDM. In fact, we are aware of no other weir-type elastomer diaphragm on the market that is available with this level of performance.

For more information on Grade 17HP EPDM or any other ITT diaphragms please contact:

Paul L. McClune, Jr. - Product Manager,
Pure-Flo Solutions Group
Paul.mcclune@itt.com



Luke Ciarfello

"Can-Do" ATTITUDE

In May 2005, a Project Engineer from a New England based Pharmaceutical company contacted Pure-Flo Solutions Group, regarding a vessel fabrication need. The customer explained that he needed to increase the size of a vessel from 2000 L to 3000 L on site. He stressed that the project only had a small window of time for completion and was very critical for the company. Field Fabricator Randy Colwell and the Pure-Flo Field Service team worked 12 hours a day, 7 days a week to complete the project. The vessel had to be cut in half, including the dimple jacket and a larger section welded in place.

Throughout the project, Pure-Flo Technical Sales Representative Jeff Marshall kept in contact with the customer and followed up with the Pure-Flo Field Service team to ensure that everything was running smoothly. Jeff knew that the Field Service team would do a great job for the customer, because of the positive feedback he had recently gotten from two other pharmaceutical companies with similar projects.

The project was completed on time and the customer was very satisfied with the work done. At the end of the project Jeff heard "Boy they sure can weld, the guys were incredible!" from another satisfied customer.



Randy Colwell, Field Fabricator

UPCOMING EVENTS

- ISPE Delaware Valley, January, 2006
- Interphex Puerto Rico, San Juan, PR - February 16-17, 2006
- ISPE Winter Conference, Tampa, FL - February 20-22, 2006
- ISPE Rocky Mountain, Boulder, CO - February, 2006
- ISPE South Atlantic, Durham, NC - March 1, 2006
- ISPE Great Lakes, Chicago, IL - March 7-8, 2006
- ISPE San Francisco, San Francisco, CA - March 9, 2006

Be sure to find us at the next trade show event in your area!



How to Contact Pure-Flo Solutions Group

Please note that all facilities are now named Pure-Flo, as demonstrated below. The sites will be differentiated by the city and state (ex. Pure-Flo in Lancaster, PA). Also note that the facility in Danvers, MA has a new mailing address.

Any Precision related questions can be directed to:

Technical Contact: Mike Doherty, (262) 564-6785
Customer Service: Randy Colwell, (417) 848-0040

www.ittpureflo.com

Pure-Flo Headquarters
33 Centerville Road
Lancaster, PA 17603-2064 USA
Phone: 1-800-366-1111
Phone: 717-509-2200
Fax: 717-509-2336

Pure-Flo
PO Box 325
Danvers, MA 01923
Phone: 978-774-6777
Fax: 978-750-6219

Pure-Flo
110-B West Cochran
Simi Valley, CA 93065
Phone: 805-520-7200
Fax: 805-520-7205

Pure-Flo
9625 55th Street
Kenosha, WI 53144
Phone: 262-654-6466
Fax: 262-658-0694

Pure-Flo
Richards Street
Kirkham, Lancashire
PR4 2HU, England
Phone: +44 (0)1772 682696
Fax: + 44 (0)1772 686006

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To add your name to our mailing list email Heather Sandoe at heather.sandoe@itt.com or call (717) 509-2208.