Medical Silicone Conference

April 6-7, 2010 • Hyatt Regency Minneapolis

Brought to you by: Medical Design

LEARN FROM THE EXPERTS AT THIS DYNAMIC, TWO-DAY EVENT!!

TUESDAY SESSIONS

Improve Product Design & Reliability and Reduce Cost via Multi-Component Molding of Liquid Silicone Rubber Over Thermoplastics

Eric Bishop, Marketing Manager for Shin-Etsu Silicones and David Wolgemuth, Senior LSR Engineer for Phillips Plastics will discuss how innovations in LSR chemistry allow for 2-shot and insert overmolding of silicone on a variety of engineering thermoplastics, including polycarbonate, without the use of primers or pre-treatment. The silicone chemically bonds to the substrate in the mold yielding 100% cohesive failure in pull-testing. Products are compliant with USP Class VI and ISO 10993 standards and are available in a wide range of hardnesses to fit numerous applications.

Silicones for Long-Term Implantable Devices

Bob Umland, National Sales Manager: NuSil Silicone Technology LLC will address the understanding of silicones for long-term implantation and identify the importance of support for regulatory standards and requirements, including FDA Master Files. He will take a look into the future of implantable devices and define the benefits of incorporating Active Pharmaceutical Ingredients into silicones for combination products.

Can Antimicrobial Silicone Reduce the Risk of Medical Device-Related Infections?

Presented by K. Mark Wiencek, PhD, Milliken & Company. Hospital Acquired Infection liability issues are front and center and affecting device OEMs more than ever. Wiencek will address the important and growing role of antimicrobial silicone.

Multi Dimensions in Silicone Rubber Fabricating

Paul Mazelin, Marketing Manager, Specialty Silicone Fabricators will discuss the various disciplines of silicone rubber fabrication and how manufacturing techniques have developed over the years. This presentation will examine how standard processes are being challenged by new ideas coming from device designers such as the impact of combination products and how these developments can limit some fabricating processes.

KEYNOTE ADDRESS

Dangerous Documents: Avoiding Land Mines in Your FDA Records and Emails

Former U.S. DOJ Prosecutor and Advamed Special Counsel on FDA compliance Nancy Singer will address how documents in your firm's files likely contain phrases which, if your company is ever sued, can be taken out of context to infer inappropriate or negligent conduct. Learn how to avoid this costly problem.

WEDNESDAY SESSIONS

The Challenges of Manufacturing Combination Components

Presented by Jane Cleary, Director of Quality Assurance, ProMed Pharma, LLC. Differences in regulatory requirements between manufacturing medical devices and pharmaceutical products present unique challenges to silicone molding. Cleary will discuss some of the challenges in producing combination components in terms of facility design, quality system, and resource requirements.

Virtual Part, Mold & Process Evaluation: The Key for Cost Reduction from Part Development to Production.

Kaushik Manek, SIGMA Plastic Services, Inc. will discuss a methodology to use polymer system simulation beyond common flow analysis. Technical aspects of silicone part, mold, and process evaluation will be discussed as well as the savings potential using a holistic development approach.

Tooling for Liquid Silicone Rubber

Presented by Greg Roembke, President, Roembke Mfg & Design, Inc. Part geometries continue to be more demanding in medical device applications. Roembke will discuss achievable machining tolerances and mold requirements as well as achievable tolerances from the molding perspective. Obtaining better consistency during the molding process is critical in volume production. Greg will address how to ensure long-term quality and compliance.

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