MEDICAL PLASTICS MINITEC

Anaheim, California • February 4, 2019

Presented by SPE Medical Plastics Division and SPE Southern California Section

SPEAKERS

Keynote: Materials for Medical Applications

Jacqueline A. Anim

Principal Materials Engineer
Ethicon & OneMD (JNJ)

About the Speaker

Jackie is a principal material engineer for Ethicon, a subsidiary of Johnson & Johnson that manufacturers surgical systems and instruments. She currently serves as a subject matter expert for the company as it aims to leverage various blends of polymer technologies to innovate in the design and manufacturing of digital and non-digital devices and instruments. In her role, Jackie provides leadership and direction in the identification and selection of polymer base materials for both sustaining and new product developments at Ethicon and other businesses within Johnson and Johnson (JNJ).

Jackie is a certified Six Sigma green belt champion with more than 24 years of experience in material science and material application engineering. She led the very first medical material data Management System called integrated material optimization environment (iMOE) to manage material selection holistically at Ethicon.
Jackie in 2015 received the JNJ Global Surgery Award for Scientific Excellence for her role in leading the development and implementation of an injection moldable electro-mechanical proprietary material for harmonic powered medical devices. She is also passionate about educating and sharing material knowledge within the Industry.

Jackie earned a MS in Chemical Engineering from the University of Dayton in Dayton, Ohio. She has a BS degree in Chemical Engineering from University of Science & Technology, Ghana.

Jackie is a member of the Society of Plastic Engineers and a member of the American Institute of Chemical Engineers AIChE. She has 7 publications and 9 patents relative to plastic applications.

Morning Session: Polymer excipient technology for extended release of API

Dr. Greg Moakes

Lead, Field Development
Celanese Corporation

Summary

The polymer industry has a crucial role to play in the changing landscape of API delivery. Patient outcomes are strongly affected by compliance. Compliance can in turn be increased by eliminating undesirable elements of drug delivery such as injection site discomfort, incorrect dosage of self-administered therapies, and side effects due to fluctuating blood serum concentrations. Excipient technologies serve to address these concerns while in many cases preventing side effects associated with first pass metabolism. This briefing will focus on aligning our polymer excipient technology with evolving small molecule and biologic therapies. This presentation will cover a broad range of literature examples where Ethylene Vinyl Acetate (EVA) is used to create a tortuous path for API delivery. Examples shown will cover subcutaneous, transdermal, oral, and intraocular implant examples.

About the Speaker

Dr. Greg Moakes, a physical chemist by training, leads the Field Development team for the Celanese Corporation medical polymers business.

Greg and his team use medical and implant grade products to create technical solutions for the medical device and pharmaceutical industries.

Greg received undergraduate degrees in Chemistry from the University of Leeds in the UK. He also holds a Ph.D. in Electroanalytical Chemistry from the Georgia Institute of Technology, and a Master's in Business Administration from Southern Methodist University.

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Morning Session: Materials and process technology solutions for designing connected medical devices

Manish Nandi

Staff Scientist, Healthcare Industry Technology
SABIC Specialties

Summary

The future trend for medical devices for diagnostics, monitoring, and drug delivery are miniaturization and wireless connection to mobile phones or other receivers. Designers are often challenged by new needs. This presentation will focus on materials and process technologies SABIC has developed to incorporate connectivity, from antennas to EMI shielding, in these devices.

Poster Session: Polymer and Geometry Selection of Injection Molded Microneedles

About the Speaker

Manish Nandi is a Staff Scientist in Healthcare Industry Technology group at SABIC Specialties working on new product and technology solutions for healthcare applications. Prior to joining SABIC, from 2003-2011, Manish worked in area of new technology and product development at W. L. Gore and Associates. Prior to that, he worked for ARCO/Lyondell Chemical for over ten years in various Technology roles in their R&D. Manish received his Doctorate in Chemistry & Polymer Science from the Pennsylvania State University. Manish holds multiple patents and is the author of several technical papers in materials chemistry and polymers.

Morning Session: Biodegradable/ Resorbable Polymers: Recent Themes and Challenges in the Medical Device Industry

Dr. Rob Klein

Lead Medical Polymer Scientist/Engineer
Stress Engineering

Summary

The medical device field has a growing number of engineering and specialty resins available for use in biodegradable/resorbable devices. These devices may be used on tissue or organs or be implanted. Devices that often use these resins may include bandages, tissue scaffolds, repair meshes, surgical markers, sutures, screws, and drug delivery devices. These polymer resins face a different set of challenges than typical plastic resins in terms of processing, testing, and performance in vivo. Stress Engineering will review the current state of biodegradable/resorbable medical resins and then provide specific examples from our work highlighting processing challenges, common test protocols, and key performance metrics.

About the Speaker

Dr. Klein is the lead medical polymer scientist/engineer at Stress Engineering and has been with SES for over 4 years. He has more than 10 years of industry experience in activities such as polymer testing, material selection, new material development and validation, accelerated aging and life prediction, and failure analysis.

This has included multiple recent efforts in biodegradable and resorbable material development and testing for medical devices.

In the medical sector, efforts have spanned plastics, thermosets, elastomers, and polymeric fluids for both single-use and reusable devices.

Prior to SES, Dr. Klein worked at Luna Innovations in Charlottesville, VA; and Sandia National Laboratories in Albuquerque.

He holds a B.S. in Chemical Engineering from University of California Santa Barbara, and M.S. and Ph.D. in Materials Science and Engineering from Penn State University. He is a current member of the Society of Plastics Engineering and the American Chemical Society.

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Morning Session: Friction Reducing Materials for Medical Devices

Dr. Bob Hergenrother

Senior Director of Research and Development
Biocoat

Summary

Vascular devices such as catheters and guidewires utilize friction-reducing materials to minimize the friction between vascular tissues or other devices, reduce procedure times and enhance maneuverability. The materials can be additives to the polymer or coatings to the device surface that are either hydrophobic materials, such as polytetrafluoroethylene (PTFE), or hydrophilic coatings. The materials have a range of frictional forces, with hydrophilic hydrogel coatings typically having the lowest frictional forces. Friction evaluations can utilize test apparatus that measure the force needed to move a test item with an applied normal force or in a simulated use model that track the force as a function of insertion length. It is important to measure the foreign material particulate generation from the device movement to understand the potential embolic and other hazards in the vasculature. Performance testing results comparing hydrophilic coatings, fluorinated polymers and other additives to polymers will be shown.

About the Speaker

Robert Hergenrother, Ph.D., is Senior Director of Research and Development at Biocoat. Prior to joining Biocoat, he was Director of Medical Technology Development at Southern Research and Professor of Biomedical Engineering at the University of Alabama at Birmingham.

Earlier in his career, Hergenrother held multiple positions at Surmodics, Inc., serving most recently as senior director of research and development, and at Target Therapeutics (now Stryker Neurovascular), where he developed endovascular medical devices to treat diseases of the brain.

Hergenrother has led the launch of over 15 new products in the medical device and coatings areas. He has 24 issued U.S. patents and more than 25 scientific publications. Hergenrother holds a Ph.D. in chemical engineering from the University of Wisconsin and Bachelor of Science in chemical engineering from the University of Notre Dame.

Morning Session: Design Considerations for Medical Plastics with CAE & FEA

Dr. Alan Wedgewood

Product and Pprocess Development / Material Testing and Modeling
DuPont

Summary

When applied early in the device prototyping, simulation technology can reduce time to market, identify design deficiencies, assess the mechanical performance of a medical device, and enhance design optimization. Several design and simulation approaches are available, including Computer Aided Engineering (CAE) and Finite Element Analysis (FEA). Key to the successful use of these simulation approaches is having accurate mathematical representations of the materials being used. These mathematical representations or material laws allow for accurate simulation of the device's response to applied loads and environmental changes. The data required to generate these material laws, often require the use of advanced test methods. In some cases, simulation of the test itself is necessary to extract the required data. This presentation discusses the application of advance testing in support of the development of these material laws and how they are applied to support the design of medical devices with examples based upon DuPont materials.

About the Speaker

Alan Wedgewood has over 40 years of experience in product and process development / material testing and modeling. At Dupont, Alan has investigated a wide range of materials, including advanced composites, fiber reinforced engineering polymers, rubbers and nanometals.

His recent work has focused on supporting application developments for the automotive, electronics, industrial and healthcare markets, with advanced testing and modeling. His materials physics understanding of the behavior of these materials has been used to develop unique advanced test methods to elucidate their strain rate dependency, nonlinear viscoelasticity, and progressive damage failure.

These application developments have been further supported with advanced material models for anisotropic micromechanics, fatigue, creep, stress relaxation and failure predictions.

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Morning Session: Medical Device Plastics and Adhesives - A Design Approach

JoAnne Moody

Summary

A successful Medical Device development approach for both adhesives and polymers includes a roadmap for product design. Although there are numerous ways to bond materials, often the designer is faced with bonding dissimilar materials and a difficult design where only an adhesive is the right bonding solution. Without a proven methodology to follow, product teams find themselves in a failure loop, without a methodology to resolve bonding challenges and prevent downstream problems. With unsolved failures, often the product team, or company, faces a "shut down" situation. The steps for adhesive/polymer bond success include design evaluation, an understanding of adhesive fundamentals, chemical compatibility, joint design principles, regulatory issues, testing, and processing. A case study of a Medical Device moving from single-use to multi-use requirements will be provided. This design approach includes key factors for success and a roadmap to aid in project management and risk mitigation.

About the Speaker

JoAnne Moody, with 25+ years' experience in medical devices, provides technical expertise, fresh insights, and solutions to challenging adhesive/plastics bonding and joint design problems. As the Principal Consultant and President of Zeta Scientific LLC, Ms. Moody pursues her passion in solving materials science problems from startups to Fortune 500 companies, training teams to overcome hurdles, and successfully moving products forward. Her experience encompasses R&D, process, testing, scaleup, product transfers, and low-to-high volume manufacturing.

Prior to consulting, Ms. Moody's professional employment included 3M, Boston Scientific, EndoSonics Corporation, Raychem (now Tyco Electronics), and Liquidity Nanotechnology Corporation. Ms. Moody is also recognized in Silicon Valley for event planning, nonprofit collaboration, and student outreach. Her degrees include MS in Chemical Engineering and Materials Science (University of MN) and BA Chemistry (Hamline University, MN).

Morning Session: Compounding via Twin Screw Extrusion for 3D Filaments

Charlie Martin

President/General Manager
Leistritz Extrusion

Summary

Twin screw extruders (TSEs) are commonly used to compound plastics formulations to impart desired properties into a 3D filament. Polymers, additives, particulates and active ingredients are metered into the TSE process section, where rotating screws impart shear and energy to facilitate mixing, devolatilization and reactive extrusion. Pellets are often produced that then are fed into a single screw extruder mated to a downstream system that makes a 3D filament. The same downstream system can be mated to the twin screw extruder to make a 3D filament in one-step, which results in the final product having one less heat and shear history. TSE compounding fundamentals and a comparison of direct extrusion versus pelletization and a 2nd stage single screw extrusion operation, with the benefits of each, will presented and explained.

About the Speaker

As President/General Manager of Leistritz Extrusion, Charlie is responsible for the management of a company that provides manufacturing equipment and engineering services to the plastics, medical and pharmaceutical industries in the USA and around the world.

Extensively published in trade publications, textbooks and journals, Charlie has delivered 200+ technical presentations at wide-ranging international events, and is the co-editor of the textbook Pharmaceutical Extrusion Technology. He has also been awarded 2 extrusion related patents.

Charlie serves on the Board of Directors for the Society of Plastics Engineers (SPE) Extrusion Division, the Polymer Processing Institute @ New Jersey Institute of Technology, and also on the Technical Advisory Board for Teel Plastics.

Charlie earned his undergraduate degree from Gettysburg College and an MBA from Rutgers University.

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Afternoon Session: Modifications to Medical Cooling and Vacuum Tanks to Minimize Water Issues from Bio-Films, Endotoxins and Pyrogens

Bob Bessemer
VP Extrusion Technology
Novatec

Summary
Processors who extrude medical tubing, especially those used for in-body procedures, must be extremely aware of processing water conditions and test on a weekly, if not daily, basis. Water circulation tanks and vacuum tanks used for cooling and sizing the medical tubing can benefit from many features, which will be discussed in this presentation.

Medical tanks should be designed for extreme ease of cleaning. Specialized fittings, known as Tri-Clove fittings, should be used to minimize threads exposed to the process water. The tank and all water contact surfaces must be made of minimally 304-L Stainless Steel and if possible electro-polished to further minimize germ growth. Filtration is extremely important with minimally a 5 micron filter used and an ultra-violet filter as well.

With proper features built into these medical extrusion tanks, water conditioning and the cleaning process can be greatly enhanced.

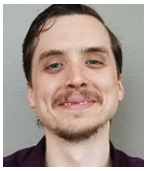
About the Speaker
Bob Bessemer, currently works as a Downstream Extrusion Consultant with focus on enhancements to equipment and processes.

Bob previously worked for The Conair Group, Inc. as Senior Technical Advisor for Downstream Extrusion Equipment for 26 years. Bob has worked for several other downstream plastics extrusion equipment manufacturers over the past 36 years both with engineering/development and sales.

With major focus on developing, sizing, and cutting equipment specific to medical and pharma applications, Bob has 6 patents.A major goal has been to better control the variables of the extrusion process and eliminate the so called “Black Art”.

He has a degree from Penn State University for business administration, but maintains a focus on engineering and development. Bob has written many papers and delivered seminars to the industry to help advance technology.

Afternoon Session: Considerations for Extruding Water Sensitive Polymers



Christian Herrild
Director of Growth Strategies
Teel

Summary
There is growing interest in the medical market for polymers that can be used as drug delivery vehicles or other highly specialized applications. Many of these materials are water soluble or experience significant physical changes on exposure to water. The extrusion cooling process usually requires some amount of water contact for tight tolerance control. Using water for these materials can be accomplished, if the process is thoughtfully designed and carefully controlled. Considerations for setting up such a process will be discussed.

About the Speaker
Christian Herrild has a diverse background in the plastics and chemical fields. He is Teel’s Director of Growth Strategies. He researches and evaluates markets and technologies, manages diverse projects, and helps set Teel’s strategic plan. In addition, he manages branding and marketing efforts for Teel. Previously, Christian was Teel’s Director of Sales and Marketing and managed its sales and customer service areas. Christian works closely with Teel’s technical team, including new product launches with key customers. Christian also serves as in-house counsel for Teel.

Christian graduated cum laude from University of Wisconsin — Madison Law School in 2012 and earned his MBA from the UW School of Business in 2011. He has a strong technical background, with undergraduate degrees in both Mathematics and Chemistry from Marquette University, where in won several awards for his chemistry work as an undergraduate. Prior to his advanced schooling, he spent two years as an industrial synthetic chemist.

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Afternoon Session: Scientific Screening Methods for Medical Polymers Demonstrating Compatibility with Drugs and Disinfectants

Tom Meehan

Technical Service Representative
Eastman Chemical Company

Summary
This technical presentation will discuss a screening protocol by which medical device design engineers, material scientists, and procurement professionals can compare in a shortened timeframe, different medical device plastics' responses after exposure to both drugs and/or disinfectants that they might encounter while in service. Common clinical failures of medical devices include cracking, touch surface degradation, part discoloration and external housing failures. This protocol utilizes existing ASTM tests that are familiar to the design community to report and rank the materials' behavior.

About the Speaker
Tom Meehan is a technical service representative for Eastman Chemical Company. In this role, he is responsible for supporting North American medical device designers and manufacturers who are considering the use of Eastman Tritan™ copolyester in addition to those already using the material. Assistance with pretrial preparation, on-site sampling support, and postsampling testing comprise the bulk of his responsibilities.

Tom joined Eastman in June of 1985, working in a variety of technical service and application development positions supporting Eastman polymers in injection molding, blow molding and extrusion. He joined Intralox, LLC in 2000, serving as process development manager and senior polymer engineer. Then, in 2013, he re-joined Eastman, supporting the medical device market for Eastman copolyesters in a technical support capacity.

He holds a B.S. in chemical engineering from Tulane University and a M.B.A. from the University of New Orleans.

Afternoon Session: Influence of Stabilizers on Property Retention of Thin Wall Tubing

Dr. Chris Moran

R&D Engineer
Compounding Solutions

Summary
Degradation on the surface of thin wall medical tubing influences bulk mechanical properties more so than in standard test specimens. This study aims to characterize the degradation behavior of tubing with 0.004" wall thickness made from PEBA and TPU, with and without stabilization packages. Tubing is aged under various conditions to elucidate the relative contributions of thermal-oxidation, photo-oxidation, and hydrolysis degradation mechanisms on mechanical performance. Tensile testing and GPC are used to observe degradation over time of stabilized and non-stabilized tubes, and to relate their molecular weight distributions to their mechanical integrity. To calculate the Arrhenius parameters of this system, in which multiple reactions occur with spatial variability, time-temperature superposition is shown to be a superior to the typical approach of using Q10 factors. Compounding stabilizers into PEBA and TPU resins prior to extruding tubing is shown to drastically improve shelf life and resistance to oxidation and UV light.

About the Speaker
Chris Moran is a R&D Engineer at Compounding Solutions. He earned his BS from Clarkson University and Ph.D. from Colorado School of Mines, both in Chemical Engineering.

Chris Became interested in polymers and medical devices during an internship at InVivo Therapeutics where he developed PLGA scaffolds for a tissue engineering application. His thesis work focused on understanding chemical structure, morphology, and physical property relationships in bio-based polymer blends and composites. Several projects that Chris led include determining the miscibility of blends between polyamide-4,10 and polyamide-6,10, elucidating stereocomplexation phenomena in PLA and PMMA and using it in fiberglass reinforced composites.

Chris began his career at Compounding Solutions in January 2018, shortly after finishing his thesis. He is dedicated to formulation development and is eager to bring his knowledge of polymer science and chemistry to the medical plastics industry.

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Afternoon Session: Miniaturized Medicine on the Rise

Donna Bibber

Vice President of Business Development
Isometric Micro Molding, Inc.

Summary
It doesn't take a brain surgeon (wait, yes it does) to understand the need for tiny devices that can maneuver in delicate tissue, tiny arteries, rigid ligaments, or membrane-like scaffolds. The trend continues and corresponding need for micro components and assemblies that enable devices across all medical and drug delivery market segments including: Neurology; Endocrinology; Oncology; Ophthalmology; Cardiology; Orthopedics; Pediatrics; Urology; ENT.

These tiny devices are being designed for futuristic exploration and treatments through tiny tubes and lumens via veins, arteries, capillaries, digestive systems, and natural orifices. These miniature devices are required to be both collapsible and expandable, flexible yet strong, rigid yet dissolvable. These are not simple challenges, however they are being met with an elite group of micro molders who dedicate their lives and company solely on enabling these extremely tiny and tight tolerance devices. The miniaturization trend will continue with devices even smaller and with immediate diagnostic capabilities- a unique value chain, creating mutual value in the medical and drug delivery device industry.

About the Speaker
Donna Bibber is the Vice President of Business Development at Isometric Micro Molding, Inc. She earned a Bachelor of Science in Plastic Engineering from the University of Massachusetts-Lowell in 1988.

Donna has assisted in over 1,000 micro molding and assembly device programs. Ms. Bibber's plastics engineering background, expertise and unique problem-solving skills earned her an excellent reputation and is recognized nationally and internationally for her work in micro manufacturing. Her expertise in intraocular implants, bio-resorbable polymers, and PEEK implants gave rise to many new devices commercially available today.

She is affiliated with several professional organizations and is a board member for SPE's Micro/Nano SIG. Donna has multiple technical publications, and has won several industry awards including being Voted on the List of 100 Notable People in Medical Devices in 2008.

Afternoon Session: Long-Acting Implants: Design for Durable Drug Delivery

Seth Forster

Associate Principal Scientist
Merck Research Laboratories

Summary
Patient access, compliance, and appropriate dosing of therapies are essential to the success of any treatment. The currently used standard oral tablet administered daily requires extensive supply and distribution networks, frequent access to trained medical care, and consistent patient diligence. If technically feasible, long-acting implants are likely a better way to reduce patient, caregiver or doctor intervention and overall health care costs.

To successfully develop a long-acting implant, potent and stable active pharmaceutical ingredients (APIs) are required but not sufficient. Drug release will be impacted by the design of the implant, the physical and chemical properties of excipients, especially rate-controlling polymers, and the manufacturing process, often co-extrusion or injection molding. Drug rates from micrograms to milligrams per day can be achieved, controlled by drug loading, polymer chemistry, and product design.

About the Speaker
Seth Forster is part of the Specialty Dosage Forms Formulation team at Merck Research Laboratories in West Point, Pennsylvania, focused on novel pharmaceutical dosage forms and process technology. He has more than 12 years of experience developing pharmaceutical products. For the last three years, he has been focused on long-acting drug-eluting implant formulation and process development. Seth has a BS in Chemical Engineering from Purdue University in West Lafayette, Indiana, and a MS in Pharmaceutics from Temple University in Philadelphia, Pennsylvania.

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Afternoon Session: Development of Guidance for the Interconnect-ability between Vial Container Closure Systems and Vial Transfer Devices

Naresh Budhavaram
Senior Consultant Engineer, Device Division
Eli Lilly

Summary
Vial transfer systems are increasingly being used by Health Care Providers (HCP) during the administration of therapeutic agents in vial presentations. The main reason being safety improvement to the HCP from needle sticks. This, however, has led to an increase in complaints from the HCPs (Ex: High Push force, Stopper getting pushed into the vial). Considering that vials and transfer devices are produced by separate manufacturers, manufacturers are experiencing difficulty in resolving complaints directed to their firm. In effect, any one manufacturer can only control the half of the connection that it has designed and produced. Variations in design, materials, and functional performance on the 'other' mating half cannot be controlled even though it may play significantly into the faulty connection. This occurs despite manufacturers utilizing design controls and exercising testing with known and available associate devices, usability testing, etc. To address this issue, members from pharmaceutical, elastomer and transfer device companies formed a consortium and reached out to a Product Quality Research Institute (PQRI). One of the primary goals of this work is to establish standards for the evaluation of the connection between vial systems and vial transfer devices.

About the Speaker
Naresh Budhavaram, is a Senior Consultant Engineer in the Device Division at Eli Lilly. He leads material selection and evaluation efforts for new products within R&D division. He is also a materials SME (plastics and elastomers) for compendia and other regulatory activities. Before joining Lilly, Naresh worked as a product development engineer at Celanese. In this role his main focus was developing engineering thermoplastic and bio-based grades for automotive, consumer and electronic applications. Naresh obtained his bachelors in chemical engineering from Osmania University, Masters in chemical engineering from University of Mississippi and has a Doctorate in Biological Systems Engineering from Virginia Tech.

Poster Session: Advantages of Liquid Crystal Polymers for precision thin-wall design & molding of combination drug delivery device components

Don DeMello
Principal Field Development Engineer
Celanese Engineered Materials

Summary
Liquid Crystal Polymer (LCP) thermoplastics are well-known in the consumer electronics industry for tight tolerance designs with high stiffness and strength, plus rapid cycle times and extreme flow to fill sub-mm wall sections. Processing benefits allow for micromolding replication of details and economical device volumes in the millions of units. These same advantages are translatable to precision combination drug delivery devices which incorporate complex mechanisms and wireless connected electronics for pharma prescription adherence goals.

Specifically, LCP resins can help designers and engineers achieve more compact, intricate components thru thinwall molding even as low as 0.3mm (0.012in) nominal wall without sacrificing mechanical stiffness and strength as LCP polymer chains are inherently stiffer & stronger than many other neat thermoplastics. This can be an advantage in wearable/on body devices where light weighting, compact form factors, and liberating more internal space for pharma dose & components are critical.

About the Speaker
Don is a Principal Field Development Engineer with the medical polymers business of Celanese Engineered Materials. Celanese is The Chemistry Inside Innovation™ and has been providing polymer solutions to the medical device industry for decades.

Don has a BSME from Worcester Polytechnic Institute and since university, has worked in the engineering resins industry for almost 30 years in a variety of application & market development roles across a wide range of markets.

He enjoys working with customers on the forefront of new & improved product developments where resin specification decisions are made based on design & performance needs.

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Panelist & Poster Session: New generation flame retardant materials - exceptional compatibility with most healthcare disinfectants

Dr. Yubiao Liu
Global Technical Platform Lead
Eastman Chemical Company

Summary
Healthcare-associated infections must be decreased for healthcare systems to continue being reimbursed for care. This means disinfecting protocols encouraged by the Centers for Disease Control must be followed and are more aggressive than ever before. Plastics in healthcare, especially those used in housings and hardware of electronic equipment have begun to fail over the last 10-15 years at an alarming rate. Better, more disinfectant ready plastics are required to give durability over the expected life of the device. Polymer scientists discovered that Eastman Tritan™ copolyester has excellent chemical resistance in the dishwasher, and later determined that the same polymer chemistry was even more beneficial in plastics used in medical equipment where resistance to most healthcare disinfectants is crucial. This presentation will substantiate the material performance, especially chemical resistance claims with disinfectants, when Tritan™ is used in compounded flame retardant materials for medical equipment.

About the Speaker
Yubiao Liu, Ph.D., is the global technical platform lead in Eastman specialty plastics medical device segment at Eastman Chemical Company, in Kingsport, Tenn., USA. Liu supports medical customers globally with a greater focus on developing new products to address previously unmet needs for medical device housings and electronics. With over 12 years of experience in the medical industry specialized in polymer synthesis and material evaluation, Liu is an authority in the field.

He joined Eastman in 2012 as the medical application development representative, specializing in Tritan™ copolyester for applications in the medical device industry. Prior to his time at Eastman, in 2006, Liu was a research scientist at Greatbatch Medical, working on the development of biomimetic coating and on an antimicrobial coating project. He has eight years of medical industry experience in polymer and biomaterial synthesis and polymer material evaluation, and has provided support to 510(k) submissions.

Liu earned a bachelor's degree in material science and engineering from the University of Science and Technology of China and a doctorate in chemistry from the University of Akron. He conducted his postdoctoral research at the University of Akron and Emory University School of Medicine, focusing on polymer synthesis and biomaterial surface modification.

Poster Session: Healthcare Liquid Silicone Rubber for Low Temperature Overmolding Applications

Roger Hendrick
Application Engineer and Technical Service Representative
Dow Silicones Corporation

Summary
Liquid Silicone Rubber (LSR) refers to injection moldable thermosetting elastomeric products. The development of LSR products suitable for overmolding onto thermoplastic components such as those made from copolyester has been accomplished with new LSR technologies broadening medical device design options. In consideration of thermoplastic heat deflection temperatures it is necessary to rapidly cure suitable LSRs at temperatures less than 110 °C whilst delivering physical properties such as tensile, tear, clarity, and mixed pot-life typical to standard LSR. Characteristics such as these along with compliance to medical device requirements as defined by USP Class VI make them suitable for medical applications like respiratory care, medical housings and external communicating devices.

About the Speaker
Roger Hendrick has more than 25 years of experience with Dow Corning Corporation, Dow Chemical and DuPont. He is currently an application engineer and technical service representative for Dow Silicones Corporation, as well as a Six Sigma Black Belt. He has devoted his entire career to healthcare, working in manufacturing and quality engineering roles prior to his current Science & Technology responsibilities.

He has significant experience in application and process development as well as product commercialization of silicone elastomers used in medical devices for molding and extrusion. In 2015, Dow Corning recognized his contributions with the prestigious Application Engineering Excellence Award. Roger earned his bachelor's degree from Saginaw Valley State University in 1992.

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Poster Session: Shaken not stirred? How will USP661.1 and ICH Q3D impact your pharmaceutical packaging materials cocktail?

Selvaanish Selvam
Business Development Engineer
Clariant

Summary
USP661.1 is a new standard for pharmaceutical packaging and drug delivery devices that doesn't take effect until May 2020, when it will impact all current and future drugs on the US market. In addition, the ICH-Q3D guideline strengthens the risk assessment process by evaluating packaging to ensure it is not the source of elemental impurities in drugs.

During the transitional period, the FDA allows the industry to make new filings under the older <661> or the new <661.1> standard, but in 2020, all existing and new drug/package combinations will need to be tested and compliant to the new standard.

Compliance with <661.1> involves a significant modernization of test methods and a more robust risk assessment process. The major consequence of this change is that in 2020, the 'food contact statements' that have supported the use of many materials in drug packaging will be deemed 'insufficient' to support their future use.

About the Speaker
Selvaanish Selvam is a Business Development Engineer at Clariant. He is a recent graduate from Case Western Reserve University with a Master's Degree in Biomedical Engineering and a minor in Chemistry. In addition to his degree, Selvaanish was on the Dean's Council at Case Western and a past President of their Biomedical Engineering Society. As an intern for over 4 years at the Cleveland Clinic, Selvaanish participated in the development of a portable air-oxygen blender for neonates. This unique device has been applied for patent protection.

Poster Session: Medical Material Selection — It is More Than Just Materials

Brad Davison
Engineering Manager
PolyOne

Summary
As the medical industry continues to evolve, patient demand is putting increased pressure on medical device manufacturers to bring innovative technologies to market. These technologies are enhancing device functionality by changing how and where healthcare happens. Selecting the right materials for the application requires more than just a supplier, it requires a partner that can help throughout the process from concept to production, enabling speed to market. Engaging a partner early in the design process ensures the material will meet the functional requirements of the design, will utilize the optimal manufacturing process, and withstand the demands of the end application. Determining the right material and process from the start means reduced design iterations, risk mitigation during the regulatory approval process and improved manufacturability, allowing manufacturers to get their devices to market on time and on budget.

About the Speaker
Brad Davison is a Plastics Engineer who has been working in the plastics industry since 1998. Brad earned his Plastics Engineering degree from Penn State Behrend's PLET program in 1999 and has held various positions within the automotive and material industries including; Product Development Engineer, Program Manager, Senior Process Engineer, National Technical Service Rep, and National Application Development Engineer. He is currently the Engineering Manager for PolyOne's Specialty Engineered Materials business. Brad is a member of SPE, Penn State's PLET advisory board and American Injection Molding's advisory boards. He has also created several injection molding training modules to enhance plastics processing knowledge within PolyOne. Brad resides in Ohio.

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