

GREETINGS FROM THE CHAIR



Dear Fellow Medical Plastics Division Members:

Welcome to our newsletter!

I would like to call your attention to three important topics in this communication.

All members should have received an email from the SPE HQ for our Board of Director election which is currently under way. We have eight outstanding candidates in the ballot. Please review their biographies and cast your vote today! This is a great opportunity to get involved in the future of our division.

We have partnered with SPE's Southern California Division for a technical symposium on Medical Plastics on February 4 in Anaheim, CA, during the MD&M show. Please do not miss this learning opportunity and register today to attend the event.

A summary of our division's technical program during ANTEC 2019 is provided in the newsletter. Our technical programming committee has worked hard to review and select the best papers for the meeting. Please register for ANTEC to attend these presentations and meet other members for a great networking opportunity.

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GREETINGS FROM THE CHAIR

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Finally, I would like to thank PolyOne for their sponsorship and would like to invite other organizations to support the Medical Plastics Division.

Please send me note if you have any suggestions to make our division stronger.

At your service,

Vipul

Do you have questions about MPD Membership?

Please email Ed Fewkes
fewkesej@corning.com

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

MEET YOUR SPE MPD BOARD OF DIRECTORS

2018-2019 MPD Board Appointments (1-year terms)



Suneel Bandi, Evonik

- Technical Programming & Communications Committees



Victoria Nawaby, Patina Solutions

- Education Committee Co-Chair



Anil Mahapatro, Wichita State University

- Technical Programming & Awards Committees

MEET YOUR SPE MPD BOARD OF DIRECTORS

MPD Board Members with Term Expiring in 2019



Michael Wallick, Invibio

- Awards Committee Co-Chair



Bhavin Shah, Tepha

- Member



Why not you?

- Member



Why not your colleague?

- Member



Looking for volunteers

- Member



Are you interested in running for the upcoming election?

Please email Louis Somlai
somlai_louis@lilly.com

MEET YOUR SPE MPD BOARD OF DIRECTORS

MPD Board Members with Term Expiring in 2020



Ravishankar Ayyar, Eli Lilly and Company

- Membership co-chair & Awards co-chair



Ed Fewkes, Corning

- Membership co-chair



Ajay Padsalgikar, DSM

- ANTEC 2019 Technical Program Committee



Louis Somlai, Eli Lilly and Company

- Communications Chair; Newsletter Editor

MEET YOUR SPE MPD BOARD OF DIRECTORS

MPD Board Members with Term Expiring in 2021



Ali Ashter, Getinge Group

- Vice Chair; Treasurer / Finance Committee



Margie Hanna, Czuba Enterprises

- Member - Finance Committee



Ned LeMaster, DuPont

- Secretary; Technical Program – Webinars



Maureen Reitman, Exponent

- Member – Technical Program Committee & Awards Committee



Amin Sedighiamiri, Eli Lilly & Company

- ANTEC 2019 Technical Program Committee

MEET YOUR SPE MPD BOARD OF DIRECTORS



Vipul Davé, Johnson & Johnson

• Division Chair



Pierre Moulinié, Covestro

• Past Chair



Len Czuba, Czuba Enterprises

• Councilor



Kathy Schacht, SPE

• SPE Liaison

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

MEDICAL PLASTICS DIVISION COMMITTEES

Division Chair Vipul Davé ('19)	Vice-Chair Ali Ashter ('21) <ul style="list-style-type: none"> • Education Committee Oversight • Membership Committee Oversight 	Past Chair Pierre Moulinié <ul style="list-style-type: none"> • Awards Committee Oversight • Assistant Treasurer • Nominating Committee
Technical Committee Director: Vipul Dave ('19) <ul style="list-style-type: none"> • ANTEC '19 co-TPCs : • Ajay Padsalgikar ('20); Amin Sedighiamiri ('21) • Webinars Lead: Ned LeMaster ('21) • Members: Maureen Reitman ('21); • Suneel Bandi ('19); Anil Mahapatro ('19) 	Secretary Ned LeMaster ('21)	Councilor Len Czuba ('21)
Education Committee <ul style="list-style-type: none"> • Co-Chair: Pierre Moulinié • Co-Chair: Victoria Nawaby ('19) 	Communications Committee Chair: Louis Somlai ('20) <ul style="list-style-type: none"> • Newsletter: Louis Somlai ('20) • Marketing and Outreach: Suneel Bandi ('19) • Historian: Vacant 	Membership Committee <ul style="list-style-type: none"> • Co-Chair: Ed Fewkes ('20) • Co-Chair: Ravi Ayyar ('20) • Members: Suneel Bandi ('19)
Awards Committee <ul style="list-style-type: none"> • Co-Chair: Michael Wallick ('19) • Co-chair: Ravishankar Ayyar ('20) • Member: Anil Mahapatro ('19) 	Finance Committee Chair: Bhavin Shah ('19) <ul style="list-style-type: none"> • Treasurer: Ali Ashter ('21) • MPD Chair: Vipul Davé ('19) • Ass't Treasurer: Pierre Moulinié • Members: Margie Hanna ('21); • Michael Teahan 	

Are you interested in volunteering for the BOD?

Please email Vipul Davé
VDave1@its.jnj.com

NEWSLETTER EDITOR

GREETINGS FROM THE NEWSLETTER EDITOR



Greetings fellow MPD Members!

Welcome to the latest edition of our award winning newsletter! I appreciate your efforts to help me improve this communication tool; please send feedback my way: somlai_louis@lilly.com

ANTEC2019 is just around the corner, which means time for elections! Within this 1Q2019 newsletter you will find eight excellent candidates seeking to volunteer for five open board positions. A separate email notice to the MPD membership has already come out and electronic polls will close this Friday 01FEB2019. Please email me if you did not receive a ballot!

Serving on the BOD is a volunteer position and requires you to attend monthly meetings, committee service, and attending our annual MPD face to face board of directors meeting at ANTEC. We are also seeking SPE MPD members in good standing who might be interested in serving on specific committees (finance, education, membership, and awards); if interested, please reach out directly to me (somlai_louis@lilly.com).

Regarding my last communication on our SPE MPD Twitter presence: my apologies for the typo, but our SPE MPD twitter feed can be found at: **@SPE_MPD**; Twitter users check it out!

Finally, a big thank you to PolyOne Corporation for their continued sponsorship in 2019. Your board has recognized the need to increase fundraising for the division so we have renewed our efforts towards this funding avenue and sponsorship. If you are aware of a firm or organization that would benefit from advertising in our newsletter please let them and me know.

Best regards,

Louis

Newsletter Suggestions? Want to Advertise?

Please email Louis Somlai

somlai_louis@lilly.com

A wireframe illustration of medical equipment, including a mobile cart with drawers and a large table on wheels, set against a dark blue background with a grid pattern.

MORE THAN MATERIALS

**Solutions that help
you win, from concept
to marketplace.**

- Polymer Distribution
- Engineered Polymers and TPEs
- Healthcare Vinyl Solutions
- Pre-certified Polymer Colorants and Additives

Backed by the Power of PolyOne.

To learn more, visit polyone.com
or call 1.866.POLYONE

PolyOne

MPD NEWSLETTER SPONSORSHIPS

Sponsors...

We are seeking Sponsor Display Ads for our Award-winning Division Newsletter! To show your support of the Society of Plastics Engineers and in particular, the Medical Plastics Division, please consider taking part in this important communication support effort.

Sizes Available	(Full year amount, i.e. 3 issues)
<i>Full page</i>	\$1,250
<i>Half page</i>	\$750
<i>Quarter page</i>	\$400
<i>Eighth page</i>	\$250

LISTED ADVERTISING PRICES REPRESENT A 50% DISCOUNT
IN EFFECT UNTIL FEBRUARY 15, 2019
ACT NOW!!!

The newsletter, as scheduled, is prepared and circulated **three times per year** (*plus the occasional 4th or bonus issue*). Every Medical Plastics Division member receives a copy emailed directly to their listed address. Additional copies are also circulated (via the Chain) in our continuing effort to reach new and prospective members and other interested individuals.

To show your support please contact Louis Somlai at 317.209.4719 (email: somlai_louis@lilly.com).

Thank-you for your support!

COUNCILOR'S REPORT



Medical Plastics Division Councilor Report

Dear Fellow Medical Plastics Division members,

Our division is in the home stretch preparing for three wonderful events that we'd like to encourage you to do all you can to attend.

A MiniTec (a fully packed one-day conference) co-sponsored by the Medical Plastics Division with the Southern California Section will be held next week, Monday the 4th of Feb. I hope you get this alert in time to plan to join us at the Sheraton Convention Center Hotel in Anaheim. See details on the SPE website under "events". You can also just click on this link: <https://www.4spe.org/i4a/pages/index.cfm?pageID=4157>

Our second involvement is with the MD&M conference program being held concurrently with the MD&M Expo. We are hosting the Tuesday track titled "Technical Solutions" beginning at 8:25a. See the conference website: https://ahm19.mapyourshow.com/7_0/sessions/index.cfm?srch-type=sessiontrack&srch-query=9&srch-showresults=true I will be moderating what I am sure will be another exciting program! Join us.

Finally, our ANTEC Technical Program Committee has planned a very full day of programming on Monday of ANTEC week, i.e. March 18th. Come support your division, listen to great speakers and learn from those that are doing it! See the ANTEC technical program for details: <https://www.4spe.org/files/events/2019/ANTEC/2019ANTECInspireProgram.pdf>

And this year, there will be plenty of fun networking events planned for all!

Continued on the next page...

COUNCILOR'S REPORT

Continued from the previous page...

Your Board members are leading the organizing committees that put these event on and we would appreciate it you would support these efforts with your attendance. Hope to see you at one or all of our programming events!

Stay warm,

Len Czuba (from a cold Chicago!)

Distinguished, Honored Service Fellow of SPE

MPD Councilor 2015 - 2021

Past SPE President 2005 - 2006

Do you have questions about MPD Membership?

Please email Ed Fewkes

fewkesej@corning.com

TREASURER'S REPORT



TREASURER'S REPORT – Ali Ashter Last Updated January 7, 2019

Treasurers report as of January 7, 2019

Balance as of September 28, 2018

\$ 20,887.39

INCOME

Income Type	Amount
SPE Rebate	\$ 1,035.00
TOTAL INCOME	\$ 1,035.00

EXPENSE

Expense Type	Amount
Student Activities	\$ 1,000.00
TOTAL EXPENSE	\$ 1,000.00

FUNDS AVAILABLE AS OF January 7, 2019

\$ 20,922.39

Do you have questions about the Treasurer Report?

Please email Ali Ashter
ashter2000@gmail.com

MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



George Gorman – Teel Plastics

George started his extensive career in plastics as an extruder operator making films and nettings associated with filtration and healthcare markets for Applied Extrusion Technologies. George held various roles including Production Lead and Product Development Technician before segueing into the commercial side of the business. George held previous strategic sales roles with both PEXCO, and ITW Medical, prior to joining Teel Plastics. George's primary responsibility is business development for extrusions and injection molded thermoplastics utilized in the medical device market.



MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Dr. Jennifer Hoffman - AirXpanders

Dr. Jennifer Hoffman is Director of R&D at AirXpanders, a start-up medical device company that manufactures a breast tissue expander used in two-stage breast reconstruction post-mastectomy. She led the design and development of the current generation device and leads on-going efforts to improve performance, reduce scrap/COGS, and ensure regulatory compliance. Prior to AirXpanders, Dr. Hoffman was a polymer consultant with Exponent Failure Analysis Associates for 12 years where she provided product development support for industrial clients and technical expertise for product liability cases. Jennifer has been actively involved on several professional society boards and as a Volunteer Team Leader for Second Harvest Food Bank for the past decade. Dr. Hoffman is currently SPE Golden Gate Section Councilor and Treasurer (past-President), Failure Analysis & Prevention Special Interest Group (FAPSIG) Best Paper Award Chair (past TPC/Chair), and a Golden Gate Polymer Forum Director. Dr. Hoffman earned her Bachelor's in Materials Science and Engineering from the University of Michigan and Ph.D. in Materials Engineering Science from Virginia Tech.



MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Yubiao Liu, PhD – Eastman Chemical Company

Yubiao Liu, Ph.D., is the global technical platform lead in 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 13 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 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. He earned a bachelor's degree in material science and engineering from USTC in China, and a doctorate in chemistry from the University of Akron. He has 15 peer reviewed publications and holds 5 US patents.



MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Anil Mahapatro – Wichita State University

Anil Mahapatro, is an Associate Professor in the department of Biomedical Engineering at Wichita State University, Wichita, KS. Anil Mahapatro holds a BE (Bachelors of Engineering) in Polymer Engineering (University of Pune, India), MS in Polymer Science and Technology (University of Manchester, United Kingdom) and a PhD in Materials Chemistry from Polytechnic University, Brooklyn, NY, USA and a Post-Doctoral Fellowship (Biomedical Engineering) from University of Texas at San-Antonio. Dr. Mahapatro is a Professional Engineer (PE) and a Fellow of the Institution of Engineering and Technology (FIET).

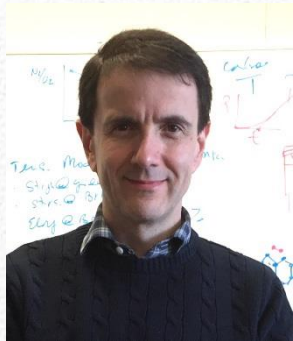
Dr. Mahapatro's research efforts have focused on developing novel biomaterials for clinical relevant applications. Current research projects in his laboratory include: development of novel polymeric biomaterials for 3D printing, biodegradable metallic implants for cardiovascular stents and fracture fixation devices, scaffolds for bone tissue engineering, multifunctional theranostic biodegradable nanoparticles for cancer therapy. Dr. Mahapatro has secured external funding over \$2.5 million (PI and collaborative efforts) and has completed several projects in the field of biomaterials resulting in mentoring of 3 doctoral, 11 masters, and over 30 undergraduate students. He has 58 peer reviewed publications (30 peer reviewed journal papers, 22 peer reviewed conference papers and 6 book chapters), 3 patents, 2 books ("Biomaterials" and "Polymers for Biomedical Applications") and over 50 presentations.

Dr. Mahapatro is currently serving (2018-2019) on the SPE Medical Plastic Division Board of Directors in the Technical Programming and Awards Committees and would like to serve the Medical Plastic Division again in these roles. He has held several leadership positions in the past with American Chemical Society (ACS). He was the board member of Division of Polymer Chemistry (POLY) [ACS, 2002-2008] and Younger Chemists Committee (YCC) [ACS, 2004-2009]. He has served as the chair of Strategic planning subcommittee (YCC, ACS, 2008-2009), Division of Colloid and Surface Chemistry (symposium chair: Surface Chemistry in Biological & Medical Applications, 2009-2012). He was the primary symposium organizer of 5 symposiums at ACS national meetings including Biomaterials and Bioengineering (Fall 2009, ACS National Meeting, Washington, DC) and Polymers for Biomedical Applications (Fall 2006, ACS national meeting, San Francisco).



MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Pierre Moulinié – Covestro

With almost 20 years technical experience with Polycarbonate resins, Pierre has been Global Technology Lead for Healthcare at Covestro's Polycarbonates Business and serving the Healthcare market for over 10 years. A Medical Plastics Division Board member for almost 5 years and the current past-chair, Pierre is currently helping the Medical Plastics Division be a routine contributor to SPE's recent Webinar series.

Pierre has co-authored various ANTEC papers, book chapters and Journal Articles and Patent Applications over the past 25 years and values the technical exchanges, networking and re-connecting with old friends that is possible through Societies like SPE. Being a Division Board Member is a good way to “give back” and Pierre hopes to extend his time on the Medical Plastics Division Board.



Medical Plastics Division – Board of Director Candidate Bios



Arghavan Victoria Nawaby – Patina Solutions

Victoria is a senior member of SPE and has been a part of the society for 17 years. Since her admission in 2000 she served as a member of the board of directors - Thermoplastic Materials and Foams division between 2000 and 2010. She obtained her doctorate in Physical Chemistry from Carleton University (Ottawa, CANADA) in 1999, and her career in the plastics industry was initiated at the National Research Council of Canada as an NSERC Postdoctoral Scholar in polymer physics. She then joined the National Research Council of Canada and was an Associate Scientist with the council in Ottawa, CANADA between 2000 and 2007 conducting fundamental and industrial research in polymer – gas systems. In 2006 she was a visiting scientist at the National Science and Industrial Institute, Tsukuba Science City, JAPAN conducting fundamental investigations on biopolymers. In late 2007 she joined Sealed Air Corporation in Dallas - Texas, & Charlotte – North Carolina, USA as a corporate scientist and was a Technical Project Manager leading R&D project from infancy to commercialization with product applications in various markets segments. In March 2018 she joined Patina Solutions, Dallas Texas, USA as a technical professional and consultant. She has authored one book chapter, has over 21 refereed scientific publications, delivered 44 invited & conference presentations, holds one US and one European patent, and has 2 trade secrets.

MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Bhavin Shah – Tepha Inc.

I was born in Mumbai, India. I received my B.S. from Pune University, India (2005) in Polymer Engineering, M.S. (2008) and Ph.D. (2012) from University of Massachusetts Lowell in plastics engineering. I performed my doctoral work focusing on optimization of injection molding process for Polyhydroxyalkanoate's. I served as secretary for Graduate Students Association at UMASS, Lowell. I am also serving on the SPE MPD board for the current tenure.

Subsequently, I joined industry working for Tepha Inc. as a Product Development Engineer. My primary role is to provide solutions to a variety of technical issues related to device applications in orthopedic, general and plastic surgeries. I work towards, feasibility assessment, proposal generation, systems level engineering, material selection, supplier sourcing, injection molding, industrial design integration, prototyping capabilities, CAD, clinical testing market introduction, field support, DFMA (Design for Manufacturing and Assembly), and design documentation.



MPD BOD CANDIDATE BIOS

Medical Plastics Division – Board of Director Candidate Bios



Michael Wallick – Invibio Biomaterial Solutions

Michael Wallick graduated magna cum laude from Huntington University and has a combined 20 years of experience with polymers, 7 years were spent in the automotive sector with engineered grade polymers, and the last 13 years focused in the medical sector with PAEK's, UHMWPE, Ultem, PLA's and other biocompatible polymers for long term implantation applications. Michael currently serves as the Global Technical Support Manager for Invibio Biomaterial Solutions. Prior to Invibio, Michael was employed as a Polymer Research Scientist and injection molding subject matter expert with Zimmer-Biomet. He has completed training in Scientific Molding, program and machine setting for both Engel and Arburg, as well as achieving Bronze level Moldflow certification. Michael is an active member of the Society for Plastics Engineers where he serves on the Board of Directors for the Medical Polymers Division, and is a voting member for ASTM where he sits on subcommittees under F04 Medical and Surgical Materials and Devices, and D20 Plastics. Michael also has three patents to his name and five more patents pending in the field of medical polymers.



SPE MPD WEBINARS

The Medical Plastics Division is pleased to announce the success of its second webinar of the 2018 calendar year. A total of 93 participants, out of 199 registrants, were in attendance on December 13th, 2018.

A big thank you to the webinar speaker, and our own chair, Vipul Davé for his excellent presentation on Materials for Medical Applications. Thank you also to Louis Somlai and Ravi Ayyar for supporting as moderators.

Don't worry, if you missed Vipul's presentation or were unable to attend, the webinar can be found in the SPE Library or by following the link provided here: <https://www.4spe.org/i4a/pages/index.cfm?pageid=4443>

The Medical Plastics Division and Webinar Team plans to host a series of webinars during 2019, with a goal of at least three to four. Tentative timing for the next Webinar is February after MiniTec '19. Some of the topics in consideration include: Advances in Medical Tubing Materials, Drug Delivery and Implantable Materials, Materials for Excipient Release, Relevant Changes in Regulatory Directives, Biodegradable & Resorbable Polymers in Med Device, Best Practices for Introduction of New Polymers in Med Device, Speed to Market through Improved Development, and Advances in Friction Reducing Materials. We are even considering a series on project management.

We welcome your interest to participate, as well as suggestions for topics and/or speakers. Please contact Pierre Moulinié (pierre.moulinie@covestro.com), Victoria Nawaby (nawabyv@hotmail.com), or Ned LeMaster (ned.e.lemaster@dupont.com) with any suggestions.



WEBINAR

**MATERIALS FOR
MEDICAL
APPLICATIONS**

 DEC. 13, 2019
1PM-2PM



**FORMER MEDICAL PLASTICS
DIVISION BOARD MEMBER
KENNETH PAWLAK
HONORED**

Kenneth Pawlak

During the November 7th Reception and Awards Banquet, the University of Illinois, Chicago, College of Engineering honored Kenneth Pawlak with their 2018 Engineering Alumni Outstanding Achievement Award for his career accomplishments.

This award is presented to alumni who, through their achievement in their field of engineering, have significantly enhanced the industry and who inspire and help to instill a sense of pride among the alumni, students, faculty and staff of UIC.

Ken has over 45 years of experience in medical plastic product design and development with an emphasis on medical devices and pharmaceutical packaging. He holds 26 product and molding process patents. Ken's creativity and experience has been acknowledged by the Plastics Industry with the following awards:

- R&D 100 Award by R&D Magazine in 1995 and 2016.
- Design Innovator Award - Injection Molding Magazine & Gabriel Inc. in 1995
- World Star Packing Award by the United Nations, World Packaging Organization in 1988.

In 2016, Ken was inducted into the prestigious Plastics Pioneers Association.

Ken is a senior member of the Society of Plastics Engineers, Past Chairman of the Product Design and Development Division, Past Chairman of the Rotational Molding Division, and served on the Medical Plastics Division, Board of Directors.

Ken has a BSE, Biomedical Engineering, from the University of IL, Chicago and an MBA from the Lake Forest Graduate School of Management.

Submitted by:

Glenn L. Beall

Palisades-New Jersey Section Meeting

Thursday, January 17, 2018

Fox Hollow Golf Club

59 Fox Chase Run, Branchburg, NJ

Polycarbonates: Innovation for Healthcare

presented by Pierre Moulinie, Covestro

Board meeting – 4 pm

Networking - 5:30 pm

Dinner meeting and speaker - 6 pm

All activities will be in the clubhouse

Members and guests \$45, Students free with RSVP

RSVP by Jan. 16

RSVP to Pete Hayles, Email-peterhayles11@gmail.com

732-569-2368

Polycarbonates Innovation for Healthcare

The influences on medical device and pharmaceutical companies are very different today than just a few years ago. This presentation will briefly discuss some of the newer needs for the healthcare industry and the implications for resin suppliers. With the new healthcare challenges as a backdrop, we will also share a few examples that illustrate how the technical community continues to learn surprising new things about materials like polycarbonate and the so-called “engineering thermoplastics pyramid.” How these key learnings are applied to product innovation and alignment to healthcare needs will also be discussed.

Biography: Pierre Moulinie

Pierre has been volunteering on the Medical Plastics Division Board of Directors for almost 5 years and is the Divisions’ Past-Chair. Previously, he served on the Board of the Engineering Properties and Structure Division, including Chair from 2008-2009. A frequent contributor to SPE conferences and ANTEC papers, Pierre’s most recent publication is Chapter 10 in the 2016 edition of the “Thermoplastics Handbook”, which summarizes developments in polycarbonate since the original book was published in 1997. He has been active with Polycarbonates for almost 20 years, and today he is Global Technology Lead for Healthcare in the Polycarbonates Business Unit at Covestro LLC.

CALL FOR ELECTIONS – MPD BOD



ANTEC2019 is just around the corner, which means time for elections! An email notice to the MPD membership will be coming out in the next few weeks.

Serving on the BOD is a volunteer position and requires your attendance at monthly teleconferences / meetings, committee service, and attending our annual MPD face to face board of directors meeting at ANTEC.

SPE MPD members in good standing can submit their interest in running for open board of director positions by reaching out directly to me (somlai_louis@lilly.com).

Are you interested in running for the upcoming election?

Please email Louis Somlai
somlai_louis@lilly.com

UPCOMING EVENTS



MEDICAL PLASTICS MINITEC

Anaheim, California • February 4, 2019

*Presented by SPE Medical Plastics Division and
SPE Southern California Section*



A LOOK TO THE FUTURE OF MEDICAL DEVICE MATERIALS & PROCESSING

A one day conference where industry leaders and experts will discuss the latest developments in the area of medical plastics.

This MiniTec will be held the Monday, February 4th – the day before the opening of the 2019 MD&M West Expo & Conference in the shadow of the Anaheim Convention Center.

At least ten Speakers will present in two sessions covering the latest technology in Medical Device Materials and Processing. Session breakdown is as follows:

- Morning Session: Future Polymer Materials Technology
- Afternoon Session: Design & Advanced Processing Technology

Benefits of attendance include:

- Education and exposure to the latest technology in Med Device Design and Processing provided by industry leaders and experts.
- Access to all papers and presentations post show.
- Networking opportunities with peers and colleagues from Med Device OEM, Part Designers, Plastic Engineers, Material Suppliers, Machine and Equipment Suppliers, and more.
- Convenience of location and timing to large Med Device Trade Show.

Ned LeMaster
+1 608.402.3268
ned.e.lemaster@dupont.com

Ashley Spittle
+1 562.217.1377
aspittle@ethorn.com

UPCOMING EVENTS

A LOOK TO THE FUTURE OF MEDICAL DEVICE MATERIALS & PROCESSING

Monday, February 4, 2019

Sheraton Park Hotel at
the Anaheim Resort
1855 S Harbor Blvd
Anaheim, CA 92802

Schedule of Events:

7 – 7:45am

Registration and
Continental Breakfast

7:45 – 8am

Keynote Speaker

8am – 7pm

Tabletop Exhibition

8am – 5pm

All Day MiniTec
(Lunch and Breaks Included)

5 – 7pm

Cocktail Reception and
Poster Session
(Included in Registration)

Register to Attend:

MiniTec (Advanced): \$125

MiniTec (On-site): \$175

Info & Online Registration:

www.4spe.org/MedPlasticsMinitec

A one day conference where 14 presentations from the industry will discuss the latest developments in the area of medical plastics.

Tentative Morning Session on New Materials & Design

Keynote Speaker

Vipul Davé – Johnson & Johnson

Polymer excipient technology for extended release of API

Greg Moakes and Don DeMello – Celanese

Materials and process technology solutions for designing connected medical devices

Manish Nandi – SABIC

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

Rob Klein – Stress Engineering Services

Friction-reducing Materials for Medical Devices

Bob Hergenrother – BioCoat, Inc.

Design Considerations for Medical Plastics with CAE & FEA

Alan Wedgewood & Helga Kuhlmann – DuPont

Medical Device Plastics and Adhesives - A Design Approach

JoAnne Moody Zeta Scientific LLC

Compounding via Twin Screw Extrusion for 3D Filaments

Charlie Martin – Leistritz

Panel Discussion - Topic to cover Materials and Chemical Resistance to Cleaning

TABLETOP EXHIBITOR OPPORTUNITIES AVAILABLE

Showcase Your Company!

- Registration Fee - \$750
- Registration includes 1 admission
- Company name recognition published in promotions and on event signage!
- Booth setup 7 - 8am; requests for electricity accepted

Tentative Afternoon Session on Processing & Applications

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

Bob Bessemer – Bessemer Consulting/ConAir

Considerations for Extruding Water Sensitive Polymers

Christian Herrild – Teel Plastics

Study of Lamination of PU to FEP for Medical Device Tubing

William Li – Adam Spence

Influence of Stabilizers on Property Retention of Thin Wall Tubing

Chris Moran – Compounding Solutions

Miniaturized medicine on the rise

Donna Bibber – Isometric Micro Molding

Long-Acting Implants: Design for Durable Drug Delivery

Seth P. Forster – Merck

Development of Guidance for the Interconnectability between Vial Container Closure Systems and Vial Transfer Devices

Naresh Budhavaram – Eli Lilly

Reception and Poster Session

(Includes Cocktails and Hors d'oeuvres)

SPONSOR OPPORTUNITIES AVAILABLE

Company Name Recognition published in
promotions and displayed on signage!

- Corporate: \$1000 (includes 2 admissions)
- Lunch Sponsor: \$500 (2 available)
- Breakfast Sponsor: \$400 (2 available)
- Break Sponsor: \$100 (5 available)
- Reception Sponsor: \$300 (2 available)

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2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

Keynote: Materials for Medical Applications



Dr. Vipul Davé

Head, Self Care Technology Group
Johnson & Johnson Consumer Inc.

About the Speaker

Dr. Vipul Davé is currently a Senior Research Director and Fellow, and Head of the Self Care Technology Group at Johnson & Johnson Consumer Inc. In this role, Vipul leads the technology organization and develops new technologies and capabilities internally and through external partners.

Vipul joined J&J in 1996 and has previously held various positions within the Consumer and Medical Device sectors of the company. Prior to that he worked at Warner Lambert. Most recently, Vipul was responsible for leading the Self Care Technology effort in the development of novel delivery systems and for the conception and design of consumer insight driven novel oral pharmaceutical dosage forms. Vipul has been working closely with strategic partners on the assessment, development and customization of innovative and proprietary materials.

Vipul holds a PhD in Materials Engineering Science from Virginia Tech, Blacksburg, VA and an MS in Polymer Science from the University of Massachusetts, Lowell, MA. Vipul is an inventor of over 28 granted US patents and 46 US patent applications, authored over 30 peer reviewed publications in journals and books, and presented over 70 papers at technical conferences in the fields of polymers, drug delivery, medical devices and material science & engineering. Vipul was elected as a Fellow of the American Institute for Medical and Biological Engineering's (AIMBE) College of Fellows in 2013; and as a Fellow of Society of Plastics Engineers in 2017. He is the current chair for SPE's Medical Plastics Division.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

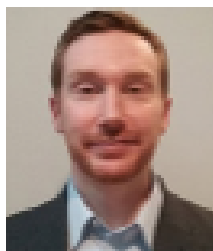
Poster Session: Polymer and Geometry Selection of Injection Molded Microneedles

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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).

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

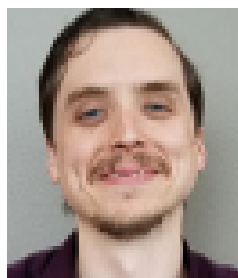
Bob previously worked for The Conair Group, Inc. as Senior Technical Advisor for Downstream Extrusion Equipment for 26 years. Bob has worked for several other downstream plastics extrusion equipment manufacturers over the past 36 years both with engineering/development and sales.

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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 he won several awards for his chemistry work as an undergraduate. Prior to his advanced schooling, he spent two years as an industrial synthetic chemist.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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

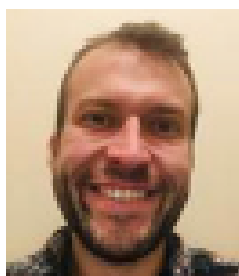
Donna Bibber is the Vice President of Business Development at Isometric Micro Molding, Inc. She earned a Bachelor of Science in Plastic Engineering from the University of Massachusetts-Lowell in 1988.

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

UPCOMING EVENTS

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

2019 SPE MPD MINITEC PRELIMINARY SPEAKER PROFILES

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.

UPCOMING EVENTS



ANTEC® 2019
Detroit, MI • March 18-21, 2019



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Submission deadline has passed
speaker submissions now being accepted for ANTEC 2020

YOU ARE INVITED TO SUBMIT A PAPER FOR PUBLICATION & PRESENTATION

- Podium and poster presentations showcasing the latest in industrial, national laboratory and academic work
- Share your findings in polymer research or new and improved products and technologies

TOPICS WILL INCLUDE

- Additive Manufacturing/3D Printing
- Automotive
- Bioplastics
- Blow Molding
- Building and Infrastructure
- Color & Appearance
- Composites
- Decorating and Assembly / Joining
- Electrical & Electronic
- Engineering Properties & Structures
- Extrusion
- Failure Analysis
- Flexible Packaging
- Foams
- Injection Molding
- Medical Plastics
- Mold Technology
- Plastic Analysis
- Sustainability
- Plastic Pipe and Fittings
- Plastics Recycling
- Polymer Analysis
- Polymer Modifiers & Additives
- Product Design & Development
- Rheology
- Rotational Molding
- Thermoforming
- Thermoplastics Materials
- Thermosets
- Vinyl Plastics

UPCOMING EVENTS



ANTEC® 2019

Detroit, MI • March 18-21, 2019

CO-HOSTED BY SPE DETROIT

SCHEDULE OVERVIEW

Check back often, as we add more details. Events and times are subject to change.

Sunday March 17

6:00 pm – 8:00 pm

ACCLAIM – A Celebration of Inspiring Plastics Professionals

ANTEC® Opening Reception – All Attendees Welcome

ANTEC® INSPIRE 2019

Monday March 18

7:45am – 8:00am	SPE Annual Business Meeting
8:00am – 8:45am	Plenary Speaker
8:00am – 5:00pm	Plastics for Life Parts on display
9:00am – 12:00pm	Technical Sessions
12:00pm – 2:00pm	Student Poster Judging
2:00pm – 5:00pm	Technical Sessions
1:00pm – 5:00pm	Exhibitor Setup
5:30pm – 7:30pm	ANTEC® Punchbowl Social (offsite)

Tuesday March 19

7:00am – 7:30am	Cold Runner
7:00am – 11:00am	Exhibitor Setup
8:00am – 8:45am	Plenary Speaker
8:00am – 5:00pm	Plastics for Life® Parts on display
9:00am – 12:00pm	Technical Sessions
11:00am	Exhibit Floor Opening Ceremony
11:00am – 6:30pm	Exhibit Floor Open
12:00pm – 2:00pm	Women in Plastics Lunch (Everyone Welcome)
12:00pm – 2:00pm	Student Poster Judging
2:00pm – 5:00pm	Technical Sessions
5:00pm – 6:30pm	Brewfest Detroit (Exhibitor Reception)
6:30pm – 9:00pm	Chapter Events

Wednesday March 20

8:00am – 8:45am	Plenary Speaker
8:00am – 12:00pm	Plastics for Life® Parts on display
9:00am – 12:00pm	Technical Sessions

ANTEC® INSIGHT 2019: What's happening in plastics—from the people who know

Wednesday March 20

12:00pm – 5:00pm	Plastics for Life® Parts on display
1:00pm – 1:45pm	Keynote
2:00pm – 5:00pm	Insight Tracks
5:00pm – 6:30pm	Motown Magic (Exhibitor Reception)
6:30pm – 9:00pm	SPE Chapter Events
7:00pm – 11:00pm	SPE Fowling (Football/Bowling) Tournament – 21 and over after 9pm

Thursday March 21

7:30am – 8:00am	Plastics for Life® Winners Announced
8:00am – 8:45am	Keynote
9:00am – 11:30am	Insight Sessions
8:30am – 1:00pm	Exhibit Floor Open
1:00pm – 5:00pm	Exhibit Floor Teardown
1:00pm – 1:45pm	Keynote
1:45pm – 4:00pm	Sustainability/Environmental/Circular Economy Presentations

ANTEC® 2019

DETROIT | MARCH 18-21
DETROIT MARRIOTT AT
THE RENAISSANCE CENTER



Medical Plastics Division

ANTEC® 2019 CALL FOR PAPERS

Submission Deadline: October 19, 2018

Type of Papers/Presentations:

- **Submission deadline has passed**
 - **speaker submissions now being accepted for ANTEC 2020**
- content is still under review, the presentation has to be reviewed before acceptance

Topics of Interest Include:

- | | |
|--|---|
| • Novel Materials/Chemistries | • Micro-molding |
| • High Performance Materials/Composites | • Medical Textiles and Woven Structures |
| • Implantable Materials | • Surface Modifications, Coatings and Additives |
| • Absorbable Materials | • Diagnostics Devices and Methods |
| • Drug Delivery Devices | • Modeling and Characterization Methods |
| • Medical Devices for Different Applications | • Bio-Derived Materials |
| • Additive Manufacturing | |

UPCOMING EVENTS

Medical Plastics Agenda

Date March 18 2019

Room Duluth (90)

Moderator Victoria Nawaby

Theme - Processing for Medical Applications

Time	Speaker	Paper
9:00 - 9:45	<i>Donna Bibber (Invited)</i>	Micro Injection Molding Hydrophobic and Hydrophilic 3D Surfaces
9:45 - 10:30	<i>Roger Narayan (Invited)</i>	Additive manufacturing of photopolymers for biomedical applications
10:30 - 11:00	<i>Devin Schmidt</i>	Investigating the Effect of Temperature and Frequency on Dielectric Properties of Polyvinylidene Fluoride (PVDF)
11:00 - 11:30	<i>Ian Pierson</i>	Reaction Injection Molding of Polyurethane Medical Device Components
11:30 - 12:00	<i>Alex van Goudswaard</i>	Disinfectant resistant materials for medical devices

Moderator Suneel Bandi

Theme - Materials for Medical Applications

Time	Speaker	Paper
2:00 - 2:45	<i>Xiaoping Guo (Invited)</i>	Applications of Polyamide-based Thermoplastic Elastomers in Medical Devices: from Fundamentals to Engineering
2:45 - 3:30	<i>Zhenshuo Liu (Invited)</i>	Tailored Polymer Surfaces for Customized Pharmaceutical Packaging Solutions
3:30 - 4:00	<i>Jeff Haley</i>	An Injection Moldable Ultra-High Molecular Weight Polyethylene For Medical Applications
4:00 - 4:30	<i>Stefan Roth</i>	Requirements for Medical Plastics – Launch of new Guideline
4:30 - 5:00	<i>Hossam Metwally</i>	Medical Plastics: Review of Material Models Required for Simulation Through Case Studies
5:00 - 5:30	<i>Robert J. Klein</i>	Accelerated Aging and Viscoelastic properties of Medical-Grade Resins