SOCIETY OF PLASTICS ENGINEERS

Medical Plastics Division

2013 - First Quarter

Letter from the Chair:

Dear Members:

Hello!

Hopefully this newsletter finds many of you on your way to the MD&M West show in Anaheim CA. Vipul Dave has put together an all-day MedTech on Monday, February 11th that kicks off with a plenary talk by Stanton Rowe from Edwards Lifesciences on the need for innovation in the medical device world. The session is rounded out by speakers from throughout the industry covering the gamut of new materials for medical devices. Be sure to join the speakers and attendees for a reception immediately following the session!

Next month we will also be holding elections for new board members to replace those whose terms expire this year. This is a great way to get involved with other industry professionals as well as to shape the content of our technical sessions and expand our reach into developing geographies. Please let me know if you are interested in running for one of the five available spots.

Speaking of which, our division will be one of many SPE divisions participating in the first TopCon in China to be held in December 2013 in Shanghai. Harrison Yu will be soliciting for papers and leveraging contacts at both China-based companies and multi-nationals growing in this region. The medical device industry is critical to growth of healthcare services and enables our division to provide a forum for an exchange of information about topics ranging from development of devices to regulatory challenges. Many of our current board members will also be engaged in brain-storming ideas for this session, so please reach out to Harrison at harrisonyu@comcast.net to be part of this first-ever conference.

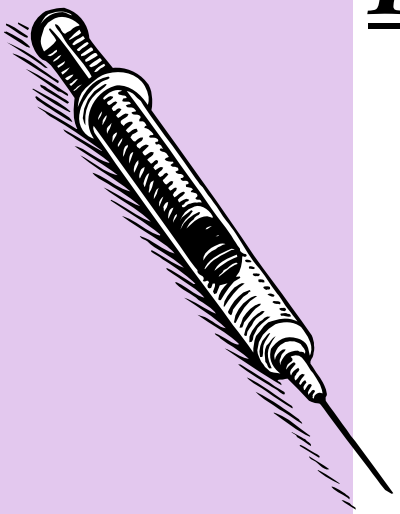
I'd also like our membership to continue to look for opportunities to present Mini-Tec sessions. With our vast number of sections, the best way to present the story behind medical devices is through the local sections. Please contact Jim Madenjian at jmplastics@aol.com or Len Czuba at lczuba@aol.com.

I look forward to seeing everybody at ANTEC this year. Monday will bring a joint session with the Marketing and Management SIG followed by a BOD meeting and dinner. We have sessions on Tuesday and Wednesday with Professor Jim Anderson from Case Western Reserve University (www.cwru.edu) providing a plenary talk during the Wednesday morning session. Wednesday is also an opportunity to attend the New Technology Forum organized by Len Czuba followed by yet another reception, the one held jointly with the EPS Division. We should all leave Cincinnati full of good ideas and good food!

Thanks for all of your support!

Jill Martin
2012 – 2013 Chair

Inside



Upcoming Conferences
ANTEC 2013 and MD&M West

Goals and Objectives
2012 – 2013

Nominations for the Medical Plastics Board of Directors Now Open

In This Issue

MEDICAL PLASTICS DIVISION-S.P.E.

Treasurer's Report as of October 23, 2012

INCOME

None

Balance as of August 10, 2012 $34,053.53

EXPENSES

Council expenses	[$1,155.37]
Telecom-BOD	[$143.30]

Funds available: October 23, 2012 $32,754.89

PAUL G. GERMAN, TREASURER

23-OCT-12

From The Editor:

The Medical Plastics Division of the Society of Plastics Engineers has close ties with the MD&M conferences, not only through shared interests but through shared membership. Several of our members are frequently instrumental in the planning and conducting of the programs and sessions presented at these biannual conferences. The program for MD&M West being held in Anaheim CA is detailed in this issue.

The preliminary version of the MDP program is listed in the issue as well. In addition to the presentations, other scheduled activities include the Board of Directors meeting, the MDP business meeting, and the MDP annual dinner. All are welcome to attend any of these activities but I especially hope that you will join us at the MDP dinner on Monday night.

The MDP Board of Directors is looking for new membership. See page 7 for a description of the responsibilities of a board member. I hope that you will seriously consider participation. I have found my last five years professionally and personally rewarding.

In the next issue of this newsletter, we will have the final ANTEC 2013 program for the Medical Plastics Division. I hope to see you there.

Norris M. Tollefson

The Medical Plastics Division received the Gold Pinnacle Award in 2012 for recognition of its achievements in developing membership value for the Society of Plastics Engineers in four categories:

Organization **Technical Programming**
Membership **Communication**

Your input is needed.

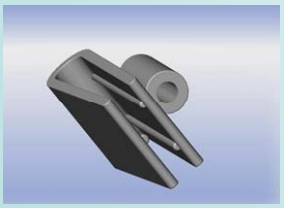
The four categories listed above are those that SPE considers valuable to the Society and to its membership. Please tell us how the Medical Plastic Division can better serve you, its membership, in any or each of these categories.

Think of this as an exercise in free association. Here are some topics to get you started:

Materials Devices Design Quality
Validations Compliance Composites Safety
Implantables Regulatory Manufacturing

If these words spark any ideas for future topics, please email your thoughts to me, your editor, at norris.tollefson@cibavision.com.

Medical Plastics



Materials

Devices

Medicine

ANTEC 2013

Duke Energy Convention Center
April 22-24
Cincinnati, Ohio, USA

Medical Plastics Division

Activities and Programs

Monday Afternoon	M33	Joint Panel with Marketing and Management
Monday Evening	5:30 – 7:00	Medical Plastics Division Board of Directors Meeting
Monday Evening		Medical Plastics Division Dinner
Tuesday Morning		Past Chairman Breakfast (time and location TBD)
Tuesday Morning	T32	MPD Session – sponsored papers and presentations
Tuesday Morning		Medical Plastics Division Business Meeting Following T32 session
Wednesday Morning	W?	MPD Session – sponsored papers and presentations
Wednesday Afternoon		**Polymer Applications in Health** New Technology Forum
Wednesday Afternoon		Reception jointly sponsored by MPD and EPSDIV Following New Technology Forum

For more information, go to www.4spe.org

Medical Plastics Division

Planned Program for ANTEC 2013

T32 - Tuesday Afternoon

1592047	Cold Gas Plasma in the Surface Modification of Medical Plastics	Sahagian, Khoren; Larner, Mikki; Kaplan, Stephen L
1590412	Developing Polymer/Ceramic Scaffolds via Thermally Induced Phase Separation for Bone Tissue Engineering	Akbarzadeh, Rosa; Hagen, Matthew; Yousefi, Amy
1590211	Design and Fabrication of Polymer/Ceramic Scaffolds for Bone Tissue Engineering	Minton, Joshua; Janney, Cara; Focke, Carlie; Yousefi, Amy
1474685	New Scientific Approaches for the Integration of the Statistical Design of Experiments for the Validation of Injection Molding Processes in Medical Technology	Mueller, Andrea; Seul, Thomas
1592149	The Effects of Type and Loading of Radiopaque Fillers on the Properties of Polyether Block Amide Compounds	Boyden, Breanna G.; Nilajkar, Amar; O'Neil, Charles
1589897	Synthesis and characterization of PVA/SBMA crosslinked hydrogels with low fouling property	Xu, Shouping; Zeng, Renchang; Lin, Changpeng; Pan, Huichan; Cai, Zhiqi; Wen, Xiufang; Pi, Pihui; Cheng, Jiang
1583498	Thermoplastic Polycarbonate Based Polyurethanes	Walder, Anthony; Makal, Umit; Kulkarni, Pallavi
1591384	An Electroactive Activator made with cellulose/Gamma ferric Oxide/Polypyrrole	Chowdhury, Nargis A.

W? – Wednesday Morning

	Title to Be Announced **Keynote Speaker**	James M. Anderson, MD, PhD
1592193	Performance Evaluation and Morphology Observation of PET/PP Blends in Injection Molding	Otsuka, Tadashi
1592030	The Mechanical Properties and Degree of Crystallinity of Biomedical Grade PEEK	Yakacki, Christopher M
1591720	Fracture Toughness Of A Medical Grade Ultra High Molecular Weight Polyethylene Using A Single Specimen Method	Brignola, Christopher; Shabeer, Ahamed; Guthorn, Paul; Zamiski, Gerald
1579791	A Nanoscaled Three Dimensional Structure Created By Using Electrospun Poly(ε Caprolactone) (PCL) Nanofibers and Induced PCL Crystallization	Wang, Xiaofeng; Han, Wenjuan; Salick, Max R.; Wang, Xiaodong; Cui, Zhixiang; Peng, Yiyan; Han, Jian; Turng, Lih Sheng; Li, Qian

New Technology Forum

Polymer Applications in Health

Wednesday Afternoon

Putting Electrospun Nanofibers to Work for Biomedical Research	Younan Xia
Resorbable Polymers: Melt Processing	Larry Thacther
Differentiating Biological Response to DES polymers	Barbara Huibregtse
The Application of Bioresorbable Polymers to Vascular Medical Devices	James Oberhauser
Value-driven Engineering and U.S. Global Competitiveness	Frank Douglas
Global Regulatory Guidelines for the Design and Development of Medical Devices	Scott Sardeson

Board of Directors for the Medical Plastics Division

Nominations are now open.
Elections will be held in March 2013.

The Board of Directors is made up of approximately 20 elected members that generally serve three year terms in a staggered fashion so that each year we elect five new board members. Officers serve one or two year terms with the exception of our Councilor to the SPE who serves a three year term.

Elections will be held next month. Any member of the Medical Plastics Division may nominate another member. Any member may nominate him/herself.

If you are interested in participating in the Medical Plastics division as a member of the Board of Directors, please contact any current Board member for more information.

Requirements and Responsibilities of Board Members for the Medical Plastics Division

►Candidates for the SPE Medical Plastics Division Board of Directors must be active members of the Society of Plastics Engineers and of the Medical Plastics Division.

►Members of the Board should be involved in or have interest in some aspect of the Medical Plastics Business or a related academic field.

►Board members are expected to participate in monthly 1-hour teleconference meetings and annual in-person Board of Directors and Business meetings at SPE's Annual Technical Conference (ANTEC).

►Board members are expected to assume responsibility for specific duties, such as Secretary, Newsletter, Web-Site, Social Activities, Technical Program Chair, Membership, Student Activities, Treasurer and SPE-Council Representative.

►Board members are expected to participate in committees in some capacity to support activities such as Technical Conferences, Membership Group Activities, Financial oversight, BOD nominations, etc.

►We encourage an active membership so any one individual doesn't carry too much of a load.

Medical Plastics Division

Mission Statement

To provide a forum for technical, quality systems, and regulatory information exchange on polymers and polymer processing for the medical and healthcare industries focusing on new technologies, applications, and delivery methods.

Goals and Objectives 2012 - 2013

Officers

Jill Martin – Chair
Dan Fucella – Secretary
Margie Hanna – Councilor
Mark Bonifaccio – Chair- Elect
Paul German – Treasurer
Steve McCarthy – Past Chair

•The officers are responsible for the MPD board operations to comply with SPE Division guidelines and policies. This includes maintaining an active Board of Directors with appropriate officers and chairs. The officers challenge each member with bringing new enthusiasm to the board and their assigned area of responsibility. This will include identifying new board prospects, mentoring those new to the board and initiating new programs that will make MPD of more benefit to members and to prospective members of SPE. The officers shall be responsible for attendance and active participation at all SPE Council and Division Committee meetings as well as holding an annual business meeting.
•The Medical Plastics Division shall plan to win the Pinnacle Gold and strive to win the Communications Award.
•Board members are expected to attend board meetings or advise chairman when unable.

Technical Program Committee

Ed Fewkes - ANTEC Technical Program Chair
Henk Blom – Member
Jordan Freedman – Member
Jim Oberhauser – Member
Jim Madenjian - Member
Len Czuba – MiniTec Chair
Vipul Dave – Member
Ken Breeding – Member
Ali Ashter – Member

•The ANTEC Technical Program Committee is responsible for our ANTEC involvement with 2 days of papers including joint sessions with other divisions.
•The Technical Program Committee is responsible for managing the partnership with Canon for MDM shows, developing webinars, and managing a traveling MiniTec Road Show which can be offered to Sections interested in partnering with MPD for a medical themed half or full day conference event. The Technical Programming Committee shall provide technical programming that drives diverse member participation and networking opportunities, as well as technical programming that addresses participation in under-represented areas. The Technical Program Committee shall support new SPE technical products and support Student Activities and Programming.
•Other activities include preparing a speakers list, making it available to Sections for monthly dinner type meetings, and supporting the EuroTec and AsiaTec conferencing efforts.

Goals and Objectives 2012 – 2013
(con't.)

Communications Committee

Dan Fuccella – Secretary – Chair
John Thomas – Social Chair
Norris Tollefson - Newsletter
Harrison Yu – Website / Pinnacle

•The Communications Committee is responsible for effectively communicating with members about SPE offerings and events to foster a sense of community and to allow them to respond. This includes providing financial reports and minutes of the Board meetings to membership, offering a social event annually, and providing SPE Headquarters with best practices for member communications. In addition the Communications Committee will prepare and send out at least 3 and possibly 4 newsletters of high quality with news of activities and interest to our members, participate in the Communication Excellence Award contest, effectively use the website for better communication about MPD activities as well as a support mechanism to answer members' technical questions, and to reach out to members with monthly email blasts to promote activities.

Finance Committee

Jill Martin – Finance Committee Chair
Mark Bonifacio – Member
Paul German – Treasurer
Steve McCarthy – Member

•The finance committee is responsible for proposing the effective use of division funds as well as proposing an operating budget for best use of funds for member programs and benefits. The finance committee also develops a long-range plan for the use of funds including an annual budget and plans to raise income, and submission of the SPE Annual Financial Report and IRS 990 Form.

Membership Committee

OPEN – Membership Chair

•The membership committee is responsible for providing SPE Headquarters with names, addresses, phone and email addresses of prospective members acquired by the Medical Plastics Division. In addition the membership committee will develop communication programs and efforts to both recognize new members but to reach out to lapsed members, work with communication tools (newsletter and website) to reach prospective new members through the MDM program, to develop and implement at least one new service that offers member value, and try to increase division membership by 10%.

Recognition Committee

Len Czuba – Nominations
Maureen Reitman – Awards

•The Recognition Committee is responsible for utilizing the awards program to recognize contributions from conference speakers to student papers, working with the programming committee to identify and recognize best speaker at each conference.
•In addition the Recognition Committee will nominate and sponsor at least 1 member for either HSM or Fellow from our division, implement a Medical Plastics Division member recognition program, and use division awards to recognize significant contributions.

Medical Plastics Division - SPE
Board of Directors for 2012 - 2013

Name	2012-2013 Position	Company
Officers		
Jill Martin	Chair	Dow Chemical
Mark Bonifacio	Vice Chair / Finance	Bonifacio Consulting
Dan Fuccella	Secretary / Finance	Applied Technologies
Paul German	Treasurer	Kruger Plastics
Margie Hanna	Councilor (2012 - 2015)	Czuba Enterprises, Inc.
Steve McCarthy	Past Chair (2011 - 2012)	UMass Lowell
Board Members		
Class ending ANTEC 2013		
Vipul Dave	ANTEC Technical Program Chair	Cordis J&J
Henk Blom	ANTEC Technical Program Committee	Rollprint
Ed Fewkes	ANTEC Technical Program Committee	Corning
John Thomas	Social Chair	Bonifacio Consulting Services
Class ending ANTEC 2014		
Norris Tollefson	Newsletter Editor	CibaVision Corp./Alcon
Jim Madenjian	Communications / Social Co-chair	J.M. Engineering Associates
Harrison Yu	Website Communications / Pinnacle	Bondable Biopolymers
Jordan Freedman	Technical Program Committee	Biomet Orthopedics
Class ending ANTEC 2015		
Jodie Laughlin	Marketing - To be chartered	GE Healthcare
Maureen Reitman	Awards / Technical Program	Exponent
Ken Breeding	Marketing - To be chartered	Eastman Chemical Company
James Oberhauser	Technical Program Committee	Abbott Vascular
Ali Ashter	Technical Program Committee	EMD Millipore
ex officio		
Glenn Beall	Historian (Appointed)	Glenn Beall Plastics
Sarah Sullinger	SPE Liaison (Appointed)	SPE
Vijay Boolani	EC Liaison (Appointed)	Boolani Engineering Corporation
Gerry McNally	EMPD TPC	McNally Associates
Austin Coffey	EMPD Chair & Councilor	Waterford Institute of Technology
Committee Volunteers		
Len Czuba	MiniTec	Czuba Enterprises, Inc.

If you would like to get in touch with a member of the board, contact information may be found in the SPE Membership Directory.

Upcoming Conferences and Activities

MEDTECH SESSIONS AND SEMINARS

1E – MedTech Polymers	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Is there room for innovation in today's medical device industry?*** ***Stanton Rowe*** *Corporate VP, Advanced Technology and CSO* **Edwards Lifesciences**
9:50AM	Networking Coffee Break
10:10AM	**Opening Remarks** Chair: ***Vipul Davé****, Engineering Fellow - MD&D Global Supply Chain,* **Johnson & Johnson**
10:20AM	**Suture and fiber materials selections for cardiovascular device components** ***Ed Boarini****, Sr. VP and General Manager,* **Teleflex Medical**
10:55AM	**Using Polymers' Mechanical and Surface Properties in the Development of Stem Cell-Based Tissue Engineering Therapies** ***Byron Deorosan****, Associate,* **Exponent**
11:30AM	**Meeting the Demands of Medical Device Performance Requirements with Polymeric Bioresorbable Vascular Scaffolds** ***Ashley Kelley****, Sr. R&D Engineer,* **Abbott Vascular**
12:00PM	Lunch Break
1:00PM	**EFEP co-extrusion technology** ***John Felton****, Market Development Manager,* **Daikin America**
1:35PM	**Advances in antimicrobial plastics technology** ***Matthew Gande****, Principal Technology Specialist,* **BASF**
2:10PM	**Comparative radiopacity and mechanical properties of FDA compliant radiopacifiers** ***Jack Frautschi****, Sr. Biomaterials Scientist,* **PolyOne Corporation**
2:50PM	Networking Coffee Break
3:00PM	**MEMS intraocular drug delivery device** ***Ronalee Mann****, Senior Associate,* **Exponent**
3:30PM	**Chemical resistance of Eastman Tritan™ copolyesters and engineering polymers used in medical devices - oncology drug case study** ***Yubiao Liu****, Medical Application Development Manager,* **Eastman Chemical**
4:00PM	Day One Welcome Drinks Reception

2E – MedTech Seminar Series	
10:00AM	**Design of Implantable Devices** ***Timothy Cline*** *Chief Marketing Officer* **Valtronic** ***Thomas J. Webster*** *Dept Chair Chemical Eng* **Northwestern University** ***Marilyn Allison*** *Manager Quality Systems* **CareFusion** ***Daniel Foster*** *R&D Fellow* **Boston Scientific**
1:00PM	**Bioresorbable Polymers** ***Dennin D. Jamiolkowski*** *Distinguished Research Fellow* **Ethicon** ***Mart Eenink*** *Dir. Global Sales Biomaterialsl* **PURAC** ***Derek Mortisen*** *Senior Scientist* **Abbott Laboratories**
3:15PM	**Innovations in Orthopedic Devices** ***John Marotta*** *CEO* **Emerge Medical** ***Christopher Hunter*** *Manager External Research* **Zimmer**

3E – MedTech Seminar Series	
10:00AM	**Wireless Medical Devices** ***Jung-ik Suh*** *Marketing Program Manager* **Agilent** ***Ken Fuchs*** *Sr. Principle Architect Enterprise Systems* **Mindray** ***Phil Raymond*** *Chief Wireless Architect* **Philips Healthcare** ***Stacey Chang*** *Dir. Healthcare Practice* **IDEO**
1:00PM	**Developing Medical Mobile Apps** ***Shawna Gvazdaukas*** *VP Head of Devices* **Sanofi** ***Nikhil J. George*** *Chief Engineer* **Mobisante** ***Scott Thiel*** *Senior Regulatory Consultant* **Anson Group**
3:15PM	**Mircoelectronics and Sensors** ***Jose Fernandez Villasenor*** *Electrical Engineer* **Freescale Semiconductor** ***Gary Johnson*** *Sales Director* **Triad Semiconductor** ***Marks Phelps*** *Sr. Program Director* **Medtronic**

4E – MedTech Seminar Series	
	Innovation in Cardio Devices ***Lisa Jennings*** *Founder, CSO* **ARISTE Medical** ***Crystal Cunanan*** *Dir. Tissue Engineering* **Boston Scientific**
	Power Source Technologies ***Glenn Amatucci*** *Professor Material Science* **Rutgers University** ***Kevin White*** *Sr. Managing Scientist* **Exponent** ***Paul Beach*** *President* **Quallion**

VALIDATION, TESTING & TRIALS

1B – Risk Management & Quality Control	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Is there room for innovation in today's medical device industry?*** ***Stanton Rowe*** *Corporate Vice President, Advanced Technology and Chief Scientific Officer* **Edwards Lifesciences**
9:50AM	Networking Coffee Break
10:10AM	**Applying 14971:2012 to achieve compliance with QSR (21 CFR 820): Building an integrated QMS and implementing best practices in Risk Management** ***Frank Pokrop****, Director Regulatory Affairs,* **CareFusion**
11:10AM	**Implementing ISO 13845:2012 (Quality Management Systems) effectively and understanding the new expectations from regulatory bodies** ***Marcelo Trevino****, Sr Regulatory Compliance Manager – Heart Valves Center of Excellence,* **Medtronic**
12:00PM	Lunch Break
1:00PM	**A simplified defensible approach to the Validation of Quality System Software** ***Thomas Bento****, Sr. Regulatory Consultant,* **Certified Compliance Solutions**
2:00PM	**Risk Analysis technique workshop I** ***James (Rusty) Lusk****, Principal,* **Quality Systems International**
2:50PM	Networking Coffee Break
3:10PM	**Risk Analysis technique workshop II** ***James (Rusty) Lusk****, Principal,* **Quality Systems International**
4:00PM	End of Day One

2B – Validation: Process & Method	
9:00AM	**Plenary Session: Keynote Speech** ***Kim Blickenstaff*** *President and Chief Executive Officer* **Tandem Diabetes Care**
9:50AM	Networking Coffee Break
10:10AM	**How to Design a Better Reliability Test Program I** ***Mike Silverman****, Managing Partner,* **Ops A La Carte**
11:10AM	**How to Design a Better Reliability Test Program II** ***Mike Silverman****, Managing Partner,* **Ops A La Carte**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Polymer Technology for Implantables: Devices and Excipients** presented by **Lubrizol**
1:00PM	**Process validation: Mastering the guidance and creating a total program** ***Karema W. Chantasirivisal****, Process Validation Manager,* **Boston Scientific**
2:00PM	**Applying statistical methods to process validation** ***Chris Wyman****, Principal Quality Engineer; Corporate SME, Statistical Techniques,* **Boston Scientific**
2:50PM	Networking Coffee Break
3:10PM	**Materials process validation for medical devices** ***Allan Kimble****, Materials Process Validation Manager,* **DePuy Synthes – Johnson & Johnson**
4:00PM	End of Day Two

3B – Updates on Test Standards	
9:00AM	**Plenary Session: Keynote Speech** ***Marc Madou*** *Chancellor's Professor and BioMEMS Lab Director* **UC Irvine**
9:50AM	Networking Coffee Break
10:10AM	**Implementing IEC 60601-1 3rd Edition: Electrical testing (FDA consensus standard)**
11:10AM	**Update on ASTM F2914: Shelf life testing for endovascular devices and the determination of aging mechanism** ***Fuh-Wei Tang****, Research Advisor Polymer R&D, Bioabsorbable Vascular Solutions,* **Abbott Vascular**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Portable Power Considerations for Medical Devices** presented by **Electrochem Medical**
1:00PM	**Biocompatibility and Chemistry Testing Workshop** A comprehensive workshop to help you understand the newest biocompatibility testing standards in order to be in compliance and improve your in-house techniques ***Thor Rollins****, Biocompatibility Specialist,* **Nelson Laboratories**
2:50PM	Networking Coffee Break
3:10PM	**Biocompatibility and Chemistry Testing Workshop (cont'd)** ***Thor Rollins****, Biocompatibility Specialist,* **Nelson Laboratories**
4:00PM	End of Day Three

4B – Success in Pre-clinical Studies and Clinical Trials	
9:00AM	**Plenary Session: Closing Keynote Speech** ***David Gollaher*** *President and Chief Executive Officer* **CHI-California Healthcare Institute**
9:50AM	Networking Coffee Break
10:10AM	**Preparing Investigational Device Exemption (IDE) applications for clinical studies and understanding the new Pre-Submission Program** ***Denise McEachern****, VP Global Regulatory Affairs,* **Bausch + Lomb Surgical**
11:10AM	**Step-by-step guide to pre-clinical and bench studies** ***Janie Mandrusov****, Director or Preclinical and Clinical Development,* **SinuSys Corp**
12:00PM	Lunch Break
1:00PM	**Designing a clinical trial strategy for success** ***Michael A. Daniel****, President,* **Daniel & Daniel Consulting**
2:00PM	**Applications of biostatistics to the design, execution and analysis of clinical trials for medical devices** ***Lei Peng****, Associate Director of Biostatistics,* **Abbott Vascular**
2:50PM	Networking Coffee Break
3:10PM	**Cost savings in clinical trials: Practical strategies and tools** ***Mariam Mirgoli****, Director of Clinical Solutions,* **Abbott Vascular**
4:00PM	End of Day Four

REGULATORY SUBMISSION & APPROVAL

1C – Regulatory Updates and the FDA Perspective	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Is there room for innovation in today's medical device industry?*** ***Stanton Rowe*** *Corporate Vice President, Advanced Technology and Chief Scientific Officer* **Edwards Lifesciences**
9:50AM	Networking Coffee Break
10:10AM	**FDASIA Recap: Clarifying the review process and the benefit-risk determinations for PMA and de novo applications**
11:10AM	**Reviewing the 510(k) Triage and Quick Review pilot program and an update on the new process**
12:00PM	Lunch Break
1:00PM	**FDA Los Angeles District Update and the FDA Globalization Initiative** ***Alonza Cruse****, Director,* **FDA – Los Angeles District Office** ***Dan Solis****, Director of Import Operations,* **FDA – Los Angeles District Office**
2:00PM	**New requirements for home use devices: IEC 60601-1-11:2010 and FDA draft guidance – Will a new design review be necessary?** ***Mary Weick-Brady****, Director of Home-Use Device Initiative,* **FDA CDRH**
2:50PM	Networking Coffee Break
3:10PM	**Panel Discussion: Interacting with regulatory agencies and Notified Bodies** ***Michael Morton****, Senior Director of Global Regulatory Affairs,* **Medtronic**
4:00PM	End of Day One

2C – Regulatory Strategies & Compliance in Practice	
9:00AM	**Plenary Session: Keynote Speech** ***Kim Blickenstaff*** *President and Chief Executive Officer* **Tandem Diabetes Care**
9:50AM	Networking Coffee Break
10:10AM	**Regulatory strategies for 2013: The art of framing a successful submission** ***Michael Morton****, Senior Director of Global Regulatory Affairs,* **Medtronic**
11:10AM	**Nanotechnology and nanomaterials in medical devices – The regulatory frontier** ***Mary Gray****, Manager of Regulatory Affairs,* **DePuy Synthes - Johnson & Johnson**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Polymer Technology for Implantables: Devices and Excipients** presented by **Lubrizol**
1:00PM	**Strategies for the 510(k) pathway: Submission & approval** ***Mark DuVal****, President,* **DuVal & Associates**
2:00PM	**Strategies for the PMA pathway: Submission & approval** ***Susan Petersen-Stejskal****, VP Clinical Research,* **BioControl-Medical**
2:50PM	Networking Coffee Break
3:10PM	**Strategies for the combination product pathway: Submission & approval** ***Winifred Wu****, President,* **Strategic Regulatory Partners LLC** and former VP Regulatory and Medical Affairs, **Medtronic**
4:00PM	End of Day Two

3C – UDI & Traceability	
9:00AM	**Plenary Session: Keynote Speech** ***Marc Madou*** *Chancellor's Professor and BioMEMS Lab Director* **UC Irvine**
9:50AM	Networking Coffee Break
10:10AM	**Session Chair's Opening Remarks** ***Steve Cochran**, Chief Technology Officer,* **GHX**
10:20AM	**Unique Device Identifier: FDA update and plan for the industry** ***Jay Crowley**, Senior Advisor Patient Safety,* **FDA**
11:10AM	**Industry perspective: Where is the industry at in terms of implementation? The next steps** ***Jackie Elkin**, Global Process Owner - Standard Product Identification,* **Medtronic**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Portable Power Considerations for Medical Devices** presented by **Electrochem Medical**
1:00PM	**Panel discussion: Creating a roadmap for UDI compliance from multiple perspectives** *MODERATOR:* ***Karen Conway**, Executive Director,* **GHX** ***Jay Crowley**, Sr. Advisor Patient Safety,* **FDA** ***Jackie Elkin**, Global Process Owner - Standard Product Identification,* **Medtronic** ***Siobhan O'Bara**, Vice President,* **GS1 Healthcare US** ***Joe Pleasant**, CIO,* **Premier**
2:00PM	**Leveraging GS1 standards to comply with UDI** ***MJ Wyllie**, Sr. Director Healthcare,* **GS1 Healthcare US**
2:50PM	Networking Coffee Break
3:10PM	**Reviewing labeling and packaging solutions for UDI-compliant medical devices** ***Dawn Fowler**, Sr. Manager of Global Labeling and Document Control,* **Endologix**
4:00PM	End of Day Three

4C – Globalization: Compliance & Commercialization	
9:00AM	**Plenary Session: Closing Keynote Speech** ***David Gollaher*** *President and Chief Executive Officer* **CHI-California Healthcare Institute**
9:50AM	Networking Coffee Break
10:10AM	**Internationalization of medical devices: Regulatory and commercialization challenges** ***Mark Gayle**, VP Global Post Market Surveillance and Quality Assurance,* **Boston Scientific** ***Bharat Jain**, Director of Global Quality Program Management – Emerging Markets,* **Boston Scientific**
11:10AM	**Bringing medical devices to Japan** ***Kirk Zeller**, Director of International Market Development,* **Codman Neurovascular – Johnson & Johnson** ***Minori Nakano Carlsson**, Sr. International Regulatory Affairs Manager,* **Medtronic**
12:00PM	Lunch Break
1:00PM	**Bringing medical devices to China** ***Wenkai Ma**, Director of Global Regulatory Affairs,* **Allergan China**
2:00PM	**EU Regulatory Update: MDD, AIMDD and IVDD** ***Chris Sarner**, Project Manager,* **DEKRA Certification B.V.**
2:50PM	Networking Coffee Break
3:10PM	**Fast track to CE Marking: Strategies for timely compliance and commercialization** ***Uwe Degenhardt**, Division Manager of Active Medical Devices,* **TÜV SÜD America**
4:00PM	End of Day Four

POST-MARKET COMPLIANCE & PRODUCTION

1D – Sustaining Compliance	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Stanton Rowe*** *Corporate VP, Advanced Technology and Chief Scientific Officer* **Edwards Lifesciences**
9:50AM	Networking Coffee Break
10:10AM	**Understanding the FDA national strategy for post-market surveillance**
11:10AM	**Meeting the Medical Device Reporting (MDR) requirement for post-market compliance** ***Javad Seyedzadah**, Senior VP of Regulatory Affairs and Quality Assurance,* **Gambro**
12:00PM	Lunch Break
1:00PM	**Building an effective complaint handling system to stay compliant** ***Richard DeRisio**, Vice President of Global Quality Assurance and Regulatory Affairs,* **Covidien**
2:00PM	**Fulfilling the FDA device tracking requirements**
2:50PM	Networking Coffee Break
3:10PM	**Meeting the new requirements of EU Vigilance Reporting: MEDDEV 2.12/1 Revision 7**
4:00PM	End of Day One

2D – Medical Device Crisis Management	
9:00AM	**Plenary Session: Keynote Speech** ***Kim Blickenstaff*** *President and Chief Executive Officer* **Tandem Diabetes Care**
9:50AM	Networking Coffee Break
10:10AM	**Practical steps to prepare for FDA inspections and Notified Body assessments** ***Niedre M. Heckman**, Manager Regulatory Affairs, Global Regulatory Affairs BioScience,* **Baxter Healthcare**
11:10AM	**Post-inspection strategies: Steps to respond to Form 483, Warning Letters and Establishment Inspection Report (EIR)** ***Jim Kozick**, Former Director of Domestic Investigations,* **FDA LA District**
12:00PM	Lunch Break
1:00PM	**Devising a recall strategy: Dealing with Removals and Corrections (FDA)** ***Rita Hoffman**, Former Branch Chief,* **Recalls CDRH**
2:00PM	**Best practices in implementing Corrective and Preventive Actions (CAPA)** ***Coral Ramos**, CAPA Leader,* **GE Healthcare**
2:50PM	Networking Coffee Break
3:10PM	**Root cause analysis for CAPA**
4:00PM	End of Day Two

3D – Scale-up Strategies & New Manufacturing Technologies	
9:00AM	**Plenary Session: Keynote Speech** ***Marc Madou*** *Chancellor's Professor and BioMEMS Lab Director* **UC Irvine**
9:50AM	Networking Coffee Break
10:10AM	**Devising scale-up strategies for successful high-volume production while meeting all compliance requirements** ***Delores Morrison**, Sr. Director of Engineering,* **Edwards Lifesciences**
11:10AM	**Best practices in cost control in medical device manufacturing to maximize productivity**
12:00PM	Lunch Break
1:00PM	**Applying lean principles to medical device manufacturing**
2:00PM	**Innovations in additive manufacturing: Transitioning from rapid prototyping to rapid manufacturing** ***Roger Narayan**, Professor Materials Science and Engineering,* **North Carolina University**
2:50PM	Networking Coffee Break
3:10PM	**Advantages of 3D-MID technology in miniaturizing medical devices** ***Albert Birkicht**, Managing Director,* **Harting AG**
4:00PM	End of Day Three

4D – Outsourcing & Supplier Management	
9:00AM	**Plenary Session: Closing Keynote Speech** ***David Gollaher*** *President and CEO* **California Healthcare Institute**
9:50AM	Networking Coffee Break
10:10AM	**Intellectual Property (IP) issues and open innovation challenges when working with suppliers** ***David J. Dykeman**, Shareholder and Patent Attorney,* **Greenberg Traurig**
11:10AM	**Panel Discussion: Creating a successful partnership with suppliers and contract manufacturers** *MODERATOR:* ***Olen Chiddix**, Director of Materials,* **Pathway Medical Technologies** ***Thomas Ebertowski**, Director of Global Supplier Quality Assurance,* **Boston Scientific** ***Todd McCaslin**, Global Sourcing Director,* **Boston Scientific** ***David J. Dykeman**, Shareholder and Patent Attorney,* **Greenberg Traurig**
12:00PM	Lunch Break
1:00PM	**Purchasing and supplier controls: Maintaining quality agreements to manage and minimize risk** ***Gary Hartman**, Global Supplier Quality Manager - Surgical,* **Bausch + Lomb**
2:00PM	**Establishing performance management systems and metrics to drive efficiency, reduce costs, boost quality and enhance supplier value** ***Thomas Ebertowski**, Director of Global Supplier Quality Assurance,* **Boston Scientific**
2:50PM	Networking Coffee Break
3:10PM	**Overcoming the cultural and operational challenges of working with international suppliers in emerging economies through robust qualification and effective monitoring to ensure full transparency** ***Yong Cho**, Sr. Technical Manager,* **Genentech**
4:00PM	End of Day Four

M&M WEST

DESIGN & PROTOTYPE

1A – Concept Ideation & Implementation	
9:00AM	**Plenary Session: Opening Keynote Speech** ***Is there room for innovation in today's medical device industry?*** ***Stanton Rowe*** *Corporate Vice President, Advanced Technology and Chief Scientific Officer* **Edwards Lifesciences** >More
9:50AM	Networking Coffee Break
10:10AM	**Assumption Storming: Disruptive innovations in medical devices** **Part 1: Experiencing the Design Problem** ***Craig Lauchner**, Innovation Program Manager,* **Medtronic**
11:10AM	**Part 2: Learning to be disruptive** ***Craig Lauchner**, Innovation Program Manager,* **Medtronic**
12:00PM	Lunch Break
1:00PM	**Creativity workshop – Using Design Thinking methodology to discover creative solutions to your device development challenges** ***Stacey Chang**, Associate Partner and Director of Health & Wellness practice,* **IDEO** ***Brian Mason**, Lead of Medical Products Group,* **IDEO** ***Jesse Fourt**, Senior Program Lead,* **IDEO**
2:00PM	**Design for Six Sigma—Steps to execute design concepts** ***Georgette Belair**, VP R&D and co-author of "Implementing Design for Six Sigma – A Leader's Guide",* **Ossur America Inc.**
2:50PM	Networking Coffee Break
3:10PM	**How to capitalize on the consumerization of medical devices?** ***Sonny Vu**, CEO and Founder,* **Misfit Wearables**
4:00PM	End of Day One

2A – Design for Speed	
9:00AM	**Plenary Session: Keynote Speech** ***Kim Blickenstaff** President and Chief Executive Officer* **Tandem Diabetes Care**
9:50AM	Networking Coffee Break
10:10AM	**Prototyping workshop – Building to Think** ***Stacey Chang**, Associate Partner and Director of Health & Wellness practice,* **IDEO** ***Brian Mason**, Lead of Medical Products Group,* **IDEO** ***Jesse Fourt**, Senior Program Lead,* **IDEO**
11:10AM	**Utilizing advances in computational modeling and simulation platforms to accelerate design**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Polymer Technology for Implantables: Devices and Excipients** presented by **Lubrizol**
1:00PM	**Software Design for Six Sigma: Best practices and Agile development** ***Vivek Vasudeva**, Co-Founder,* **SWReliability.com** *(Former Director of Engineering, Medtronic)*
2:00PM	**Optimizing the use of COMSOL Multiphysics in design projects** ***John F. Kalafut**, Director of Research and Strategy,* **MEDRAD Innovations/Bayer Healthcare**
2:50PM	Networking Coffee Break
3:10PM	**Motion capture for the heart: A close look at the CyberHeart design project at Medtronic** ***Aaron Oliker**, Co-Founder,* **BioDigital Systems**
4:00PM	End of Day Two

3A – Design Controls for Quality, Safety & Effectiveness	
9:00AM	**Plenary Session: Keynote Speech** ***Marc Madou** Chancellor's Professor and BioMEMS Lab Director* **UC Irvine**
9:50AM	Networking Coffee Break
10:10AM	**Optimizing Medical Device Development via Systems Engineering** ***Martin Coe**, Systems Engineer CSEP,* **Covidien**
11:10AM	**Human Factors Pre-Market Review: Incorporating HF engineering into risk management** **Ron Kaye**, HF Pre-Market Review Team Leader, **FDA CDRH**
12:00PM	General Lunch Break & Networking: RSVP Required Lunch & Learn Session – **Portable Power Considerations for Medical Devices** presented by **Electrochem Medical**
1:00PM	**Meeting the FDA-recognized IEC 62304:2006 standard: Medical software processes** ***Dan Olivier**, President,* **Certified Compliance Solutions**
2:00PM	**Innovating with quality in mind – A new theme in medical device development** ***David Amor**, Design Quality Engineer,* **St. Jude Medical** *and Sr. Innovation Fellow,* **University of Minnesota**
2:50PM	Networking Coffee Break
3:10PM	**Integrating Pharmaceutical Technology Transfer Practices into a Design Control System for Combination/Convergent Medical Products** ***Roy R. Fennimore, Jr.**, Research Fellow, Product & Process Scientific Solutions (P^2S^2)* – **Johnson & Johnson**
4:00PM	End of Day Three

4A – Materials Selection & Qualification	
9:00AM	**Plenary Session: Closing Keynote Speech** ***David Gollaher** President and Chief Executive Officer* **CHI-California Healthcare Institute** >More
9:50AM	Networking Coffee Break
10:10AM	**Developing and implementing an effective and robust materials selection process for medical devices** ***Glenn White**, Associate Director of Device Technology,* **Novartis Pharmaceuticals**
11:10AM	**Selecting materials for implantable electronic devices** ***Mike Colvin**, Senior Research Fellow,* **Boston Scientific**
12:00PM	Lunch Break
1:00PM	**Panel Discussion: Selecting and working with material suppliers to ensure quality and streamline CAPA systems** ***Michael Checketts**, Division Director of QA/RA and Technology,* **Ametek Engineered Medical Components** ***Olen Chiddix**, Director of Materials,* **Pathway Medical Technologies** ***Yong Cho**, Sr. Technical Manager,* **Genentech**
2:00PM	**Materials selection based on the new RoHS requirements: Selecting alternative lead-free alloys for circuit boards assembly** ***Simin Bagheri**, M.A.Sc., P.Eng. Customer Engagement Lead,* **Celestica Inc.**
2:50PM	Networking Coffee Break
3:10PM	**Selecting materials for miniaturization**
4:00PM	End of Day Four

Society of Plastics Engineers

Medical Plastics Division

MiniTec Program

The Medical Plastics Division is reaching out to other divisions and local Sections of SPE through its **MiniTec** program. A **MiniTec** conference is built on a local scale, a downsized RETEC, which is supported by the Medical Plastics Division and does not require approval by SPE headquarters. **MiniTec** is for SPE sections that want to sponsor a local event featuring medical plastics. Any SPE section can sponsor a **MiniTec**.

The Medical Plastics Division **MiniTec** program is here to help your section promote and educate their members about plastics and the medical industry. The MPD has organized a speaker list from which we can assist sections in organizing a **MiniTec.** The **MiniTec** event may be half-day, full day, or two day session with whatever theme the section thinks would be of interest to their members. Some suggested themes are: materials, design, processing, quality, or validation of medical products.

How does **MiniTec** work? Your section determines subject matter and duration that would be of interest to their local members and submits request to MPD for speakers.

Cost depends on speaker travel expenses, and maybe speaker fee if volunteers are not available. Your Section, MPD, and headquarters get equal share of income from the event.

If your section is interested in participating and interested in setting up a **MiniTec** conference, please email your request to Jim Madenjian at jmplastics@aol.com, or telephone: 781-837-0584. Please insert “MiniTec Request” in subject line to avoid deletion by spam filtering.

Recent Conferences and Activities

Society of Plastics Engineers

ANTEC Mumbai a Success

Mumbai, India, December 10, 2012: The Society of Plastic Engineers (SPE) held its prestigious ANTEC conference in Mumbai, India, December 6-7, 2012. This was the first time in the Society's 70 years of existence that ANTEC has ever been organized outside North America. This was also the largest-ever conference on plastics and polymers in India, with 178 papers presented across seven parallel tracks over two days.

SPE further enhanced its educational mission at this event by organizing special hands-on workshops on three key areas of plastics engineering: thermoforming, injection molding, and medical plastics devices.

The total attendance for the conference and workshops was over 450 delegates, and the event was supported by the entire local and international plastics industry.

The conference also hosted a special Plenary Session with three distinguished speakers. Shri Manohar Parrikar, Chief Minister of Goa, was the guest of honor and gave a special address to attendees. Dr. Ernesto Occhiello, Executive Vice President, Technology and Innovation at SABIC, spoke on plastics for sustainability, and announced further investments by SABIC in R&D centers on polymers and plastics technology in India. Dr. Ajit Sapre, Group President, Research & Technology at Reliance Industries, gave his address on business and technology trends and challenges for the Indian plastics industry.

The networking reception and dinner with the honored guests from the plenary sessions attracted additional executives from the plastics industry to this event, bringing the total attendance close to 500.

SPE President Jim Griffing announced that ANTEC will be hosted again in India in December 2014. “Given the response to this first event from sponsors, delegates and speakers, we expect a much larger conference in 2014,” Griffing said. He also thanked and congratulated the SPE India team, and, in particular, Vijay Boolani, Conference Chair, and the inspiration behind ANTEC Mumbai, without whose dedication and support this event would not have been possible. Griffing also added that SPE would organize its first ANTEC in the Middle East in Dubai in January 2014, and that the first SPE conference in China is planned for December 2013. “With EUROTEC in Lyon, France, planned for July 4–5, 2013, SPE can now be considered the first and only global Society active in the plastics industry world-wide,” concluded Griffing.

ANTEC® MUMBAI

Renaissance Mumbai Convention Centre Hotel
December 6-7, 2012
Mumbai, India

A selection of titles from the ANTEC Mumbai program

Title	Author	Session
Biodegradable Polyurethanes Reinforced with Green Nanofibers for Regenerative Applications	Hamza Nakhoda	Advances in Materials-1
PLA/PGA Scaffold Prepared by Solvent Casting/Particulate Leaching (SCPL) to Improve Pore Connectivity Within Tissue Engineering Scaffolds	Smita Mohanty	Advances in Materials-1
Process Induced Molecular Miscibility of Injection Moulded Poly(L-lactic acid) / Poly(ε-caprolactone) Blends	Satyabrata Ghosh	Advances in Materials-2
Synthesis of Manganese Ricinoleate Itaconic Dextrose Mixed with Bisdimethylamino Benzophenone and Their Effect on Photo and Biodegradation of Low Density Polyethylene Films	Santhoskumar A. Umapathi	Advances in Materials Performance-2
Biobased, Biodegradable Polymer Coating for Packaging Applications	Vishal Bavishi	Advances in Materials-3
PLA/Chitosan Nanobiocomposite for Food Packaging Applications	Akhilesh Pal	Advances in Materials-5
Isolation and Characterization of Microalgae Strains for Biopolymer and Bioplastic Production	Hector Hernandez	Advances in Materials-7
Polymeric Biomaterial Based Hydrogels: Admiral Medical Device for Biomedical Applications	Nab Saha	Advances in Materials Performance-8

October 24, 2012 Board of Directors Meeting
of the
Medical Plastics Division of the Society of Plastics Engineers

The teleconference meeting was called to order by MPD Board Chair Jill Martin at 11:15am (CT). Board members in attendance: Steve McCarthy, Jill Martin, Mark Bonifacio, Dan Fuccella, Paul German, Ed Fewkes, John Thomas, Norris Tollefson, Jim Madenjian, Jodie Laughlin, Ken Breeding, James Oberhauser, Glenn Beall, and Sarah Sullinger

1) Approval of July 16, 2012 BOD meeting minutes:
   Moved: Norris Tollefson, Second: Paul German; Carried

2) Treasurer's Report – Paul German
   a) Division Balance as of August 10, 2012: $34,053.56
      i) Income: $0.00
      ii) Expenses:
         (1) Council Expense: $1,155.37
         (2) BOD Telecon meeting $143.30
   b) Division Balance as of October 23, 2012: $32,754.89
   c) Filing with IRS in mid- November
   d) Jill Martin to schedule finance committee meeting for November prior to SPE deadline. All Board members are welcome to attend
      i) Work on budget for 2013:
         (1) $2,500 for Student Activities Fund at 2012 ANTEC
         (2) $1,000 for Best Student Paper Award at 2012 ANTEC
      ii) Decide on where to invest the ~$15K currently in the SPE Investment Fund. Current options yield < 2% interest.

3) Technical Program Committee –
   a) MD&M in Anaheim February 2013 – Jill Martin for Vipul Dave
      i) Committed for a full day
      ii) Deadline for papers October 31, 2012
      iii) Need 3 or 4 speakers
      iv) Jill to provide list of draft topics thus far submitted
      v) Try to cross functionalize with industries
      vi) Additional suggested topics:
         (1) "Processing of plastics for medical applications"
         (2) "Material Substitution"
         (3) "Process / surface Relationships"
         (4) Cross-functionalize with other industries
   b) ANTEC Report – Ed Fewkes:
      i) Received one paper draft as of 10-24-12
      ii) Difficulty getting access to papers on line (Thomas-Reuters)
      iii) Have reviewers in place
      iv) Paper draft submission deadline pushed out to November 28, 2012

i) Final paper submission due in for review by December 22, 2012
ii) Jim Oberhauser to assist Jill Martin in contacting Case Western for speakers
iii) Norris to compile topics to be provided by Board members for presentation to the Board
iv) Key note speaker (consider Case Western Jim Anderson, biomedical, imaging interface; check on Roger Marchand, CTR; Marko Costa) Potential topics:
(1) What is happening in the medical plastics market
(2) Regulatory activity
(3) Product design

2) Membership: - Jim Madenjian
a) Jim Madenjian to contact Sarah Sullinger for an updated list of MPD members.
b) Jim Madenjian, Jill Martin, and Sarah Sullinger to compare number of members listed with the number that run for the Board or are otherwise active

3) Travelling MiniTec - Jim Madenjian
a) No inquiries from any of the sections;
b) Dan to confirm interest of Piedmont Coastal & Carolinas sections
c) Midwest - nothing happened yet but will use newsletter to try to reach
d) Jim Madenjian to send write-up to all BOD so that they can be distributed to sections
e) Jill Martin to check with South Texas section
f) Jodie Laughlin and Glenn Beall to check with Chicago & Milwaukee sections

4) Communications
a) Newsletter – Norris Tollefson: 4th Quarter Newsletter is scheduled to go out before Thanksgiving. Looking for content
b) Jim Madenjian to send MiniTec information to Norris Tollefson
c) Website – Harrison Yu: Norris Tollefson and Jill Martin are to send Harrison information for the website

5) MPD Councilor report – Margie Hanna (reported November 12,2012)
SPE International Council Meeting was held September, 2012, Dearborn, MI
a) 2012 is SPE's 70th Anniversary
b) Officer Election results:

i)	President-elect:	Vijay Boolani
ii)	Senior Vice President:	Raed Al-Zu'bi
iii)	Vice President:	Dick Cameron
iv)	CCOW Chair:	Wayne Vander Zanden

c) Membership midyear was 14,883
d) EuroTec Barcelona cleared $65K
e) ANTEC ORLANDO cleared $195K
f) Upcoming:

1st ANTEC- Mumbai:	December 2012
ANTEC- Cincinnati:	April 2013
EUROTEC-Lyon:	July 2012

a) An ANTEC-style Conference is being discussed in Shanghai China for mid-November 2013. Member feedback and Division support is being sought
b) Headquarters continues improvements to our website. Upgrades to the system are expected to begin soon
c) Some errors in our Rebate System were detected. Over the last several years the wrong formula was used in assessing rebates. Council voted to ignore past errors in rebates and received assurance that Sections & Divisions will receive any the correct rebate funding due them in 2012. The financial transparency promised appears to be effect
d) Our next Council meeting, a teleconference meeting, will be December 5, 2012

2) SPE Liaison report – Sarah Sullinger
   a) Sarah Sullinger has taken over as liaison to the Sections, Divisions, & SIGs. Board members can contact Sarah via email, ssullinger@4spe.org, or by phone 203-740-5422
   b) Lauren McCarthy is no longer with SPE. Sue Wojnicki (swojnicki@4spe.org) and Barbara Spain (bspain@4spe.org) can answer any event related (ANTEC) questions we might have
   c) Elections for the upcoming leadership year (2013-2014) were held at the September 15 Council Meeting, results as follows:
      i) President-elect: Vijay Boolani
      ii) Senior Vice President: Raed Al-Zu'bi
      iii) Vice President: Dick Cameron (3-year term)
   d) HSM & Fellows applications are due by October 30, 2012
   e) Pinnacle and Communications Excellence applications are due by December 31, 2012

3) Unfinished business: none

4) New business: none

5) Board meeting was adjourned 12:56 (CT).
   Moved: Norris Tollefson, Second: Paul German; Carried

Submitted:
Dan Fuccella
MPD Board Secretary
November 14, 2012

TRENDS IN POLYMER MATERIALS FOR THE MEDICAL INDUSTRY AND A REVIEW OF EASTMAN TRITAN™ COPOLYESTER

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Abstract

There are a wide variety of polymers available for the medical industry including polypropylenes (PP), acrylics, styrenics, polycarbonates (PC), and copolyesters. Each polymer has its own unique set of benefits and deciding which polymer to use depends on ongoing and anticipated changes in the industry, cost, and fitness-for-use (FFU) requirements. In this presentation, we provide insight into factors driving industry changes and trends and the polymers emerging to meet those needs. Recently, Eastman Tritan™ copolyester was introduced into the medical market and has generated considerable interest due to the clarity, outstanding toughness and chemical resistance resulting from the unique chemistry of the polymer. The combination of properties, in addition to being BPA-free, makes Tritan™ well suited to meet these emerging trends in medical devices and packaging applications. In this paper we compare the transparency, heat resistance, sterilization, toughness, and chemical resistance of the variety of plastics in the context of the current trends and drivers in the medical industry. This information is intended to aid designers and engineers in selecting the appropriate polymer for their application.

Background

While numerous polymeric materials have been used in the medical industry for specific attributes; PP, acrylics, styrenics, PC and copolyesters are perhaps the materials most often used. If clarity and toughness are important PC has been traditionally preferred.

PC, however, is known to suffer from chemical attack under a variety of conditions. For example, stress cracking can occur in the hot and wet environment of an autoclave, upon exposure to chemicals such as pharmaceuticals, isopropyl alcohol (IPA), lipids, and disinfectants, or in applications where stress exists (for example, residual stresses from molding processes).

Eastman copolyesters have been used for a number of years in a variety of medical applications for their clarity, toughness and chemical resistance. However, the heat resistance of copolyesters has historically been limited, and exposure to elevated temperatures is not recommended due to thermal deformation. Eastman Chemical Company introduced Tritan™ copolyester in October 2007, and this product has improved heat resistance and processability resulting from a proprietary chemistry enabled by an elevated glass transition temperature (T_g). (1) The improved heat resistance in combination with the excellent chemical resistance allows the material to withstand the high temperature, caustic environment of a dishwasher. Taking advantage of the ability to be repeatedly dishwashed, other unique properties, and the BPA-free chemistry, Tritan™ has been rapidly adopted in the housewares market, water bottles and infant care products.

In February 2009 Tritan™ copolyester was introduced to the medical industry. Market adoption in medical has been for the same reasons as other markets - clarity, toughness and chemical resistance. In this paper we review the properties of Eastman Tritan™ copolyesters and discuss the properties in context of the major new trends in the medical industry driving polymer technology: 1) patient safety and comfort, 2) cost containment and 3) the emerging trend of sustainability. Note there is significant overlap in these three trends. For example, improving patient safety and comfort can reduce overall costs by lowering insurance claims. Physical properties of several classes of polymers, such as PP, styrenics, acrylics, PC and Tritan™ are compared. We conclude, based on the data discussed and the material requirements and needs in the industry, Tritan™ is an excellent choice for medical applications.

Discussion

Tritan™ vs. Other Medical Polymers

The three grades of Tritan™ used for medical devices are MX711 (standard grade), MX731 (high flow grade) and developmental grade K0890-487A (high T_g grade). An additional grade, Tritan™ MP100 is available for medical packaging. Table 1 lists some relevant properties for these materials. A comparison of the clarity (transmission and haze), heat deflection temperature (HDT), sterilization, toughness and chemical resistance (IPA and lipids) among the major classes of medical polymers vs. Tritan™ is shown in Tables 2 and 3.

Tritan™ provides excellent clarity and transparency with waterlike, neutral color. Haze levels are less than 1%, with transmission ranging between 90 and 92%. High transparency is extremely important for patient safety so that blood flow, medicine delivery, blood clots, air bubbles or debris can be detected. The only medical polymer listed that is not transparent is PP.

The HDT of MX711 is 85 °C at 1.82 MPa with a T_g of about 109 °C. The HDT of MX731 is 81 °C at 1.82 MPa with a T_g similar to MX711. For K0890-487A, the HDT is 109 °C at 1.82 MPa with a T_g about 118 °C. These values are comparable with most other polymers listed in Table 2. However, PC has the highest HDT which provides autoclavability under limited conditions due to reasons discussed earlier.

Sterilization by autoclave, radiation and ethylene oxide (EtO) gas is also clearly important for patient safety and comfort. PP can be repeatedly autoclaved, despite not having a high HDT but may suffer from odor and chain scission. Tritan™ is not autoclavable and will deform under high temperatures and pressures (> 121°C and 1000 mbar). Tritan™ is capable of radiation sterilization and EtO sterilization without loss in properties and with minimal color shift. Figure 1 shows the color shift measured using the CIELAB color scale (b*) and with photographs after 50 kGy of e-beam radiation for samples of Tritan™ MX711, gamma resistant PC, standard grade PC and acrylic. The CIELAB measurements and photographs clearly show that the color of Tritan™ shifts significantly less than PC. Less color shift can produce better aesthetics, increase patient comfort, and enables customers to ship products faster.

Tritan™ provides superior toughness. In tests of elongation to break and notched Izod impact toughness, Tritan™ shows desirable properties. These materials show no break notched Izod impact results not only at 3.175 mm (1/8") thickness, but at 6.35 mm (1/4") thickness as well. Elongation to break for the MX711 and MX731 grades are 210% while K0890-487A is 140%. These values (Izod and % elongation) are comparable to PC and much greater than styrenics, acrylics and PP, of which the latter are known to be brittle and have poor drop impact resistance. A tough polymer is essential to prevent cracking and breakage that can lead to device leaks, malfunction, and compromises in patient safety.

Tritan™ MP100 for medical packaging applications is also extremely tough as a thin extruded film (0.25 mm). The tear resistance and tensile strength are listed in Table 1. This extremely tough, durable material is designed for safer medical packaging. As a result, using Tritan™ MP100 can improve patient safety and comfort and reduce cost by protecting expensive devices, provide a better sterilization barrier and reduce company resources investigating part and packaging failures.

Table 3 compares the chemical resistance of several polymers after exposure to IPA and lipids. In these experiments, samples are exposed to the chemical for 24 h under 1.5% strain, and the impact energy (J) is then measured. The styrenics and acrylics have a combination of poor initial toughness and poor chemical resistance. Tritan™ MX711 and MX731, standard grade PC and PP have excellent property retention after chemical exposure. As we will discuss, the increase in hospital acquired infections (HAIs) has made chemical resistance more valuable than ever. Finally, note that the chemical resistance of Tritan MX731 (high flow) is better than high flow PC. The increasing trend towards reducing cost and creating a more sustainable story by using less material has driven device manufacturers to down gauge. As devices are down gauged and become thinner and more difficult to fill the mold, high flow polymers with excellent toughness will play a bigger role.

Applications where toughness and chemical resistance are not required but clarity is important may use an acrylic or styrenic. For applications where both toughness and clarity are not needed but chemical resistance is an issue, PP may meet the fitness for use requirements. Tritan™ copolyester and PC have an excellent balance of clarity, toughness and chemical resistance. However, to meet the chemical resistance requirements for aggressive chemicals used to combat hospital acquired infections (HAIs), Tritan™ is particularly well suited.

Hospital Acquired Infections (HAIs)

The Center for Disease Control (CDC) estimates that 8 – 10% of hospital patients become infected each year, resulting in an annual cost between 28 and 34 billion dollars. (2) In an effort to eliminate HAIs, improve patient safety and comfort, and reduce liability costs, hospitals have increased the use of aggressive disinfectants such as formaldehyde, IPA, quaternary amines, phenolics, and Virex TB™. These chemicals can repeatedly contact polymers used in medical devices and can cause stress cracking and subsequent part failure.

Evaluating if a polymer can safely contact these disinfectants is accomplished by chemical resistance testing. Using an impact test (Table 3), we previously showed that Tritan™ and PC are in a class by themselves with respect to toughness and chemical resistance. In another commonly used test, tensile bars are exposed to chemicals for 24 hours under constant strain and then evaluated by a tensile (stress-strain) test. The constant strain (and resulting stress) in combination with chemical attack can lead to crazing and cracking. Examples of these test results are shown in Figure 2 and 3 for PC and

Tritan™ after exposure to IPA and Virex TB™, respectively. The results from this test show that IPA and Virex TB™ can reduce the elongation to break of both PC and Tritan™. At higher strains, and during exposure to very aggressive chemicals, PC will tend to snap and break under strain prior to tensile testing. This is because crazes in PC will tend to rapidly grow into cracks. Copolyesters and Tritan™, in contrast to PC, will form stable crazes and no crack will form. The differences in craze stability can prevent device failure and compromises to patient safety.

Chemical resistance tests conducted in the lab after chemical exposure at fixed strain are an excellent screening tool for predicting how a chemical will interact with a polymer. However, one should conduct more definitive tests using actual molded articles because the results and conclusions based on these tests are sometimes different. The discrepancy between tests conducted on a lab scale tests compared to an actual molded articles can be attributed to design, different processing history, subsequent in-mold residual stress, the inherent residual stress in the polymer, as well as the state (tensile vs. compressive) of stress. Furthermore, there are often differences in polymer properties that should be considered. Examples of these are the initial toughness, whether the sample has underwent annealing, and sensitivity to wall thickness and notches. Acrylics, PP, styrenics have poor initial toughness. PC is well known to have high levels of residual stress and is often annealed. Tritan™, in contrast to PC, does not need annealing since it has low residual stresses. Due to the many factors that can affect the test results, it is important to test the actual molded article. Figures 4 and 5 show pictures of actual molded parts after exposure to either IPA or Virex TB™, respectively. In both cases, PC was observed to crack after exposure to the chemical disinfectant while Tritan™ did not. However, based on the tensile and impact chemical resistance data, the suitability of the polymer for the application was unclear.

Based on the chemical resistance tests using fixed strain experiments and actual molded articles, Tritan™ has both the toughness and chemical resistance needed to meet the fitness for use requirements of medical devices exposed to chemical disinfectants. The excellent chemical resistance enables hospitals to reduce HAIs by providing a safe environment for the patient and allows device manufacturers to cut energy cost by eliminating annealing.

Summary

Eastman Tritan™ copolyester is very clear, extremely tough and shows excellent chemical resistance to lipids, IPA and a variety of other aggressive chemical disinfectants. This combination of properties, in addition to being BPA-free, makes Tritan™ well suited to applications in contact with aggressive hospital disinfectants where device and packaging safety, as well as lower energy and materials cost are important. Overall, Tritan™ is suited to meet the medical industry's emerging material requirements driven by trends of improved patient safety and comfort, cost containment, and sustainability.

Acknowledgements

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References

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2. The Direct Medical Costs of Healthcare-Associated Infections in the U.S. Hospitals and the Benefits of Prevention, CDC, 2009.

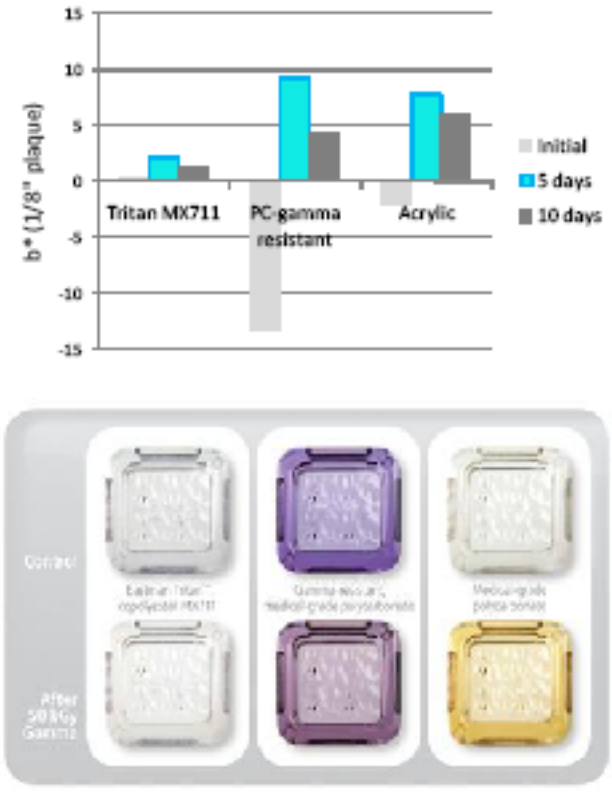

Figure 1. Color shift measured using CIELAB color (b*) and photography after 50 kGy of e-beam radiation for samples of Tritan™ MX711, gamma resistant PC and standard grade PC and acrylic. Positive and negative b* values correspond to a yellow and blue hue, respectively.

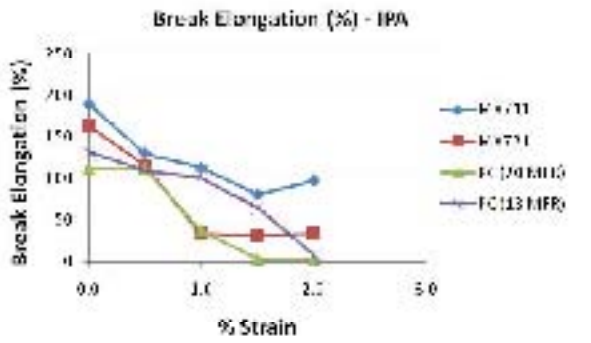

Figure 2. Chemical resistance data (% break elongation as a function of fixed strain) after exposure to isopropyl alcohol (24h) for Tritan™ and PC.

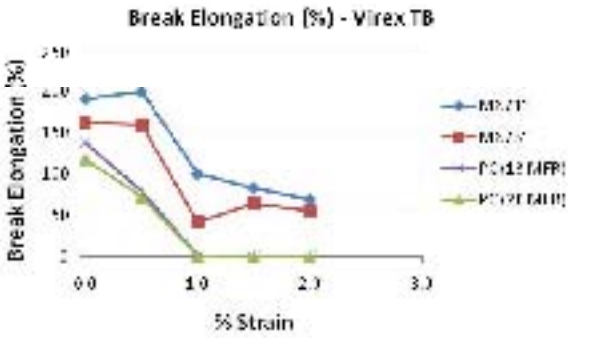

Figure 3. Chemical resistance data (% break elongation as a function of fixed strain) after exposure to Virex TB™ (24h) for Tritan™ and PC.

Figure 4. PC medical device after exposure to 24 hours of isopropyl alcohol. A large crack is visible in the circled area.

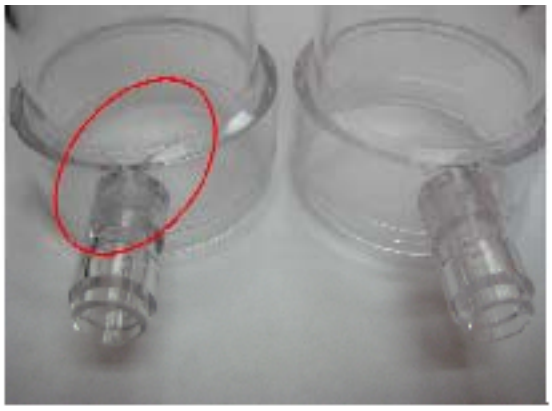

Figure 5. Dialyzer housings after exposure to Virex TB™. The PC housing on the left shows a significant crack (visible in the circled area) after 8 hours exposure. The Tritan™ housing on the right has not cracked after 120 hours exposure.

Table 1. Physical and mechanical properties of selected Eastman Tritan™ Copolyester resins. The three grades of Tritan™ used for medical devices are MX711 (standard grade), MX731 (high flow grade) and developmental grade K0890-487A (high Tg grade). An additional grade, Tritan™ MP100 is available for medical packaging.

Property	*Test Method*	*Tritan™ MX711*	*Tritan™ MX731*	*Tritan™ K0890-487A*	*Tritan™ MP100*
Mechanical Properties (Injection Molded)					
Mold Shrinkage (mm/mm)	D955	0.005-0.007	0.005-0.007	0.005-0.007	
Elongation @ Break, %	D638	210	210	140	
Flexural Modulus, MPa	D638	1550	1575	1585	
Izod Impact Strength, Notched	D256				
@ 23°C, J/m		980	860	650	
@ -40°C, J/m		110			
Izod Impact Strength, Unnotched	D4812				
@ 23°C, J/m		NB	NB	NB	
@ -40°C, J/m		NB			
Impact Resistance, @ Max Load	D3763				
@ 23°C, J		61			
@ -40°C, J		61			
Thermal Properties					
Heat Deflection Temperature	D648				
@ 0.455 MPa, °C		99	94	109	
@ 1.82 MPa, °C		85	81	92	
Optical Properties					
Haze, %	D1003	< 1	< 1	< 1	< 1
Total Transmittance, %	D1003	90	91	92	92
Mechanical Properties (Extruded Film 0.25 mm)					
Elmendorf Tear Resistance, N	D1922				
Machine Direction					5
Transverse Direction					5
PPT Tear Resistance, N	D2582				
Machine Direction					42
Transverse Direction					56
Tensile Strength @ Break, MPa	D882				
Machine Direction					59
Transverse Direction					52

NB = No Break

Table 2. General polymer properties for medical applications including Tritan™. Green highlighted cells indicate relatively good properties. Pink highlighted cells indicate relatively poor properties. For sterilization: Rad (radiation), Auto (autoclave), EtO (ethylene oxide). Values listed for styrenics and acrylics are for both standard and impact modified grades.

Polymer	Transmission (%)	Haze (%)	HDT (°C) 1.8 MPa	Sterilization	Toughness (J/cm)
Tritan MX711	90.1	0.42	85	Rad/EtO	9.8
Tritan MX731	90.6	0.45	81	Rad/EtO	8.6
Tritan K0890-487A	90.6	0.3	92	Rad/EtO	6.5
Copolyester (MN611)	91	0.3	65	Rad/EtO	8
PC - Standard	89.2	0.84	124	Limited Auto/ Rad/EtO	8.5
PC - High Flow	89.6	0.5	125	Limited Auto/ Rad/EtO	7.5
Polypropylene	77.9	68.4	85	Auto/ Limited Rad/EtO	0.6
Styrenic	89.2 - 92.1	0.62 - 4.51	70 - 96	Rad/EtO	0.1 - 0.7
Acrylic	92.5 - 93.7	0.54 - 2	90 - 94	Limited Rad/ EtO	0.2 - 0.6

Table 3. Chemical resistance data for selected polymers. Green highlighted cells indicate an excellent retention of properties. Yellow highlighted cells indicate a significant decrease in properties. Pink highlighted cells indicate a severe decrease in properties.

Polymer	% Retention in Impact Properties After Chemical Exposure	
	Lipids	IPA
Tritan MX711	87%	79%
Tritan MX731	90%	87%
Tritan K0890-487A	85%	32%
PC - Standard	92%	85%
PC - High Flow	53%	22%
Polypropylene	93%	94%
Styrenic	49 -89%	10 - 61%
Acrylic	61 - 77%	0 - 10 %