

Workshop at the FDA

“State of the Art in Biodegradable Metals - A Think-Tank Workshop”

March 30th 2012

U.S. Food and Drug Administration, FDA's White Oak Campus at
10903 New Hampshire Ave.
Silver Spring, MD 20993

The aim of the conference is to bring the current knowledge in this field especially Mg based systems through presentations by a select group of experts spanning academia, large industries, small entrepreneurial networks, and the FDA. A panel discussion will take place regarding current views on this emerging technology.

The proposed workshop will be ONE full day. The conference aims to summarize current literature through presentations by established world experts in the field. The speakers have been carefully selected and asked to use the published literature for their reviews.

Conference location: FDA's White Oak Campus, Conference Room 1503

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>

Conference Title: State of the Art in Biodegradable Metals

Organizer: Leon Esterowitz, National Science Foundation (NSF)
Frank Witte, MD, MHH, Hannover, Germany
Jag Sankar, NCA&T SU, NC
Steven Pollack, FDA
William Herman, FDA

Date: March 30th, 2012, Friday

08:00 – 08:15 **Opening Remarks** (Leon Esterowitz)

08:15 – 08:30 **Welcome from FDA** (Steven Pollack)

Moderator: Jag Sankar

08:30 – 09:00 Tentative Title: *In-vivo studies on Mg implants in musculoskeletal and cardiovascular applications: Current and past experiences.*

Speaker: Frank Witte, Hannover Medical School, Germany
witte.frank@mh-hannover.de

Topics to address: General concept of Biodegradable Metals
Mg implants has been used in humans already
Challenges of in-vivo and in-vitro testing (general)
Methods to measure corrosion in-vivo
Corrosion control in-vivo
Corrosion products and elemental distribution

09:00 – 09:15 Discussion

- 09:15 – 09:45 Tentative Title: ***Biodegradable Iron implants for cardiovascular applications - and outlook on musculoskeletal applications***
 Speaker: Diego Mantovani, Uni. Laval, Quebec, Canada
diego.Mantovani@gmn.ulaval.ca
 Topics: Idea of biodegradable stents, advantage of metals
 Production of pure iron stents and iron alloys
 Influence of microstructure
 Results of in-vitro and in-vivo studies
- 09:45 – 10:30 Discussion (Coffee available)
- 10:30 – 11:00 Tentative Title: ***Production of Mg alloys for biomedical purposes: the influence of microstructure and impurities on mechanical and corrosion properties***
 Speaker: Norbert Hort, Helmholtz Zentrum Geesthacht, Germany
norbert.hort@hzg.de
 Topics: Production routes for magnesium and its alloys
 Influence of production route on impurities and microstructure
 Designing biodegradable Mg alloys for specific implant purposes (examples, theory)
- 11:00 – 11:15 Discussion
- 11:15 – 11:45 Tentative Title: ***From material to device design with biodegradable metals***
 Speaker: William Wagner, University of Pittsburgh, PA, USA
wagnerwr@upmc.edu
 Topics: Alloy design and characterization
 Coatings and surface modification
 Sensors to evaluate biocompatibility
 Orthopedic, craniofacial and cardiopulmonary devices
- 11:45 – 12:00 Discussion
- 12:00 – 13:00 **Lunch and Discussion – Moderator William Wagner**
- 13:00 – 13:45 Tentative Title: ***Cytotoxicity and in-vitro test-systems for evaluation of biodegradable metals***
 Speaker: Frank Feyerabend, Helmholtz Zentrum Geesthacht, Germany
frank.feyerabend@hzg.de
 Topics: Challenges of in-vitro tests for biodegradable Mg
 How to modify existing ISO standards for cytotoxicity to test biodegradable metals
- 13:45 – 14:00 Discussion

- 14:00 - 17:00 **Moderators: Leon Esterowitz, William Herman**
- 14:00 – 14:20 Tentative Title: *Cardiovascular and orthopedic magnesium-based bioabsorption devices: Preclinical challenges*
Speaker: Louis-Georges Guy, Accel-Lab Inc., Canada
- 14:20 – 14:50 *Drug-eluting bioabsorbable magnesium stents. BIOTRONIK'S DREAMS Program*, Biotronik (Germany)
- 14:50 – 15:10 *Magnesium as a degradable implant material: In vivo experience at Synthes*, Synthes (Switzerland)
- 15:10 – 15:30 Discussion (*Coffee available*)
- 15:30 – 15:50 *In Vivo Evaluation of the Corrosion Rate, Corrosion Mode and Biocompatibility of Mg-Al Alloys in a Hemodynamic Environment*, Transluminal Technologie, LLC (US)
- 15:50 – 16:10 *Biodegradable pure magnesium bone implant*, E-ande (China)
- 16:10 – 16:25 *Resorbable Metals – From Concept to Implant*, Biomet (US)
- 16:25 – 16:40 *Development of biodegradable magnesium implants for traumatological applications*, aap Implantate AG (Germany)
- 16:40 – 16:55 *The ASM view on Biodegradable Metals - current and future activities*, Gary Mushock (ASM)
- 17:00 – 18:00 **Panel Discussion**
Moderators: Borovetz, Esterowitz and Herman

Participants

Conference Academic Speakers	Feyerabend, Hort, Mantovani, Wagner, Witte,
FDA representative (cardiovascular applications)	TBA
FDA representative (musculoskeletal applications)	TBA
Physicians	John White, MD Kenneth Trauner, MD

18:00 – 18:15 ***Wrap up and Farewell***