# Presentations posted for Battery-Powered Medical Devices Workshop: Challenges and Opportunities, July 30-31, 2013

U.S. Food & Drug Administration

Batteries play a significant role in the overall safety, performance, and reliability of many life-saving and life-sustaining medical devices. As more medical devices become computerized, compact, and mobile, the number of battery-powered medical devices will continue to increase. While many different components can potentially impact the safety and effectiveness of medical devices, the battery is one of the most critical components. Unexpected depletion or failure of the battery can cause the device to stop functioning properly, preventing the device from delivering life-sustaining or life-saving therapy. The Association for the Advancement of Medical Instrumentation (AAMI) has identified battery management as one of the top 10 challenges for hospital's biomedical departments.

While the FDA has confidence that medical devices currently being marketed will continue to function appropriately, there are opportunities to further improve their overall performance and safety. The FDA organized a Battery-Powered Medical Devices Workshop on July 30-31, 2013 to create awareness of the potential challenges related to battery-powered medical devices and to collaboratively develop ways of ensuring the continued performance and reliability of these devices. The participants included a broad group of stakeholders that are responsible for the design, testing, manufacturing, integration, regulation, selection, purchase, storage, maintenance, and use of batteries throughout the total product life cycle of battery-powered medical devices. The first day focused on the current and future challenges with batteries and battery-powered medical devices. The second day focused on the opportunities, potential solutions, and next steps. Both days included keynote and introductory presentations in the morning intended to encourage further discussion during the breakout sessions in the afternoon.

- Date, Time and Location [1]
- Webcast Archive [2]
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- Agenda [4]
- Registration [5]
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- Contact Us [7]

## Date, Time and Location

This meeting was held July 30 and 31, 2013, beginning at 8:00 a.m. at the following location:

**FDA White Oak Campus**
**10903 New Hampshire Avenue**
**Bldg. 31, Room 1503 (the Great Room)**
**Silver Spring, MD, 20993**

- Campus Information, Travel Information, and Directions [8]

## Webcast Archive

Day 1

- Morning session 1: Introductions and Keynotes [9]
- Morning session 2: Challenges [10]
- Webcast session 1: Panel discussion [11]
- Webcast session 2: Panel discussion [12]

Day 2

- Morning session 1: Keynote address and review of Day 1 webcast [13]
- Morning session 2: Opportunities [14]
- Webcast session 3: Panel discussion [15]
- Afternoon session: Future technologies and brainstorming presentations [16]

## Agenda

| | **Agenda-Day 1, July 30, 2013 Challenges** |
|---|---|
| 8:00-9:00 | Registration and Networking |
| | **Morning Presentations**<br>Moderator: Iacovos Kyprianou, Senior Science Health Advisor, CDRH, FDA |
| 9:00-9:15 | William Maisel, Deputy Center Director for Science, CDRH, FDA<br>Welcome and opening remarks |
| 9:15-9:35 | **Keynote Presentation**<br>RADM Nicole Lurie, USPHS, Assistant Secretary for Preparedness and Response, HHS<br>Responding to public health emergencies |
| 9:35-9:55 | Antoinette Hazlett, Surveys & Research, Medical Product Safety Network (MedSun), CDRH, FDA<br>MedSun Survey Results Overview |
| 9:55 -10:10 | Ken Skodacek, Co-Leader CDRH's Battery Working Group, CDRH, FDASetting the |

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| | Stage for Collaboration [17] |
| | **BREAK** |
| | **Challenges: Stakeholder Perspectives** |
| 10:20-10:30 | AAMI perspective, Alan Lipschultz, CEO, HealthCare Technology Consulting LLC [18] |
| 10:30-10:40 | Health Technology Management Perspective, David Marlow, Certified Biomedical Equipment Technician, University of Michigan Health System [19] |
| 10:40-10:50 | Challenges of a children's hospital, David Bradley, Director of Biomedical Engineering, Nationwide Children's [20] |
| 10:50-11:00 | Healthcare Provider Perspective, CDR Mike Krumlauf, USPHS, NIH Clinical Center [21] |
| 11:00-11:10 | ECRI Institute Perspective, Chris Lavanchy, Engineering Director, Health Devices Group, ECRI Institute [22] |
| 11:10-11:20 | FDA Perspective, Hamed Ghods, Engineer, Office of Science and Engineering Laboratories, CDRH, FDA [23] |
| 11:20-11:30 | Medical Device Manufacturer (Implantable), Michael Root, Scientist, Boston Scientific |
| 11:30-11:40 | DoD Challenges with Batteries in a Deployed Environment, MSG Curt Straub, US Army, USAMMA |
| 11:40-11:50 | Battery Manufacturer Perspective, Dominick Frustaci, VP of R&D, Greatbatch [24] |
| 11:50-12:00 | Transportation of Lithium batteries, Kevin Leary, International Transportation Specialist, Office of Hazardous Materials Safety, US Department of Transportation |
| 12:00-12:20 | Question and Answer Period / Panel Discussion<br>Panel: David Bradley, Dominick Frustaci, Hamed Ghods, Kevin Leary, Mike Krumlauf, Chris Lavanchy, Alan Lipschultz, David Marlow, Michael Root, Curt Straub |
| 12:20-12:30 | Brainstorming for Innovation, Andrew Grebe, Innovation Lab, U.S. Office of Personnel Management |
| | **LUNCH** |
| | **Afternoon Breakout Sessions for In-person and Online Participants** |

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| | What are the goals? What are the challenges? |
| 1:30-3:00 | Breakout Session 1 |
| | **BREAK** |
| 3:15-4: 45 | Breakout Session 2 |
| 4:45-5:00 | Closing Statement and Plans for Day 2 |
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| | **Agenda-Day 2, July 31, 2013 Opportunities** |
| 8:00-9:00 | Registration and Networking |
| | **Morning Presentations**<br>Moderator: Ken Skodacek, Co-Leader CDRH's Battery Working Group, FDA |
| 9:00-9:30 | Key Note Presentation, Cristin Dorgelo, Assistant Director of Grand Challenges, Office of Science and Technology Policy, Executive Office of the President Harnessing American Ingenuity through Open Innovation |
| 9:30-10:30 | Presentation and Discussion of Day 1 Brainstorming Sessions |
| | **BREAK** |
| 10:40-10:50 | Human Factors Considerations, Ron Kaye, Team Leader of Human Factors Evaluation Team, Office of Device Evaluation, CDRH, FDA [25] |
| 10:50-11:00 | Battery Standards, Rich Byczek, Global Technical Lead of Electric Vehicle & Energy Storage, Intertek |
| 11:00-11:10 | Battery Testing, Bruce Adams, VP of Sales, Cadex |
| 11:10-11:20 | Home Use Devices, Mary Weick-Brady, Senior Policy Advisor, Office of Center Director, CDRH, FDA [26] |
| 11:20-11:30 | Battery/Device integration and technologies that address patient challenges, Alex Fay, Business Development Manager, Quallion [27] |
| 11:30-11:40 | Requirements flow-down from device-to-battery and the related role of battery modeling, Craig Schmidt, Sr. Director Energy Systems, Medtronic [28] |
| 11:40-11:50 | Case for Quality & Critical to Quality, CAPT, Kim Lewandowski-Walker, USPHS, National Expert In Medical Devices, ORA, FDA [29] |
| 11:50-12:00 | Education: how can we make an impact, |

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| | Ron Charnock, CEO, KwikPoint [30] |
| 12:00-12:15 | Q/A and panel discussion<br>Panel: Bruce Adams, Mary Brady, Rich Byczek, Rich Constantineu, Ron Charnock, Alex Fay, Ron Kaye, Craig Schmidt, Kim Lewandowski Walker |
| | **LUNCH** |
| | **Afternoon Breakout Sessions for In-person and Online Participants**<br>What are the solutions? What are the next steps? |
| 1:15-2:45 | Breakout Session 3 |
| | **BREAK** |
| | **Afternoon Presentations**<br>Moderator: Charles Ho, Co-Leader CDRH's Battery Working Group, FDA |
| 3:15-3:30 | Highly Resonant Wireless Power Transfer being used to recharge implantable batteries and devices, Colin McCarthy, Product Marketing Specialist, WiTricity |
| 3:30-3:45 | Designing Battery Powered Medical Devices for public health emergencies, Philip Ferro, Director of Special Projects, office of Assistant Secretary of Preparedness and Response, HHS |
| 3:45-4:00 | Human Powered Medical Devices, Mike McAlpine, Assistant Professor, Princeton University |
| 4:00-4:45 | Presentation and Discussion of Day 2 Brainstorming Sessions [31] |
| 4:45-5:00 | Closing Statement and Next Steps |

**Breakout session details for in-person participants:**
The in-person participants were divided into 8 groups. The CDRH staff worked with the subject matter experts to facilitate the brainstorming sessions.

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| **CDRH Facilitators** | Laura Adam, Patrick Axtel, Kristen Bowsher, Carole Carey, Simon Choi, Dulciana Chan, Charles Ho, Alan Hoffman, Geetha Jayan, Ron Kaye, Alisson Kumar, Iacovos Kyprianou, Kim Lewandoski-Walker, Mimi Nguyen, Katie O'Calahan, Anindita Saha, Hilda Scharen, Pamela Scott, Jennifer Shih, Ken Skodacek, Pavel Takmakov, Victoria Wagman, Cisco Vicenti |
| **Subject matter experts** | Salil Balar (Aramark), David Bradley (Nationwide Childrens), Chaochao Chen (UMD), Ron Charnock (Kwikpoint), Alex Fay (Quallion), Dominic Frustaci |

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| | (Greatbatch), John Dumas (Hospira), CDR Mike Krumlauf USPHS (NIH), Chris Lavanchy (ECRI), Alan Lipschultz (AAMI), Mohan Misra (ITN), Joe Padilla (Interstate batteries), Michael Root (Boston Scientific), Tom Skowera (UL), William Sovitsky (USAMMA, PMMD), Like Xie (Palladium) |

**Breakout session details for webcast participants:**
During the in-person breakout sessions there was a panel discussion for the benefit of the webcast participants. On each day 5 panelists discussed challenges and opportunities and the webcast participants provided feedback or ask questions to the panel.

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| **Host/Facilitator** | Janesia Simmons (CDRH) |
| **Webcast Support staff** | Dharmesh Patel (CDRH), Sophie Wang (CDRH), Geri Smith (CDRH), Carol Krueger (CDRH), Amar Laheri (CDRH) |
| **Panelists Day 1** | Bruce Adams (Cadex), Kristen Bowsher (CDRH), Rich Constantineu (Anne Arrundel Health), Antoinette Hazlett (CDRH), Craig Schmidt (Medtronic) |
| **Panelists Day 2** | Shah Ashish (Greatbatch), Rich Byczek (INTERTEK), Hamed Ghods (CDRH), William McFarland (CDRH), Bhanu Sood (UMD) |

## Registration to Attend the Workshop

**Registration is closed as of July 19, 2013.**

There is no fee to register for the Workshop and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

## Public Comment

In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments is by 5 p.m. on August 30, 2013. Regardless of attendance at the meeting, interested persons may submit their comments regarding this workshop at http://www.regulations.gov/#!documentDetail; D=FDA-2013-N-0580-0001 [32] or to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.1061, Rockville, MD 20852.

**Workshop Details**

- Food and Beverages will be available for purchase during the breaks.
- Speakers' and Panelists' Biographies [33]

## Contact Us

If you require special accommodations due to a disability, or need additional information regarding registration, please contact Susan Monahan**,** Office of Communications and Education Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5661, FAX: 301-847-8142, susan.monahan@fda.hhs.gov [34].

For questions regarding workshop content, please contact Dr. Iacovos (Jake) Kyprianou, Center Science Council, Office of Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3609, Silver Spring, MD 20993-0002, 301-796-2601, CDRHbatteries@fda.hhs.gov [35].

**Source URL (retrieved on *08/20/2014 - 1:48am*):**
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**Links:**
[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date
[2] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#webcast
[3] http://www.gpo.gov/fdsys/pkg/FR-2013-06-05/html/2013-13244.htm
[4] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#agenda
[5] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#registration
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