Some Challenges Facing Medical Battery Manufacturers

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Greatbatch and Medical Batteries

- Greatbatch designs, develops, manufactures and provides batteries for implantable and portable medical devices:

<table>
<thead>
<tr>
<th>Applications</th>
<th>Type</th>
<th>Chemistry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td>Implantable</td>
<td>Li/I₂, LiQ₉R, LiCFₓ</td>
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<tr>
<td>ICD’s</td>
<td>Implantable</td>
<td>LiSVO, LiQ₉R</td>
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<tr>
<td>Neurostimulators</td>
<td>Implantable</td>
<td>LiQ₉R, Li-Ion</td>
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<td>AED’s</td>
<td>External</td>
<td>LiMnO₂</td>
</tr>
<tr>
<td>Orthopaedic Power Tools</td>
<td>External</td>
<td>LiFePO₄</td>
</tr>
<tr>
<td>Surgical Tools, X-ray, Ventilators, Monitors - Other</td>
<td>External</td>
<td>Li-Ion</td>
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Challenges in the Medical Space

- **Safety**
  - The persistent drive to reduce battery size, increase longevity and add device features continues to drive batteries with more power and energy in a smaller package, which inherently adds risk.

- **Innovation**
  - We need to balance the desire for better technology with the risk inherent in trying something new.

- **Reliability**
  - Implantable products have lifetimes of up to 10 years or more. We need to be able to reliably predict performance based on shorter-term testing along with a fundamental understanding of the technology.

- **Education**
  - In the Portable Medical Space the Clinicians/Technicians may not have sufficient technology specific training (e.g. Maintenance/SOC, Safety).
Challenges in the Medical Space

▪ Supply Chain
  - Many suppliers refuse to provide product for use in medical device applications due to concerns about litigation and the relatively small market opportunity.
  - In many cases, these suppliers are the largest companies with the best technologies and products.
  - Implantable medical batteries often have longer life cycles than the components used to produce them.

▪ Cost
  - Healthcare cost pressures influence manufacturers of components or commercially available power sources. These pressures can adversely affect quality and/or safety.
Challenges in the Medical Space

- **Change Management**
  - Incorporating improvements to existing products can be difficult due to the high level of resources, cost and time required to validate any change.

- **Specifications**
  - Power source specifications vary widely and may not adequately represent the actual field use or diversity of usage conditions.
    - Batteries need to be tested appropriately and in a manner that simulates usage conditions.
  - It is critical that sophisticated modeling tools be developed that have the ability to accurately predict battery performance.
    - This requires a strong understanding of the fundamental battery chemistry and availability of test data on the specific battery system.
Challenges in the Medical Space

- Regulatory

  - For implantable batteries, it is necessary to test a new battery technology for many years before it can be designed into devices. This results in slow adoption of new technologies.

  - Devices sold internationally must be submitted to multiple regulatory bodies which may have different requirements.

  - Many resources are devoted toward developing and validating sophisticated battery performance models which are intended to provide realistic performance predictions.

    - Proving the validity of these models prior to the availability of long-term test data can be a challenge.

    - Adoption of these models by the regulatory bodies in support of device submissions would help improve confidence and reliability as it is not practical to have long-term (>5 yrs), real-time test data available at time of submission.
Summary

There would be value in developing high level requirements that provide guidance relative to performance while allowing flexibility on how to demonstrate compliance to those requirements.

- Batteries and the end use applications vary substantially resulting in a myriad of potential combinations which dictate performance needs and consequently test methods.

- Specific test methods should be defined by considering the specific device/application requirements and the unique attributes of the battery system.
What is the greatest area of need as it relates to Medical Batteries?

A. Education - Performance and Use Characteristics
B. Improvements in Reliability
C. Improved Safety
D. Availability of Performance Standards
E. Other

Online Results

A: 25%
B: 32%
C: 11%
D: 24%
E: 8%

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