



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:

Applications	Type	Chemistry
Pacemakers	Implantable	Li/I ₂ , LiQ _{MR} , LiCFx
ICD's	Implantable	LiSVO, LiQ _{HR}
Neurostimulators	Implantable	LiQ _{MR} , Li-Ion
AED's	External	LiMnO ₂
Orthopaedic Power Tools	External	LiFePO ₄
Surgical Tools, X-ray, Ventilators, Monitors - Other	External	Li-Ion

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

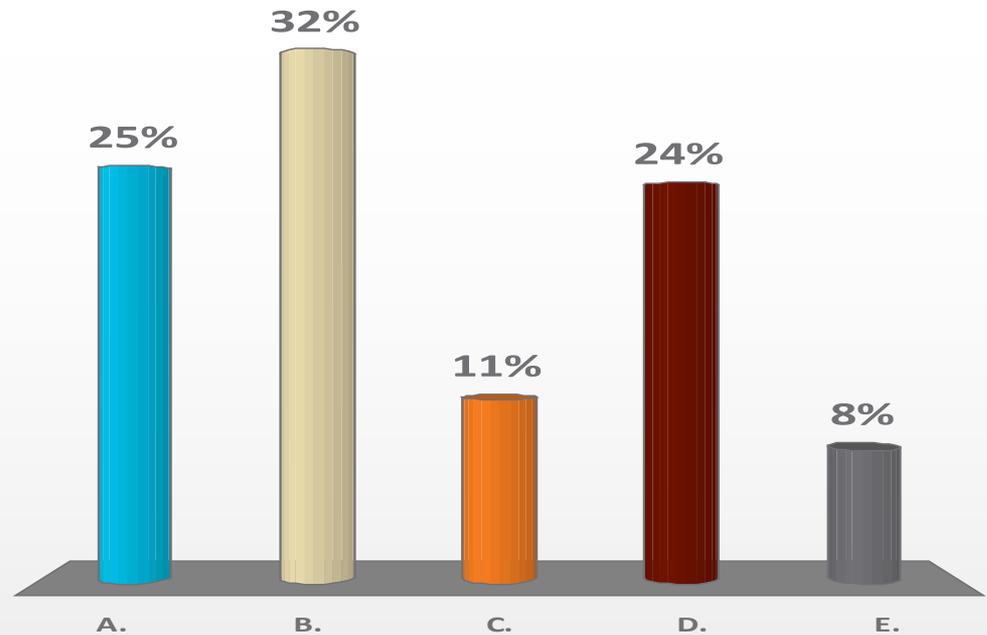
- For implantable batteries, it is necessary to test a new battery technology for many years before it can be designed into devices. This results in slow adoption of new technologies.
- Devices sold internationally must be submitted to multiple regulatory bodies which may have different requirements.
- 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

