

BATTERY SAFETY FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)



HOW SAFE ARE THE BATTERIES IN YOUR ENDS PRODUCTS?

What use (or misuse) conditions could lead to battery rupture, overheating or a “rapid thermal event”? Does your device meet Food and Drug Administration (FDA) draft guidance for battery safety?

Battery safety is a growing concern among e-cigarette and vape consumers and regulators. Under certain conditions, the lithium-ion (Li-Ion) batteries used in most ENDS devices can overheat, rupture or explode. This puts users at risk for severe burns, eye damage or other injuries and exposes the ENDS suppliers or manufacturers to liability risks. Whatever the cause, a battery fire or explosion can have significant financial and legal repercussions—and a long-term impact on your brand reputation and market share.

As a result of reported battery failures leading to consumer injuries, the FDA is moving toward tighter standards for ENDS battery safety that many manufacturers are not currently prepared to meet. Battery safety concerns have also drawn the attention of the Federal Aviation Administration and other agencies, which could limit the ways and places these devices can be used, stored and transported.

At Battelle, we're battery experts. We have decades of experience in addressing battery safety issues for highly regulated medical devices, electric vehicles and other applications where safety is critical. We can help you select the right battery for your device, build battery-protective features into your device design and prepare for emerging ENDS battery safety regulations.

ENDS BATTERY DESIGN AND SAFETY REVIEW

Batteries in ENDS can fail for a number of reasons, including:

- Internal problems within the battery itself
- Device design choices that result in damage to the battery
- Unanticipated user behaviors or environmental conditions

We can help you understand and evaluate all of the potential battery safety hazards related to your ENDS device at the battery, pack, charger and full system levels. Our battery safety experts will:

- Evaluate your device against FDA draft guidelines for ENDS battery safety
- Determine the most likely internal and external causes of battery failure
- Assign a severity ranking to each cause
- Recommend solutions to reduce the risks of an adverse event

195 ENDS battery explosions were reported between 2009 and 2016, resulting in 133 acute injuries.

Battery Safety Solutions across the Product Lifecycle

- Battery selection and testing
- Battery system design and engineering
- Battery manufacturing requirements and specifications
- Quality assurance planning
- Safety testing for ENDS products
- Instructions-for-use development
- Post-market surveillance planning



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OUR APPROACH

Failure Modes and Effects Criticality Analysis (FMECA) is a systematic approach used to evaluate battery hazards and their effects at multiple levels. Our analysis results in a comprehensive report that identifies modes of failure, fire hazards, toxicity concerns, material incompatibilities, risk mitigation strategies and data gaps.

We evaluate failure mechanisms at both the battery level and pack/system level under both normal and extreme environment and use conditions. This allows us to answer critical questions such as:

- Are the battery specifications appropriate for anticipated environment and use conditions (including likely misuse conditions)?
- How does the design of the battery system in the device impact battery safety and performance?
- What are the likely sources of damage to the battery?
- How can the battery fail as a result of this damage?
- What environment and use conditions trigger battery failures?
- How well do current design safeguards protect the battery under normal use and foreseeable misuse conditions during operation, charging, storage and transportation?
- What additional design safeguards could be put in place to reduce the risk of battery failure, heating or rupture?

OUR EXPERTS, AT YOUR SERVICE

Battelle brings together a unique blend of experience in batteries, material science, device and systems engineering, and human centric design. We have decades of experience working with the medical device industry to resolve battery safety and system design issues in a highly regulated environment. We can help you navigate emerging FDA guidance and regulations for ENDS products and apply lessons learned in other industries to help you improve the safety of your devices.

In addition to our work on device batteries, Battelle has a long history of research on tobacco and nicotine products, including e-cigarettes and vaping devices. We understand the regulatory environment for ENDS products and bring deep insights into user behaviors and how device design impacts these behaviors.

We can put together an ENDS battery safety program tailored to your needs.

Contact us today for your electronic nicotine delivery system battery safety evaluation.

Internal Failure Modes

- Particle
- Dendrites
- Separator Failure

External Failure Modes

- Cell Overcharge
- Cell Over-Discharge
- Mechanical Stress
- External Short Circuit
- External Heating
- Impact
- Puncture
- Improper Isolation

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org.

800.201.2011 | solutions@battelle.org | www.battelle.org

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