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2026 Medical Device Compliance & Certification Summit

February 2-4, 2026 | Carlsbad Inn Beach Resort

Seminar Agenda

Day 1 – Global Frameworks, IEC 60601 Series

08:30 – 09:00 **CHECK-IN & COFFEE**

09:00 – 09:15 **Welcome & Objectives**

Grant Schmidbauer, Nemko

- Overview of 2-day education program and key outcomes:
  - Navigating 60601 series, global approvals and frameworks
- Introduction of optional Day 3
  - Hands-on workshops

09:15 – 10:00 **Regulatory Landscapes: U.S., Canada, and EU**

Grant Schmidbauer, Nemko

- Understanding Regulatory Landscapes: USA, Canada, EU
- Fundamentals of the EU/MDR, USA/FDA and Canada/HC
- Technical Documents, and key differences
- Safety Agency marks (NRTL, CB, CE): what each really means

10:00 – 11:30 **Future Impacts of IEC 60601-1 4th ed**

Leo Eisner, Eisner Safety Consultants

- What devices fall under IEC 60601-1 now and future
- Understanding the current vs future 60601 structure
  - General standard
  - Collateral standards
  - Particular standards
- IEC 60601-1 4th Edition development
  - Transition timelines & impact on certified devices
  - New framework considerations
  - Design Impacts today

11:30 – 12:00 **Essential Performance**

Bill Hardin, Eisner Safety Consultants

- Particular standards based essential performance
- Risk-based essential performance approach (ISO 14971 integration)
- FDA view of Essential performance

12:00 – 13:00 **LUNCH & NETWORKING**

13:00 – 14:00 **Risk Management & Collateral Standards**

Bill Hardin, Eisner Safety Consultants

- IEC 60601-1-2: EMC - 2020 version vs future requirements
- IEC 60601-1-6: Usability
- IEC 60601-1-8: Alarms
- IEC 60601-1-11: Home healthcare & higher RF Immunity expectations
- IEC 62304 Software Lifecycle Process
  - Safety Classification of Software A, B, C or Rigor Level I, II
  - Firmware vs Software

14:00 – 15:00 **Making Standards Your Competitive Advantage - Reduce Design Cycle & Time to Market**

Leo Eisner, Eisner Safety Consultants

- When and where to Identify Standards in Design Control Process
- Proper Selection of Standards
  - Process to Identify Standards
  - Example Product – Discussion

15:00 – 15:15 **BREAK & COFFEE**

15:15 – 16:15 **EMC Compliance for Medical Devices**

Bill Hardin, Eisner Safety Consultants

- Pre-compliance strategies to reduce test failures
- Global EMC deviations by region
- FDA 2022 EMC FDA guidance implications
- IEC TS 60601-4-2 implications
- New CISPR 11:2025 requirements

16:15 – 17:00 **Roundtable Q&A**

- Open roundtable with the ‘experts’ to respond to all and any questions from the floor

Day 2 — EMC/RF, Cybersecurity, Future Standards & IVD/Lab

08:30 – 09:00 **CHECK-IN & COFFEE**

09:00 – 10:00 **RF Compliance for Medical Devices**

James Cunningham, Nemko

- Wireless coexistence per FDA guidance
  - IEEE/ANSI C63.27
  - AAMI TIR 69
- SAR testing for human exposure per FCC regulations
- MRI compatibility and labeling per FDA guidance
  - ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
- Global Market Access considerations for wireless medical devices

10:00 – 11:00 **Cybersecurity for Medical Devices (FDA & EU MDR)**

Bryan Heenan, Nemko

- FDA cybersecurity guidance expectations
- IEC 81001-1 / IEC 81001-5-1 / UL 2900-2-1 / ISO 27001 / HIPAA
- SBOM, vulnerability controls & patching
- Penetration testing, vulnerability & security requirements

11:00 – 11:15 **BREAK & COFFEE**

11:15 – 12:00 **Beyond 60601 – IVD & Lab Equipment**

Bill Hardin, Eisner Safety Consultants

- When a device falls under IEC 61010 instead of 60601
- Differences in approach & evaluation
- IEC 61326-2-6 (2025) for IVD EMC requirements
- IEC 61326-1:2000 issues to be aware of
- Industrial lab equipment EMC standards

12:00 – 13:00 **LUNCH & NETWORKING**

13:00 – 14:00 **Evaluation, Testing & Certification**

Liem Lam, Nemko

- Testing is structured: safety, EMC, software, usability
- IEC 60601-1 evaluation process: samples, inspections, documentation
- Certification path & how to avoid delays
- Common pitfalls that cause test failures or report re-work
- ASCA-Recognized Testing and Why It Matters

14:00 – 15:00 **Understanding FDA Submissions for Medical Devices**

Beky Pine, Eisner Safety Consultants

- Device Classification & Submission Routes
- What the FDA Looks for in a Submission
- Content of a High-Quality 510(k) Submission
- ASCA-Recognized Testing and Why It Matters
- Common Submission Mistakes

15:00 – 15:15 **BREAK & COFFEE**

15:15 – 16:15 **Medical Device Regulation (MDR) Requirements**

Beky Pine, Eisner Safety Consultants

- How MDR classification differs from FDA classification
- Roles of manufacturers, authorized representatives, importers, distributors
- When a Notified Body is required vs. self-declaration
- Technical Documentation Requirements (safety, EMC, radio, cyber, AI)

16:15 – 17:00 **Roundtable Q&A**

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Day 3 — Optional: Hands-On Workshops

08:30 – 09:00 **CHECK-IN & COFFEE**

09:00 – 10:15 **Build a 60601-1-2 EMC Test Plan**

Bill Hardin, Eisner Safety Consultants

- Define test samples and worst-case configurations
- Create a sample test matrix (safety + EMC + wireless)
- Select environmental conditions, operating modes & accessories
- Write correct wording for Essential Performance
- Output: Attendees walk away with a real test plan template

10:15 – 10:30 **BREAK & COFFEE**

10:30 – 12:00 **Risk Management & Essential Performance Traceability**

Bill Hardin, Eisner Safety Consultants

- Build the traceability matrix: hazards → controls → tests → results
- Update risk controls for EMC, usability, cybersecurity
- Output: A complete traceability table you can reuse

12:00 – 13:00 **LUNCH & NETWORKING**

13:00 – 14:30 **EMC/RF Failure Analysis Case**

James Cunningham, Nemko

- Review actual EMC failures:
  - ESD resets
  - Radiated immunity disruptions
  - RF packet loss
- What redesigns fixed the problems
- How to adjust your risk file & mitigation claims
- Output: Troubleshooting checklist + “design for EMC success” notes

14:30 – 14:45 **BREAK & COFFEE**

14:45 – 16:00 **Cybersecurity File Sprint**

Bryan Heenan, Nemko

- Build a threat model for a wireless medical device
- Draft an SBOM
- Document vulnerability management & patch plan
- Create a Cybersecurity Evidence Table for FDA/MDR
- Output: Starter cybersecurity file to insert into a submission

16:00 – 16:30 **Roundtable Q&A**

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