

JAMES FAIR

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Senior Regulatory Compliance Engineer

Experienced Regulatory/Compliance Engineering Project Manager in Medical, Information Technology, Consumer Appliances, Telecom Products, VSAT Satellite Communications and Lighting industries. Over twenty-six years of engineering proficiency in designing products that conforms to the requirements of applicable Regulatory, Safety, EMC, RF (VSAT) and Environmental standards. Knowledgeable in all aspects of electronics engineering research and development processes. I possess an expert standards knowledge base and proficiency in interpretation and application of standards. Possess excellent verbal & written communication skills, documentation and project management skills using Microsoft Office Suite, MS Project and Confluence.

- Product Safety
- EMC & Wireless Compliance
- Project Management
- CB Scheme, CE/UKCA Marking
- International Homologation
- Quality Management System
- Medical Device Compliance
- Medical Risk Management
- Usability
- Flammability
- Biocompatibility
- Environmental Standards
- Satellite Communications
- Telecommunication Systems
- Energy Management Systems
- NEBS (Network Equipment)
- Fluorescent Lighting Ballasts
- LED Signs and Drivers

REGULATORY/COMPLIANCE STANDARDS AND KNOWLEDGE BASE

Management	Provided project management and planning for agency compliance. Conducted product design and status reviews. Provided project status reports to management. Developed documentation management processes. Provided standards training to NPD teams. Performed Pre-compliance EMC & safety testing. Coordinated laboratory setup for UL CDTP. Maintained continuing product compliance program. Agency liaison for outside laboratory project management. Assisted NRTL and CRTL representatives during agency audits. Coordinated and managed agency production line testing.
Medical	MDD 93/42/EEC, IEC/EN 60601-1 and Collateral Standards, ANSI/AAMI ES60601-1. Technical File Maintenance. CE Marking Process. Risk Management. UDI Labeling. Particular Standards: IEC/EN 60601-2-38, IEC/EN 60601-2-52, IEC/EN 80601-2-35. Quality Management System (QMS): 21 CFR 820, ISO13485, ISO9001, ISO14971. Usability and Human Factors: IEC/EN 60601-1-6, IEC/EN 62366, HFE75. Biocompatibility: ISO 10993-1, ISO 10993-5 and ISO 10993-10. Flammability: 16CFR1633, 16CFR1632, BFD IX-11, CAL TB-117. Scales: NAWI, OIML. X-Ray: IEC/EN 60601-2-32 and 2-54. Nurse Call: UL1069.
EMC	Evaluate PCB layout and systems for EMC compliance. Provided ESD Design practices to CAD. The EMC Directive (2014/30/EU), EN 55032, EN 55035, IEC/EN 61000 series; FCC CFR47 Parts (15, 18 and 25), Canada ICES-003, Bellcore GR-1089-CORE, CISPR 11, 15 & 22. Wireless: RED Directive 2014/53/EU, FCC CFR47 Part 15 Subpart E, IEEE 802.11n(Wi-Fi), FCC CFR47 Part 25. ETSI EN Satellite RF Standards : 301-428, 301-443, 301-360, 301-459.
Safety	The LVD Directive 2014/35/EU, IEC/EN/UL 62368, ISO17025, IEC/EN 61010, IEC/EN 60335. UL Client Data Submittal Program. Safety evaluation of schematic and PCB artwork to maintain spacing. Transformer analysis. Component selection for medical devices. Risk Analysis.
Telecom	Coordinated the design of NEBS-compliant equipment. Performed thermal analysis, fire resistance design and testing. Familiar with outside plant, central office systems, customer premises equipment, DC power systems, system grounding and bonding. Regulatory: R&TTE Directive, ETSI Standards, FCC CFR47 Part 68, Industry Canada CS-03. NEBS: GR-1089-CORE, GR-63-CORE Fire Resistance, Verizon Specifications. Protocols: XDSL, FITL, OC-3, T1, E1, ISDN, V.34, DDS, LADC, WiFi, KU and KA Band.
Environmental	RoHS2 Directive 2011/65/EU, EN 50581, WEEE Directive 2012/19/EU, REACH EC 1907/2006.
Lighting	UL935, UL916, UL1958, UL8750, UL879, UL1012, UL1310, UL746C, UL Classified, NEMA IP.
Programming	C Programming, MS Basic, HTML Web Design, Visual Basic 3, Fortran IV.

PROFESSIONAL EXPERIENCE**ST ENGINEERING IDIRECT:** Herndon, VA.**2019 - Present****Senior Regulatory Compliance Engineer**

- Work closely with cross-functional teams in areas such as EMC/EMI, RF and Homologation to ensure that the products are designed and evaluated to meet Product Line Management requirements worldwide.
- Communicate changes in worldwide EMC/EMI, RF, VSAT, Product Safety and environmental standards to cross-functional teams.
- Provided Regulatory Compliance planning and design expertise in the product development design phase.
- Performed pre-compliance EMC, RF, VSAT and safety testing.
- Create technical documents to support testing and certification activities at accredited laboratories.
- Interact with worldwide regulatory agencies to complete the approval process.
- Manage and track certification schedules to support global sales efforts.

PHILIPS RESPIRONICS: New Kensington, PA.**2018-2019****Senior Compliance Engineer**

- Provided agency compliance planning for New Product Development and Sustaining Engineering projects.
- Created compliance plans for emerging regulations and changing standards for potential impacts to products.
- Completed preliminary design reviews and develop test plans to comply with product safety, IEC 60601-1 Collateral & Particular standards.
- Act as a liaison with external compliance testing & certification suppliers and regulatory bodies (Intertek).

HUGHES NETWORK SYSTEMS, LLC (Contract through SYNERGY SOLUTIONS): Germantown, MD.**2014 - 2017****Compliance Engineer**

- Provided agency compliance planning for New Product Development and Sustaining Engineering projects.
- Obtained test reports as proof of conformance to European Union Directives for LVD, EMC, RoHS and Radio.
- Managed conformance to IEC 60950, EN 55032, EN 55024, EN 50581, FCC Part 15 and 25 requirements.
- Functioned as a liaison to the following agencies: Underwriters Laboratories; TUV of North America; MET Laboratories (Eurofins); Washington Laboratories; SGS North America and F2 Laboratories.

FAIR CONSULTING DBA (Contracts with DEVICE APPROVALS COMPANY, INC.): Austin, TX.**2010 - 2015****Regulatory Consultant**

- Performed Quality Management System (FDA 21 CFR 820) documentation updates for resolution to FDA Form 483 letter. Prepared ISO 17025 Quality Management System procedures for a test laboratory.

HILL-ROM, INC.: Batesville, IN.**2010 - 2014****Advanced Codes and Standards (C&S) Engineer**

- Provided assessments and compliance planning for New Product Development projects and sustaining engineering departments.
- Applied design expertise for IEC 60601-1 3rd Edition, ANSI/AAMI ES60601-1 and IEC 60601-2-52 standards.
- Developed Verification Plans and assist Test Engineering with creating and performing compliance tests.
- Functioned as a primary contact for outside certification agencies (UL, ETL, NMI) and code authorities (AHJ's).
- Held and maintained certifying agency reports and files (CB, NRTL, OMIL, EMC, and Clinical Reports).
- Created and maintained the Technical Files for CE marking (European MDD).
- Maintained knowledge of standard changes and communicated information to the appropriate parties.
- Accomplished Member of the Change Request/Change Order Committee as the C&S Representative.
- Performed Product Risk Analysis and Regulatory Risk Assessments documentation (ISO 14971).
- Reviewed and completed test report files for Usability and Human Factors: IEC62366, IEC60601-1-6.
- Reviewed Biocompatibility documentation and reports for CE Marking technical file.
- Developed and maintained a Codes & Standards Department web page.

UNIVERSAL LIGHTING TECHNOLOGIES, INC.: Round Rock, TX.

2007 – 2010

Regulatory Engineer

- Duties included providing compliance engineering expertise for design, production, NRTL agency submittals of electronic fluorescent ballasts, lighting energy management equipment and LED products.
- Managed over 120 fluorescent ballast product safety UL submittals under UL935 and UL916 to achieve NofA.
- Provided design consulting and submittals to UL for LED products under UL8750, UL879, UL1012, and UL1310 to comply with all regulatory and customer requirements.

DELL, INC.: Austin, TX.

2005 – 2007

Regulatory Software and Peripherals (S&P) Product Safety Engineer

- Supervised and coordinated the development of the S&P Product Safety Program. Provided guidance to Dell design teams and OEM partners with issue resolution during the review and testing of new products by various regulatory agencies. Produced MS PowerPoint presentations, Project Management status updates and set the agenda for the bi-weekly Regulatory S&P Core Team Meetings with marketing stakeholders.
- Reviewed proof of safety compliance and performed risk analysis to assure conformance with all applicable standards, covering 4000 products of manufacturers seeking qualification for sale on the Dell website.
- Collaborated with the Dell legal department in performing analysis of new products and technologies. Prepared statements and offered recommendations to vendors for acquiring documentation of regulatory compliance.
- Produced and administered Regulatory Department Consumer Electronics and Product Regulatory Compliance website to effectively communicate required data to internal teams.
- Developed compliance training materials for power, educational and medical products in order to adequately train staff on all regulatory requirements.

EDUCATION

BS Engineering Management Technology: Grantham University; Lenexa, Kansas (Summa Cum Laude, 3.97 GPA).

AS Electronics and Computer Engineering Technology: Grantham University; Lenexa, Kansas (4.0 GPA).

EIP (Entertainment Industry Promotion): Art Institute of Fort Lauderdale; Fort Lauderdale, Florida (4.0 GPA).

BSEET; Electronics Engineering Technology: DeVry Institute of Technology; Chicago, Illinois (Incomplete).