Laura Elan, P.E., RAC

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EXPERIENCE

CSA Group, Redmond, Washington **2018 - Present**

Senior Manager – Cybersecurity

Innovation and Emerging Technologies, *February 2018 - Present*

Global Business Lead for CSA Group Cybersecurity regulatory and testing services for Healthcare, Industrial Controls, Home and Commercial business teams

- Cybersecurity thought leader for NA Medical Regulatory activities, including the Health Canada Scientific Advisory Committee for Digital Health Technologies and FDA CYMSAB Table Top Exercises for Cybersecurity Response.
- Achieved 3X year over year growth by expanding service portfolio with market relevant services, easy-to-use sales collateral and key customer engagement strategies
- Added ISO 17025, ISO 17065, and IECEE accredited programs to service portfolio, strengthening value proposition for cybersecurity services with key market segments.

UL LLC, Northbrook, Illinois **2012 – 2018**

Practice Lead – Digital Health & Cybersecurity Business

Engineering and Program Manager, Health Sciences, *January 2012 - Present*

Global Program Management for Digital Health and Cybersecurity regulatory and testing services.

- Global Service Leader for Digital Health / eHealth business expanding the presence and business growth for UL's Life & Health Science division and achieving initial and double digit year-over-year revenue stream growth.
- Achieved global operational competency in software validation, cybersecurity and interoperability through training and mentoring of engineering staff.
- Lead Reviewer and Subject Matter Expert for Medical Device Software and Usability standards (IEC 60601-1, IEC 62304, IEC 62366). Developed and trained global organization in software and usability conformity assessment requirements

VALIDANT, San Francisco, California **2011 - 2012**

Health Sciences Consultant, *July 2011 to January 2012*

Leadership consultant for Medical Device Industry, specializing in 2nd and 3rd Edition IEC 60601, International, and FDA compliance leadership programs

- Fast paced ramp up to initiate and lead remediation efforts for flagship medical device in Class 3 Medical Device company
- Leadership of work stream for transition current product line from 2nd Edition to 3rd Edition of IEC 60601 for US and International Markets
- Assured continued US and international regulatory compliance of flagship product line through technical file development & remediation for IEC 2nd Edition 60601-1, including IEC 60601-1-8, IEC 60601-1-6 and IEC 62304 harmonized standards.

Tegrant Corporation, Alloyd Brands, DeKalb, IL **2010 - 2011**

Vice President of Engineering and Tooling Operations, *November 2010 to May 2011*

Responsible for customer facing engineering, project management, and tooling and machinery fabrication team for $300M consumer and medical packaging solutions business.

- Established formal innovation team to commercialize new sustainable packaging platform fully integrating company design, packaging, and sealing machine competencies.

- Crafted a strategic material technology team that partnered with Marketing and Business Development to enhance internal capabilities
- Leveraged Lean Daily Management and Value Stream mapping in front end process to identify and remove D

Sloan Valve Company, Franklin Park, Illinois **2010**

Director, New Product Management, *January 2010 to November 2010*

Leader of cross functional technical and business team responsible for new product commercialization and product development process improvement for corporate and distributed new product development teams.

- Introduced best practice tools to the organization including Design for Six Sigma (DFSS), Advanced Product Quality Planning (APQP), and next generation product development subject matter.
- Improved product development communication and organizational clarity using formal and informal methods.
- Hired and developed corporate engineering and product management professionals with focus on 5% increase in new product revenue contribution by end of current year.

Baxter Healthcare, Round Lake, Illinois **2007 - 2009**

Program Director, R & D, *March 2007 to November 2009*

Technical and business leader for combination drug/medical device and client commercialization support with development activities including mechanical engineering, materials selection, manufacturing, FDA regulatory compliance.

- Team leadership and support for Baxter Top Project, a combination drug-device delivery system. Advanced platform through development completion into tech transfer and commercialization.
- Achieved successful FDA Pre-approval inspection for first-to-market drug in innovative platform and supply chain offering.
- Shared leadership in platform development, including organizational redesign to identify staffing allocations, strategic skills requirements and achievement of optimal staff ratios.
- Leadership support of innovation pipeline through market research initiation, VOC participation, and project selection.

Shure Incorporated, Niles, Illinois **2000 –2007**

Director of Engineering, *February 2006 to March 2007*

Leader of development engineering organization supporting all research, product development, life-cycle management and corporate project initiatives. Organization includes electrical & electronic design, application software development, electro-acoustic (transducer) development, mechanical engineering, wireless (RF) design. Established process to decrease resource assignment churn through integrated portfolio management.

Program Director, Personal Audio, *January 2004 to February 2006*

Responsible for planning and execution of consumer product development roadmap and lifecycle management of existing consumer product catalog through collaboration with product and technology management groups.

Director, New Product Management, *November 2003 to January 2004*

Responsible for planning and execution of corporate product roadmap through collaboration with Product and Technology Management groups.

Director, Software & Signal Processing Systems, *April 2002 to November 2003*

Responsible for software development and processes for all product development software implementation, including user interface development, embedded control, and digital signal processing software development. Established baseline software development processes which achieved successful ISO 9000 – 2000 certification.

EDUCATION

Master of Science, Computer Science, Illinois Institute of Technology, Chicago Illinois, Expected 2020, *Specialization in Cybersecurity*

Master of Science, Electrical Engineering, Illinois Institute of Technology, Chicago Illinois, 1997, *Academic Distinction*

Bachelor of Science, Electrical Engineering, University of Illinois, Champaign Illinois, 1986

CERTIFICATIONS & ORGANIZATIONS

Licensed Professional Engineer, State of Illinois
Green Belt Certification, UL University, 2013
Baxter Healthcare Project Management Professional Certification (Baxter PMP) 2009
Graduate Leadership Development Program, Center for Creative Leadership, 2006
Regulatory Affairs Certification (RAC), *Regulatory Affairs Professionals Society (RAPS) Member, 2016 - 2017*