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## SUMMARY

*Experienced labeling compliance leader, engineering team manager, and project manager acknowledged for leadership, delivery, creativity, and high technical and ethical standards in both compliance and process development. Expertise includes:*

- Medical Device Labeling Compliance Gap Analysis
- Medical Device QMS Development & Maintenance
- Labeling Subject Matter Expert for EU MDR & ISO 20417
- Team Leadership & Individual Development
- Product & Process Cost Reduction
- Ethics Training, Consultation, and Investigation

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## PROFESSIONAL EXPERIENCE

### **Cook Inc. – Bloomington, Indiana**

#### ***Manager, Labeling Assurance***

March 2022 – May 2023

Manager of Labeling Assurance Team responsible for design and documentation of all company labeling – product labels, instructions for use (IFUs), implant cards, and patient-facing information.

- Managed and prioritized the daily work of a team of engineers, product label designers, and IFU designers.
- Recognized as company subject matter expert (SME) for:
  - EU MDR 2017/745 labeling requirements
  - ISO 20417 - "Medical devices — Information to be supplied by the manufacturer"
  - ISO 15223 - "Symbols to be used with medical device labels"
- Analyzed notified body (TÜV SÜD) follow-up deficiency reports for EU MDR submissions, clarified issues/concerns, and wrote formal responses for labeling deficiencies.
- Prepared detailed gap analysis for current labeling, as well as company QMS, against ISO 20417 requirements.
- Responsible for company's quality system procedures within QMS for labeling requirements and processes.
- Led design team converting label designs from Prisym to enLabel Integrated Packaging Management (IPM)
- Reviewed and approved design change plans and change order documentation for all product changes.
- Managed website used for documentation and collaboration by all Cook Medical global labeling organizations.

#### ***Sustaining Engineer, Labeling Assurance***

August 2019 – March 2022

Engineering lead and project manager for update of all product labels, instructions for use (IFUs), implant cards, and patient-facing information for 10,000+ part numbers

- Developed gap analysis process for review of current product labeling against EU MDR requirements.
- Conducted gap analysis for four medical device product lines.
- Directed the daily work and mentored the development of a team of 12 engineers performing labeling analysis for more than 70 product families.
- Wrote and edited labeling standards for use by six Cook organizations around the globe.
- Built document management system within SharePoint for organization of 10,000+ project documents.

### **Lerch Bates Inc. – Englewood, Colorado and Bloomington, Indiana**

#### ***Elevator Consultant, Strategic Accounts***

February 2016 – February 2019

Lead vertical transportation consultant for national consulting clients, including Burlington Coat Factory Warehouse, EBI Consulting, Sunrise Senior Living, Kohl's, Howard Hughes Corporation, and Great Wolf Resorts

- Created maintenance specifications and contract documents for use as national agreements between clients and elevator service contractors across the country.
- Generated RFPs for elevator maintenance and modernization projects and provided resulting bid analysis and recommendation.
- Negotiated equitable agreements between clients and contractors regarding technical and financial performance.

## **Otis Elevator Company – Florence, South Carolina and Bloomington, Indiana**

### ***Mechanical Engineering Manager***

January 2010 – January 2016

Responsible for the engineering team developing, testing, and implementing all North American model elevator new product design, cost reduction, factory support, and field support for hoistway interface components.

- Managed engineers and lead implementation process for elevator components including hoistway entrances, door operators, machine support, vehicle hoistway guidance, human interface devices, and suspension means.
- Supported ramp up of new factory and supply chain, including frequent development of short term solutions for material shortages and quality issues.
- Led group of global system engineers in risk analysis at two-week Global FMEA event in Tianjin, China.
- Managed all North American engineering recruiting, including requisitions, resume review, on-campus recruiting, on-site interview planning, and interview process for evaluation of candidate competencies.

### ***Ethics and Compliance Officer***

July 2013 – January 2016

Leader of all ethics and compliance matters for organization of 500+ based in two geographic locations. Nominated for position by leadership team based on strong ethical leadership demonstrated in engineering management roles.

- Led investigation and discipline recommendation for all alleged and confirmed violations of the Code of Ethics.
- Provided daily consultation and interpretation of the United Technologies Corporation Code of Ethics.
- Facilitated annual Enterprise Risk Management process for operations VP and leadership team.
- Trained salaried and hourly workforce on ethics expectations via monthly presentations and communications.

## **Otis Elevator Company – Bloomington, Indiana**

### ***Value Engineering Manager***

January 2000 – December 2009

Manager of engineering team responsible for identifying, evaluating, designing and implementing cost reduction opportunities for model elevator products (low-rise hydraulic elevators and mid-rise traction elevators)

- Developed cost reduction idea generation, evaluation, design, and implementation process for North American operation that allowed for the efficient tracking and prioritization of all proposals.
- Managed hydraulic elevator benchmarking with engineers from USA, Italy, and Mexico. Event generated over \$5,300 (33%) in opportunities for 2-stop holeless systems and over \$9,600 (44%) in opportunities for 3-stop telescopic hydraulic elevators.
- Managed 2005 mid-rise elevator and packaging benchmarking with engineers from USA, China, Mexico, Korea, France, Italy, and Spain. Event generated over \$6,800 (12%) in opportunities for 9-stop belted traction elevators.
- Technical Manager for Weldless Door System program, a complete redesign of the elevator hoistway door that eliminated all welding to improve material cost, manufacturing cycle time, and aesthetics.
- Nominated for and participated in Otis University, a global corporate engineering leadership program.

### ***Ride Quality Manager***

November 1998 – January 2000

- Developed performance target (8-8-48) with marketing based on customer and consultant requirements.
- Identified elevator component improvements required to achieve performance targets.
- Taught field associates how to achieve optimal ride quality performance by using proper components, including PMT EVA system, for specific elevator speed and rise conditions.

### ***Mechanical Engineer, Systems Integration Team***

September 1993 – October 1998

- Performed structural analysis and generated 40-page and 46-page reports of calculations and explanations for the code compliance of the LRV and LRV5L hydraulic elevator vehicle structures.
- Test engineer for LVME roped hydraulic elevator system.

# CHRISTOPHER GOSS

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## **Clark Material Handling Company – Lexington, Kentucky**

### ***Mechanical Engineer, Lift System***

August 1992 – September 1993

- Designed and analyzed new two- and three-stage fork masts for Clark Genesis Series cushion and pneumatic tire lift trucks using IBM CADAM.
- Developed, coordinated, and conducted test plan for stress evaluation using brittle lacquer and bi-axial strain gages.

## **Case Construction Equipment Company – Wausau, Wisconsin**

### ***Mechanical Engineer, Special Features Custom Development Team***

June 1987 – August 1992

- Designed, analyzed, and implemented customer requested modifications of wheel loader and excavator equipment.
- Test engineer for government contract compliance testing of modified equipment for US Navy and US Marine Corps.
- Developed first 3D kinematic model for Case using Catia to evaluate lift arm linkage performance.

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## **EDUCATION**

### **Rose-Hulman Institute of Technology**

Terre Haute, IN

*Bachelor of Science in Mechanical Engineering*

### **Krannert School of Business at Purdue University**

West Lafayette, IN

*Master of Science in Management (MBA)*