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SUMMARY

- Extensive experience in medical device reprocessing product development, validation, and obtaining FDA clearances.
- Diverse technical experience and cross-disciplinary acumen applied to measurement and process problems.
- Manager, team leader and team member with team building skills.
- Created and led entrepreneurial startup to profitability.
- Experience in world markets including national and international standards development and compliance.
- Max Planck Fellow in Surface Physics.
  US Department of Energy Fellow in Physical Chemistry.
- MBA in Technology Management focused in R&D and Manufacturing.
- Co-chair of AAMI ST/Working Group 43, US National Standards Making Body for Hospital Steam Sterilizers, 2016-2019 (optional renewal through 2022)
- US Expert Delegate to ISO TC198WG11, General Criteria for Sterilization Processes and Sterilization Equipment and ISO TC198WG16, Hydrogen Peroxide Sterilization Processes

OVERVIEW

I have been employed in the medical device industry since 1990, acting as technical lead and subject matter expert in development projects and forensic analysis centered around medical device reprocessing. These projects have included capital equipment product development (peroxide vapor sterilizer, steam resistometer, ethylene oxide sterilizer control system with FDA clearance), product, software and process validation, selection of products for distribution in the sterile processing market, and creation of consultation service offerings for sterilizer validation and forensics for failed or out-of-control processes. I am a creative thinker, successfully applying any and all available solutions to solve control problems, able to pull in technologies from other areas of my experience, while focusing on cost at all times.

As a part of this work, I created and managed a small company to develop, manufacture, and market these products. Management responsibilities included guiding a team of engineers in the startup phase, as well as management of sales representatives for the distribution products, validation, and forensic services. As part of the latter work, I created marketing material (including a web site) and product branding. This also involved collaborative marketing with Honeywell for the ethylene oxide sterilizer product and with a leading German cleaning and sterilization validation laboratory (SMP GmbH) for laboratory services and quantitative washer-disinfector testing.

Capital equipment product sales have been throughout the US as well as in Europe. Validation and consultation products have included steam, ethylene oxide, and peroxide/plasma sterilizer validations, development of internal validation protocols, control software validation for GMP audits and FDA submittals, service analysis to determine weak points in client products, and CE marking of our own product for European sales.

ACHIEVEMENTS

Entrepreneurial

- Invented and developed a primary-standard sterilizer system for validation of sterilization indicators, industrial steam sterilizers and controls, vapor hydrogen peroxide generator and FDA-cleared hospital ethylene oxide sterilizer controls (over 15 industrial placements and six hospital placements). Products and processes validated and cleared under QSRs and European equivalents. CE marking achieved to enable European system sales.
- Created a company to deliver these products and related consulting services, focusing in the areas of validation and process troubleshooting.
- Advised and guided consulting clients in developing sterilization and cleaning processes, internal validation protocols, software and system validation for cGMP production equipment and FDA submittals. Represented and provided external testing resources, including protocol development for their testing.

Managerial

- Created and managed internal team and external resources to develop new sterilization validation product.
- Created and managed sales force to promote products into the healthcare end-user market.
- Managed team in consulting ventures.

Corporate Project Leadership

- Organized authorization for gas plasma sterilizer research and development project; created R&D input.
- Co-leader (with manufacturing engineer-DFM in action) and responsible manager of cross-functional team. Used statistical experimental design techniques to speed development.

Medical Device Reprocessing

- Implemented and interpreted in-system parametric process monitoring for plasma and vapor hydrogen peroxide sterilization processes. This resulted in improved understanding of the process allowed its efficient optimization, use as a validation tool, and standards compliance

- Selected materials and components for a medical device sterilizer using a corrosive chemical process. This led to improved materials compatibility of the system and no corrosion-induced downtime.
- Brought a reduced-cycle time ethylene oxide sterilization process to market and through FDA-mandated validations. The process and product provided reliable reprocessing with 25% decreased use of ethylene oxide and10-hour cycle time including aeration. Residuals reduced to below detectable limit in standard healthcare material challenges.
- Created and executed materials compatibility studies for medical device sterilization and decontamination processes using conventional and unconventional analyses. A definitive catalog of compatible materials was defined and validated, reduced risk of end-user difficulties with processes. FDA clearance was obtained.
- Out of the box look at a new sterilization process led to removal of unnecessary process and equipment features. This effort decreased build cost by 50%, lowered cycle time, improved reliability.
- In concert with testing lab partner, developed test protocols for manual and automated cleaning validation of lumened and conventional medical devices, leading to FDA clearance and EU MDD compliance.

Thirteen patent disclosures submitted with six allowed and four issued. More than 20 publications and more than 25 presentations in scientific and trade venues.

EXPERIENCE

Quality Processing Resource Group, LLC (QPRG) Richmond, VA 2015-Present

Managing Director and Chief Technical Officer: QPRG is a consulting and distribution company that provides sterile processing departments and medical device manufacturers with information and consultancy services to promote operational efficiency, hygiene and reprocessing quality, and compliance with standards and best practices. Distribution includes unique or leading-edge products that provide work process advantages to our customer based in these areas.

I have organizational and operating responsibility, provide technical services to hospital and medical device clients, and liaise to the AAMI National Standards making body.

I evaluate equipment for distribution, create regulatory and electrical safety filing packages for this equipment, source external resources for regulatory approval, execute FDA filings and regulatory interpretations for QPRG and clients, and provide technical bulletins and training for sales and service representatives.

H & W Technology, LLC/EHW Design Engineering Co. Rochester, NY 1998-Present

Founder and President: Develop, manufacture, and market validation and production sterilizers for medical device manufacturers and ethylene oxide sterilizer controls for hospitals. Provide consulting services and training in the areas of regulatory affairs, product and process validation, sterilization, disinfection, and cleaning for the medical device industry. Supply hospital sterile processing departments with useful, novel products and consulting on reprocessing issues.

- General management with responsibility for P&L, direction of new product definition and development, marketing and sales, manufacturing, personnel, and vendors.
- Support internal and client product registrations with FDA and internationally.
- Create, design, and validate products and services from concept to manufacturing. Ensure manufacturability, serviceability and marketability.
- Solicit and manage customers, consulting clients, and sales representative relationships.
- Hands-on involvement in all areas of the business.

Consultant Rochester, NY 1997-1998

Projects included: managing nutraceutical production process scale up; product design and management for lab equipment and its introduction to a new industry sector; analysis and valuation of a commodity manufacturer.

GETINGE/Castle, Inc./MDT Corporation Rochester, NY 1990-1997

Staff Scientist and Project Leader. Planned and executed research, development, commercialization, and support for medical and dental sterilization and decontamination equipment and processes. Co-authored two publications.

- Directed engineers, designers and technicians.
- Developed sterilization products and processes.
- Selected and cost engineered product components.
- Selected and supervised consultants.
- Supported product registrations.
- Worked cross-functionally to ensure manufacturability, serviceability and marketability.
- Evaluated and analyzed external intellectual property.

Genesee Optics Software Rochester, NY 1989-1990

Technical Sales Representative. Sold and marketed optical design software and systems.

- Represented company in sales and at trade shows.
- Executed marketing plan for new product introduction.
- Organized and marketed training courses.
- Authored manuals and marketing literature.
- Managed and executed targeted mailings.

Ford Motor Sales — Stuttgart, Germany — 1988-1989

Consultant. Implemented sales and marketing database. Generated advertising, organizational and contract materials. Performed sales and market analysis.

University of Maryland Extension — Heidelberg, Germany — 1988

Lecturer. Taught college mathematics courses to US Army personnel and civilians.

Fritz Haber Institute of the Max Planck Society — Berlin, Germany — 1986-1988

Research Associate and Max Planck Fellow in Surface Physics. Carried out research in Surface Physics. Co-authored more than 10 publications and presentations. Assisted group leader and lab manager in training and mentoring doctoral students. Developed understanding and capability in design and spectroscopic examination of ultrathin coating technologies and production and measurement of cryogenic temperatures for the systems being measured.

Klinger Scientific Corp. — Richmond Hill, NY — 1979-1981

Technical Sales Representative. Sold linear and rotational micro-positioning devices and optical components. Designed and tested systems of these components and provided customer support. Created second source network for optical components. Represented company at trade shows and developed successful customer relationships resulting in exceeding sales goals.

EDUCATION

Rochester Institute of Technology, Rochester, NY	MBA in Technology Management Focus: R&D, product development, and manufacturing.
New York University, New York, NY	MS, Ph.D., Physical Chemistry
Dissertation: Development of a Photoacoustic Spectrometer, Graduate Teaching Fellow and US DOE Fellow	
Hofstra University, Hempstead, NY	BS Chemistry
Brandeis University, Waltham, MA	Undergraduate coursework, Chemistry concentration

SKILLS

Languages: Fluent in German, read French.
Computer: Windows, Macintosh, and UNIX; MS Office, Visio, MS Project, statistical analysis, PLC coding. Design of Experiments for efficient process and product development.
Product Design: Software and Product Development using a Hazard Analysis-based Product Development Life Cycle Approach. Project Management using Phase/Gate paradigm.

References available upon request.