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SUMMARY

Mr. Clemens is a seasoned Engineering professional with over 40 years Product Development experience in the HealthCare and Biomedical industries. He brings extensive design and systems level experience in Drug Delivery, Respiratory Care, Blood Handling, and In Vitro Diagnostic product & technology development, Program/Project Management, Risk Management & Analysis. Mr. Clemens utilizes excellent collaborative skills to achieve the most from people and technology. Importantly, he brings a great appreciation of effective application of Quality System Regulations, ISO13485:2016 / ISO 9001 standards to all his work. Mr. Clemens also has over 20 years Expert Witness experience in the areas of Medical Device Product Liability and Patent Infringement cases.

PROFESSIONAL

Senior Consultant Associate / Program Manager – Fallbrook Engineering Inc. 1995 - 2018
Provides consulting services in the capacity of Program Manager and Senior Mechanical Engineer for a wide variety of medical device product development projects including drug delivery devices, blood handling systems, surgical tools, and in-vitro diagnostic systems. Also provides Expert Services in the areas of product liability and patent related matters.

Senior Consultant / Project Manager – BIT-Group USA, Irvine, CA 2014 - 2017
Provides part-time consulting in the capacity of Project Manager and/or Systems Engineer for various In Vitro Diagnostic product development projects.

Invetech - USA, San Diego, CA (Part of Fortive Company - split off from Danaher) - Sept 2010 to April 2012 full time – Consultant 2012 - 2016
Provides consulting services in the capacity of Program Manager and Senior Mechanical Engineer for various medical device product development projects. Additionally, Mr. Clemens advises Invetech in the development of new Clients and business in the Medical Device markets in North America. Invetech is an international product development company based in Australia specializing in Consumer and Industrial products, Life Science, In-Vitro Diagnostics, and Medical Devices.

CLEMENS CONSULTING COMPANY 1995 – Present
Technical & Management Consultant specializing in Medical Device and In Vitro Diagnostic Product Development as well as Expert Witness services for Medical Device product liability and patent litigation.

Principal Consultant / Project Manager
Provides design and development consulting services both as an independent consultant and in conjunction with various consulting associates:

Products & Areas of Expertise:

IV Drug Delivery Systems
IV Disposable Sets & Components
Insulin Delivery Systems
Drug Injector Pens
Dialysis Systems & Disposables
POC In Vitro Diagnostic Devices
Liquid Drug Inhalers
Pyrolitic Carbon Implants
Thermal Droplet Generation
Blood Pressure Monitoring Systems
Expert Witness – Medical Devices
Pulmonary Breathing Circuits
Digital Thermometry
Prostrate Seeding Needles
Liquid Biocompatible Adhesive Delivery
Active “Smart” Implants
Medical Support Appliances
Liquid Drug Humidifiers
Test Fixture Design
Manufacturing Process Development

Some Specific Experiences:

- Program Director for new Blood Separation & Collection System product line
- Co-invented a peristaltic blood pumping and control system for portable dialysis.
- Designed and optimized an insert molded ultrasonic drug aerosol generation device
- Developed several conceptual clinical and disposable Inhaler devices
- Improved design of a wearable hemodialysis system and early development of clinical trial systems
- Developed Award winning and patented fluidics design for cassette based clinical diagnostic system for DNA sample processing – Osmetech plc and now GenMark Dx
- Investigated patented low flow precision technology (Thermal Time of Flight) for application to drug delivery and blood handling systems.
- Conceived and developed a unique drug evaporation system integrated with state-of-the-art Hudson humidifiers and Siemens ventilators
- Directed Engineering design efforts for an Insulin Pump start-up company - Bionica, Inc.
- Optimized a patented venting method for sterilized laryngeal mask products.
- Developed a unique drug compatible Pellathane™ coated heater wire for breathing circuits
- Qualified a unique pressure sensing sub-system by optimizing disposable / sensor interface
- Developed RF welding process for custom pneumatic orthotics

CLEMENS CONSULTING COMPANY (con't) **1995 – present**

Clients and Associates (not inclusive):

Alaris Medical Systems
Sparton Aubrey Group
Invetech USA / AUS
Alliance Pharmaceuticals Corp
BIT-Group USA
Pozzi Wilson Atchison, LLP
Mission Medical Inc. / Terumo
White & Case, LLP
Becton Dickinson / Nanogen Inc JV
Osmetech Clinical Micro Systems
Knobbe Martens Olsen & Bear
Cohesion Inc.
Fallbrook Engineering Inc
Aerogen Inc.
InJet Digital Aerosols
Xcorporeal Inc..

CareFusion Inc., San Diego, CA (Formerly IVAC Corp. / Alaris Medical Systems / Cardinal Health) **1981-1995**

Largest U.S. medical Drug Delivery Systems and Vital Signs devices manufacturer.

Technical Leader - Development Engineering (1991-1995)

Worked in a cross-functional team environment with Marketing, Quality, and Manufacturing Team Leaders and facilitated the product concept generation, design feasibility, and business plan generation for the Signature Edition program. This was Alaris's first "Heavy-weight" program team and was run as a company within a company.

- Provided engineering management and supervision to all electrical, mechanical, software, and disposables engineering personnel (30+) for the inception, development, and introduction into production of IVAC's largest product development program in its' history (Signature Edition).

- Directed the technology investigation, selection and development of the Signature Edition fluid delivery platform system, a $35M development effort with over $300M market potential over the

following eight years. Participated in upper-management presentations and meetings developing the Signature Edition product positioning, feature selection, and final business plan.

- Traveled to 20+ major cities & 50+ Hospitals in the US and Europe to interface directly to Doctors, Clinicians, Nurses, as well as Regulatory Agencies to gather critical drug delivery knowledge to be used in a Quality Function Deployment effort. This effort resulted in the strategic focus of the entire product development program.

- Initiated & directed a competitive technical benchmarking effort of US & European drug delivery systems which provided the foundation for the marketing strategy as well as the fundamental measuring parameters for the design team.

- Responsible for both the instrumentation and plastic disposable interface, invention, detail design, and development as well as drug / system compatibility and functional conformance. Established Team Leaders in a consensus driven process to achieve business plan goals with respect to budget, timelines, and company goals. Additionally, all the design specifications, performance qualification plans and procedures, and process plans and procedures were achieved through the same process.

- Established the schedule, which all team members utilized for their planning. Helped define a new development and planning process, which was later used as a model for IVAC's SOP's. These SOP's were the basis for successful ISO 9000/9001 design control approval. I was directly involved in the ISO implementation and qualification process.

- Provided technical direction in the review and selection of all out-sourced suppliers and industrial design companies. Helped train the technical team with new skills in the area of Quality Function Deployment (QFD), DFMA, Design of Experiments (DOE), and the Performance Excellence (PE) process. Utilized all new processes in the development of the Signature Edition program.

- Managed all engineering efforts provided by several outside consultants for the program such as IDEO Industrial design / mechanical development and engineering, Battelle Labs for elastomer development, noise and vibration analysis, and Failure Analysis Associates for plastic failure analysis.

- Coordinated a patent review process for the program with Fulwider, Patton, Lee & Utecht, a Los Angeles law firm. Supervised the creation of over 50 disclosures, many of which have been filed with the U.S. Patent Office and granted patent status.

Department Manager – Mechanical Development Engineering (1984-1990)

- Managed all mechanical engineering resources of up to eighteen Engineers with an annual budget of over $1.5M. Responsibilities included the mechanical development and market introduction of six new Drug Delivery systems and over a dozen new plastic disposable products.

- Provided technical consulting participation on corporate teams in the analysis of technology being considered for purchase by the company such as syringe pumps, fluid flow control devices, rotary peristaltic pumps, and specialized medical grade pressure transducers. In this capacity also provided Expert opinions for Patent and Product Liability issues facing the company.

- Trained in Eli Lilly management program and provided Technical Resources to Lilly instrument and disposable combination products during 1990 – 1995.

- Managed the company machine shop with six Model Makers and Machining Specialists utilizing eight production mills and two CNC mills.

- Managed the Development Test Lab, which had four Senior Test Technicians and full laboratory equipment used for design verification testing. I managed the main test strategies and procedures for this test lab.

- Directed the effort to select & implement new CAD systems for the mechanical engineering resources, (SDRC-Ideas then Solidworks). I hired resources to train and maintain the system, and integrated outside suppliers who interfaced their CAM systems. Directed efforts to establish an in-house CAD-CAM link between the design group and the PCB layout group and machine shop for rapid prototyping. I implemented extensive use of rapid prototyping on all projects such as computer modeling, solid modeling, stereolithography equipment selection and capital approval, and urethane cast molds.

Department Manager – Instrument Sustaining Engineering (1981-1983)

- Managed mechanical engineering resources of eight Mechanical Engineers with an annual budget of $500K. Responsibilities included all the mechanical engineering tasks in transitioning several new Instrument products and Disposables products from development to production, while maintaining all existing production needs.

- Position supervised the combined departments of Instrument Mechanical and Disposable Products sustaining engineering. I was responsible for recruiting, training, mentoring, and reviews of all mechanical engineering personnel.

- Responsible for skillful interdepartmental collaboration between Engineering, Quality, Operations, and Marketing to resolve critical design issues impacting production, or field issues demanding immediate attention.

CARBOMEDICS INC., Austin, TX **1979 - 1981**
Manufacturer of proprietary Pyrolitic carbon coated bio-implants (e.g. heart valves)

Program Manager - Process Development Engineering

- Planned and implemented a $1M project to move an existing Pyrolite® coating facility from San Diego, Ca. to Austin, Texas. I was responsible for the technical process / facility improvements, laboratory construction, and coating process validation in the new building.

- Lead the development of a new mono-leaflet implantable heart valve

- Invented and directed the proprietary design of an accurate rotary dry chemical delivery system to feed zirconium oxide granules to a fluidized bed coating process.

EDUCATION

San Diego State University, San Diego, CA : Bachelor of Science - Mechanical Engineering, 1979

San Diego State University, San Diego, CA : MBA Coursework, 1980 – 1982

Ancillary Coursework and Certifications:

Design of Experiments (DOE)
Design for Manufacturability (DFMA)
Performance Excellence (PE)
Total Quality Management (TQM)
Quality Function Deployment (QFD)
Numerous Quality Management Skills Courses

CHARLES E. CLEMENS resume

PATENTS

US / European:

US 9,517,296 Portable Dialysis Machine
US 8,597,505 Portable Dialysis Machine
US 8,114,288 System and Method for conducting hemodialysis and hemofiltration
US 7,863,035 Fluidic Devices
US 5,563,347 Pressure Sensing Vessel Adapted to be Preloaded Against a Sensor
EP 0 781 402 Pressure Sensing Vessel Adapted to be Preloaded Against a Sensor
US 5,575,632 Engineered Pumping Segment
EP 0 781 379 Engineered Pumping Segment
US 8,771,511 Disposable Apparatus and Kit for Conducting Dialysis
US 10,034,973 Disposable Apparatus and Kit for Conduction Dialysis
US 10,092,905 Tissue Sample Container and Methods
US 10,201,311 Biopsy Tissue Sample Transport Device and Method of Using Thereof

Canadian:

CA 2,199,406 Engineered Pumping Segment

Applications – US & International pending:

US20030224371 Integrated Cartridge for Sample Manipulation
US20060040311 Integrated Cartridge for Sample Manipulation
US20040042930 Reaction Chamber with Capillary Lock for Fluid Positioning and Retention