

Triple Ring Technologies Fluidics / Microfluidics Experience

Triple Ring Technologies has extensive experience, both individually and as a team, in the development and characterization of multiple fluidic and microfluidic technologies, with an emphasis on the reliability and repeatability required for medical applications. This experience includes characterization capabilities such as computational fluid dynamics, thermodynamics, and finite element analysis. Areas in which we have direct experience include:

- Medical pump development, including:
 - Novel implantable pumps with very low dead volume
 - Wearable subcutaneous pharmaceutical infusion pumps
 - Including insulin pumps with 1 unit precision
- Liquid based pulmonary drug delivery systems including:
 - Sub-micron diameter laser fabricated disposable nozzle arrays
 - 1 micron sized aerosols with GSDs as small as 1.2
 - Durable piezo driven micron sized nozzle arrays
 - Spray drying of micron sized powder aerosols
 - Electronic and all mechanical devices
 - Multi-dose and single dose
- Needle free bolus injection systems
- Characterization systems for autoinjectors

Selected Biographical Sketches:

1. **Jeffrey Arthur Schuster, Ph.D.** has led the development of multiple liquid aerosol drug delivery platforms including microprocessor controlled and all mechanical systems. These technologies are based on generating aerosols by creating microfluidic liquid jets through micrometer and sub-micrometer sized nozzles. In addition, Dr. Schuster has contributed to the development of needle-free jet injectors, implantable pumps, and flow cytometry systems. He has authored several peer-reviewed publications and book chapters on aerosol drug delivery. He is a named inventor on 31 issued US patents and numerous foreign cases, in the areas of generation of micron scale aerosols for pulmonary delivery and needle free injection using micron sized liquid jets, and has also managed multiple patent portfolios in these areas.
2. **Peter Holst** has led and contributed to the mechanical and system engineering efforts, including architecture, detail engineering, and testing, of a number of medical device fluid delivery systems. He has also contributed to late development stage problem correction efforts. The fluid delivery systems include positive displacement hospital IV pumps,

positive displacement ambulatory delivery systems, implantable pumps, as well as positive displacement and pressure pumps for aerosol delivery systems and analytical instruments. Fluid delivery rates in these systems range from sub- μ l/s to 100's of ml/hr. He is also familiar with flow-focusing as it applies to analytical instruments (flow cells) and aerosol generation of micron sized particles.

3. **Mike Lawless** has over 25 years experience in R&D and Product Design primarily in the development of high volume Medical Devices, with responsibility for mechanisms, sensors, actuators, cases, user features, accessories and medical disposables. He was responsible for characterization and optimization of technologies to meet performance requirements in a variety of domestic and international medical markets and was awarded 27 invention patents for design innovations to ultrasonic and pressure transducers, mechanisms, disposables and new technology IV pump systems. Mike has been Team Leader and Manager of cross functional engineering teams to design, validate and release new Medical IV Pump technologies and corresponding IV sets. His work on all phases of new product development has emphasized a balanced and disciplined use of design, analysis and targeted concept testing to quickly refine the fundamentals of operation. He has expertise in design for very high volume (10+ million per year) injection molded of plastics and silicone disposables and required assembly automation.
4. **Walt Cecka** has over 25 years of experience in design and development of medical devices and drug/device combination products. Mr. Cecka has held senior management and development engineering positions at Nektar Therapeutics, Bio-Molecular Technologies, Baxter Healthcare Corporation (Novacor Division), Cholestech Corporation, Nellcor, Inc., and Beckman Instruments (Spinco Division). His product development leadership experience includes the development and commercialization of several first-to-clinic and first-to-market products, including Nektar's inhaled Amikacin combination product, the Exubera™ pulmonary insulin inhaler, Novacor's N-100 bridge to transplant heart assist pump, and diagnostic products for rapid lipid panels and blood gas monitoring (CO₂ and anesthesia agents). His skill sets also include product development planning and program management in FDA and EMEA/ISO environments, system product design, plastic component material selection and design, and design transfer for high volume manufacturing. Walt has co-authored several peer reviewed posters and holds two patents in respiratory care and pulmonary delivery devices, with additional patents pending. He holds a BSME degree from California Polytechnic State.
5. **Stuart Friedman** is an industrial physicist and systems engineer who has over 10 years experience developing technologies, capital equipment, and algorithms for a variety of biomedical and industrial fields. He is also expert at modeling and characterizing the capabilities and performance of complex instruments and imaging systems, and is effective coordinating and facilitating efficient and productive collaborations between disparate engineering and scientific disciplines. Microfluidic experience includes system architecture, analysis and performance optimization of flow cytometers, fully automated



sample preparation/purification, immunoassays and PCR assays for biothreat detection, and sample preparation for cell based assays and bioimpedance systems. Stuart has held senior scientific and systems engineering positions at KLA-Tencor, Signature Bioscience, MDS Sciex and Etec Systems, and now consults for a variety of large and small high tech and biotech companies. He has patents and technical articles in a variety of fields including electron optics/microscopy, solid state physics and biophysical modeling.

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