

Triple Ring Technologies Drug Delivery and Drug/Device Combination Product Development Experience

Triple Ring Technologies has extensive experience, both individually and as a team, in the development and characterization of multiple drug delivery technologies, with an emphasis on the reliability and repeatability required for pharmaceutical applications. This experience includes regulatory requirements, intellectual property (including freedom to operate and patentability analyses, patent writing, and U.S. and international patent prosecution), manufacturing process development including spray drying and laser micromachining of nozzles, and characterization capabilities such as delivered dose and dose uniformity, particle size, and stability studies. Areas in which we have direct experience include:

- Pulmonary drug delivery systems including:
 - Sub-micron diameter laser fabricated disposable nozzle arrays
 - Micron scale 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 prefilled single use injection systems
- Medical pump development, including:
 - Novel implantable pumps with very low dead volume
 - Wearable subcutaneous pharmaceutical infusion pumps
 - Including insulin pumps with 1 unit precision
- Characterization systems for auto-injectors

Selected Biographical Sketches:

Jeffrey Arthur Schuster, Ph.D. has led the development of multiple aerosol drug delivery platforms including microprocessor controlled and all mechanical systems, in therapeutic areas including pain management (post operative and break-through cancer pain) and diabetes management. 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 liquid aerosol generation for pulmonary delivery and needle free injection using micron sized liquid jets, and has also managed multiple patent portfolios in these areas encompassing hundreds of U.S. and foreign cases. Jeff was also the primary investigator on a phase II SBIR grant, in



collaboration with the Centers for Disease Control and Prevention, focused on the development of an inhalation based mass vaccination system for measles and other diseases.

Peter Holst has led and contributed to the mechanical and system engineering efforts, including architecture, detail engineering, and testing, and late stage problem correction, of a number of medical drug delivery systems. Peter has extensive experience in the development of drug delivery pumps, including hospital IV pumps, ambulatory delivery systems, and implantable pumps. In addition, Peter has led and contributed to the engineering development of multiple inhalation drug delivery systems, ranging from complex, feature rich systems for the titrable delivery of insulin and sophisticated pressurized metered dose inhaler based systems for migraine treatment, to low cost all mechanical and single use disposable inhalation systems.

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.

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.

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