



PETER M. LLOYD, P.E.
Consulting Mechanical Engineer

SUMMARY

Peter Lloyd is a Licensed Professional Mechanical Engineer in the State of California. He has extensive experience in the field of respiratory drug delivery, including the development of numerous novel inhalation devices and aerosolization technologies from first concept through toxicology, animal and human clinical trials. Mr. Lloyd has also been active in the generation of intellectual property surrounding these inventions. Attached is a partial list of patents and publications in this field.

Mr. Lloyd joined BEAR in 2023, bringing over 30 years of experience in mechanical engineering including design and failure analysis, medical devices and instrumentation, finite element analysis, mechanical testing, failure of mechanical connections, dynamic stability of equipment and structures, medical implants and equipment, aerosol generation and measurement, high speed photography and microscopy, manufacturing equipment, Rapid prototyping, Additive manufacturing, CNC programming and machining, automotive and aircraft component analysis and design. Extensive experience working with FDA style design controls and GMP manufacturing.

Mechanical engineering projects have included development of many medical devices and products and the equipment support their development and manufacture.

SELECT INDUSTRY EXPERIENCE

Medical Devices, Manufacturing, Plastics/Metals/Ceramics, Machining, Rapid Prototyping, Fire, Construction, Heat Exchangers, Energetic materials, Evaporation and condensation phenomena, Particle and vapor inhalation, Inhalation toxicology, pharmacokinetics and pharmacodynamics, Transportation, Sailboats, Small Aircraft, General Aviation, Automobiles, Sterility, Aseptic manufacturing. Clean room design.

EDUCATION

B.A. in Economics from University of California, Davis. Completed coursework for degree in Mechanical Engineering and Aircraft Accident Investigation. Licensed Pilot.
Licensed Professional Mechanical Engineer in California.

PROFESSIONAL AFFILIATIONS

National Society of Professional Engineers

PROFESSIONAL EXPERIENCE

2023 – present

Mechanical Engineer, Berkeley Engineering And Research, Inc.

Design and Failure Analysis, Engineering Research, Fracture Analysis, Fitness-For-Service Analysis and Mechanical Testing. Fire analysis of industrial and restaurant equipment fires, structure fires, gas grill fires, industrial oven explosions, recreational vehicle refrigerator fires. Carbon monoxide poisoning investigations. Motor vehicle accident analysis. Construction equipment accident analysis.

10/2021 –6/2022

Chief Engineer for Airja, inc.

Designed and developed handheld electromechanical pharmaceutical inhaler based on a proprietary aerosolization technology.

9/2015 to 9/2021

Chief Engineer, Flow Pharma, Pleasant Hill, CA

Managed development of evaporative powder manufacturing process from lab to clinical scale as a key component of a synthetic vaccine technology. Responsible for developing, maintaining and operating equipment to make drug laden polymer microspheres. Tested novel synthetic vaccine technology in rodent model.

8/2013 – 8/2015

Director of Aerosol Engineering, eNicotine Technology, Draper, Utah.

Developed precise pharmaceutical nicotine inhaler technology for Smoking Cessation.

11/2011 – 8/2013

Engineering Consultant for Triple Ring Technologies, Newark, CA.

At Triple Ring developed numerous designs and built prototypes of numerous medical devices, medical instruments, and drug/device combination products.

9/2010 – 9/2011

Director of Aerosol Engineering, Staccato Nicotine Project, Cypress Bioscience, San Diego, CA.

Directed the mechanical engineering of a multidose pharmaceutical nicotine inhaler with a disposable cartridge.

12/2009 – 9/2010

Mechanical Engineer, Flow Pharma, E Palo Alto, CA

Developed equipment and methods for manufacturing drug loaded bio-absorbable polymer particles in precise narrow size ranges using a technique called flow focusing

11/2000 – 5/2009

Senior Research Engineer, Alexza Pharmaceuticals Mountain View, CA

Developed early concepts and prototypes of a novel aerosol drug delivery technology including research and development of the method of generation, particle size control and measurement of the produced aerosol. Developed system for administering single breath-controlled doses to animals for pharmacokinetic studies of drug absorption from the lung and managed that system through several

preclinical studies. Also developed and maintained novel large scale aerosol generators for a long series of toxicology studies.

10/1991 – 11/2000

Mechanical Engineer/Research Engineer, Aradigm Corporation, Hayward, California
Research and development of a novel aerosol drug delivery system using a unique package integrating the liquid drug container with a single use disposable nozzle and electronically controlled device to efficiently create a liquid aerosol for deposition in the deep lung. Continued development from concept through human clinical trials.

ISSUED U.S.A. PATENTS.

- 9308208 Aerosol generating method and device 4/12/16
- 9211382 Drug condensation aerosols and kits 12/15/15
- 8955512 Method of forming an aerosol for inhalation delivery 2/17/15
- 8506935 Respiratory drug condensation aerosols and methods of making and using them
8/13/13
- 8235037 Drug condensation aerosols and kits, 08/07/12
- 8074644 Method of forming an aerosol for inhalation delivery, 12/13/11
- 7942147 Aerosol forming device for use in inhalation therapy, 05/17/11
- 7913688 Inhalation device for producing a drug aerosol, 3/29/11
- 7766013 Aerosol generating method and device. 08/3/10
- 7645442 Rapid heating drug delivery article and method of use, 1/12/10
- 7581540 Aerosol drug delivery device incorporating percussively activated heat packages,
9/01/09
- 7550133 Respiratory drug condensation aerosols and methods of making and using them,
6/23/09
- 7537009 Method of forming and aerosol for inhalation delivery. 5/26/09
- 7090830 Drug condensation aerosols and kits, 8/15/06
- 6682716 Delivery of aerosols containing small particles through an inhalation route, 1/27/04

- 6123068 Systems for the intrapulmonary delivery of aerosolized aqueous formulations, 9/26/00
- 6098620 Device for aerosolizing narcotics, 8/08/00
- 6098615 Method of reproducibly effecting a patient's glucose level, 8/08/00
- 6014969 Disposable package for use in aerosolized delivery of antibiotics, 1/18/00
- 5960792 Device for aerosolized delivery of peptide drugs, 10/05/99
- 5957124 Dynamic particle size control for aerosolized drug delivery, 9/28/99
- 5934272 Device and method of creating aerosolized mist of respiratory drug, 8/10/99
- 5915378 Creating an aerosolized formulation of insulin, 6/29/99
- 5823178 Disposable package for use in aerosolized delivery of drugs, 6/23/98
- 5770152 Collapsible container for measuring particles in a sample fluid, 6/23/98
- 5718222 Disposable package for use in aerosolized delivery of drugs, 2/17/98
- 5709202 Intrapulmonary delivery of aerosolized formulations, 1/20/98
- 5660166 Systems for the intrapulmonary delivery of aerosolized aqueous formulations, 8/26/97
- 5544646 Systems for the intrapulmonary delivery of aerosolized aqueous formulations, 8/13/96
- 5522385 Dynamic particle size control for aerosolized drug delivery, 6/04/96
- 5497763 Disposable package for intrapulmonary delivery of aerosolized formulations, 3/12/96
- 5469750 Method and apparatus for sensing flow in two directions and automatic calibration thereof, 11/28/95

SELECTED PUBLICATIONS AND REPORTS

Lloyd, P; Schuster, J; Farr, S; Lloyd, LJ; "A new unit dose, breath actuated Aerosol drug delivery system," Respiratory Drug Delivery V, Phoenix AZ, May 1996

Farr, SJ; Schuster, JA; Lloyd, P; Lloyd, LJ; Okikawa, J; Rubsamen, RM; "AERx™, Development of a novel liquid aerosol delivery system: concept to clinic," Respiratory Drug Delivery V, Phoenix AZ, May 1996

Schuster, JA; Lloyd, J; Lloyd, P; Farr, S; Gonda, I; Finlay, W; "In Vitro, In Vivo, and Theoretical Delivery from a Unit Dose Aerosol Drug Delivery Device: The AERx™ System," Abstract, 15th Annual Conference AAAR, October 1996

Schuster J, Rubsamen R, Lloyd P, Lloyd J, "The AERx aerosol delivery system", Pharm Res, Mar 1997

Wilbanks, TM; Lloyd, LJ; Lloyd, PM; Schuster, JA; "A Micron Resolution Imaging System with Sub-Micro-Second Exposure Time for Aerosol Studies" Abstract, 15th Annual Conference AAAR, October 1996

Farr, S, McElduff, A., Ward, E., Okikawa, J., Lloyd, P., Schuster, J., Mather, L. & Gonda, I. "The Mode Of Inhalation Influences The Pharmacokinetics And Pharmacodynamics Of Pulmonary Delivered Insulin In Healthy Fasted Volunteers," Pharm Res November 1997 supplement S-136

Gonda, I., Schuster, J.A., Rubsamen, R.M., Lloyd, P., Cipolla, D., and Farr, S.J., "Inhalation Delivery Systems with Compliance and Disease Management Capabilities," J Controlled Release 1998, vol 53 pp. 269-274

Farr, S.J., Warren, S.J., Lloyd, P., Okikawa, J.K., Schuster, J.A., Rowe, A.M., Rubsamen, R.M. and Taylor, G. "Comparison of In Vitro and In Vivo Efficiencies of a Novel Unit-Dose Liquid Aerosol Generator and a Pressurized Metered Dose Inhaler," Int J Pharm 2000 v.198, pp.63-70

Cipolla, D.C., Farr, S.J., Gonda, I., Herst, C.V., Lee, R.Y., Lloyd, P., McKinley, G., Rubsamen, R., Schuster, J. and Zellhoefer, C., "Design and Testing of Aerosol Delivery Systems for Reproducible Clinical Performance," J Aerosol Med 1998

Schuster, J; Rubsamen, R; Okikawa, J; Lloyd, P; Farr, SJ; Cipolla, D; Gonda, I: "Reproducible Targeted Delivery of Proteins and Peptides to the Respiratory Tract" Symposia Abstract, AAPS 1997

Schuster, J., Gonda, I., Farr, S., Cipolla, D. & Lloyd, P., "Pulmonary Administration Of Biotech Drugs - The Way They Deserved To Be Delivered," Schloss Waldeck Symposium 1997

Ward, E., McElduff, A., Lee, R., Okikawa, J., Lloyd, P., Schuster, J., Cipolla, D., Gonda, I., Mather, L. and Farr, S. "Pharmacodynamics of Pulmonary Delivered Insulin in Healthy Fasted Volunteers," ISAM Sept 22-26 1997

Rabinowitz, JD, Wensley M, Lloyd P, Myers D, Shen W, Lu A, Hodges C, Hale R, Mufson D, Zaffaroni A., "Fast onset medications through thermally generated aerosols, Journal of Pharmacology and Experimental Therapeutics, May 2004

"Ultra-fast absorption of amorphous pure drug aerosols via deep lung inhalation", Rabinowitz JD, Lloyd PM, Munzar P, Myers DJ, Cross S, Damani R, Quintana R, Spyker DA, Soni P, Cassella, JV, J Pharm Sci, November 2006

“Recirculatory pharmacokinetic model of the uptake, distribution, and bioavailability of prochlorperazine administered as a thermally generated aerosol in a single breath to dogs” Avram MJ, Henthorn TK, Spyker DA, Krejcie TC, Lloyd PM, Cassella JV, Rabinowitz JD, Drug Metab Dispos, Feb 2007.