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## Microfluidizer® high-shear technology for manufacturing pharmaceutical drug delivery nanoparticles: From development to production

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Tanotechnology has revolutionized the pharmaceutical industry, especially with the applications of using nanoparticles (NPs) as N Drug Delivery Systems (DDS). These NPs show a number of advantages comparing to conventional methods such as increased bioavailability through enhanced solubility, forming theranostic platforms by co-delivering diagnostic and therapeutic agents, overcome various transport barriers to reach to the targeting sites, and controlled release capabilities, etc. Examples of such systems include nanoemulsions, liposomes and polymer nanoparticles. Despite their great potentials, major manufacturing challenges exist such as precisely control particle size and size distribution, achieve repeatable and scalable results, comply with all cGMP requirements and product sterilizable, e.g., through terminal sterile filtration. Microfluidizer\* technology is an advanced technology that satisfies all of the requirements by delivering superior uniform shear and energy dissipation rates through the utilization of fixed geometry interaction chamber and constant process pressure. The unique benefits are presented here with three case studies. The first case study compares making an oil-in-water nanoemulsion adjuvant with post-processing sterile filtration using both of the Microfluidizer and traditional high-pressure homogenization technology. Microfluidizer was able to produce nanoemulsions have much higher filterability due to smaller droplets and narrower distribution. The process also showed excellent energy efficiency. The second and third case studies demonstrate producing and scaling up of a liposomal antibiotic formulation and fabricating two different polymer particles, one solid and the other one with embedded nanoparticles, respectively. In summary, Microfluidizer\* technology is very efficient, reliable, and well-suited for manufacturing drug delivery nanoparticles for the pharmaceutical industry from development to production.



## **Presenting Author: Biography**

Kyle M. Jandrasitz specializes In Proof of Concept Tests, Process Development With Microfluidics Processing Technology and Data Analysis. He holds a Master's of Engineer Management from the Pennsylvania State University. As well as a Bachelor's of Science, Industrial Engineering (Nanofabrication Manufacturing Technology) from Millersville University of Pennsylvania. He has been with Microfluidics International Corporation since May of 2014.

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Yang Su, PhD, is currently the New Technology Manager at Microfluidics International Corporation, IDEX Material Processing Group. He is responsible for the overall direction and development of new technology, new application development, and shares responsibility for business line strategy of new technologies. His previous role at Microfluidics was Senior Research Engineer. In his role as Senior Research Engineer, he was leading the development of the company's core technology. He received his PhD degree in Chemical and Environmental Engineering from the University of Toledo, USA. He is a member of American Association of Pharmaceutical Scientists and Controlled Release Society.

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