

Integral BioSystems LLC has tripled its Lab Space and Now Offers ANDA Drug Development Programs for Complex Products

Leveraging extensive CMC and ANDA experience and its newly expanded lab space, Integral BioSystems LLC now offers CMC development programs in complex generics.



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Bedford, MA – April 19, 2017 – With its move in mid-2016 from its former 3,500 sq. ft. facility into a 10,000 sq. ft. custom built state-of-the-art laboratory facility, Boston area drug development CRO Integral BioSystems LLC is able to offer comprehensive "soup-to-nuts" CMC-specific consulting and laboratory services (analytical method development, formulation composition reverse engineering,

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The quality of Integral's data speaks for itself." Dr. Shikha Barman formulation development, in-vitro release (IVRT), permeability, dissolution) to develop complex generic drugs for ANDA submissions.

The expanded capabilities created by tripling the size of its facility, the recent acquisition of sophisticated development tools that allow LC/MS/MS bioanalytical capabilities, as well

as the addition of the equipment needed to do dry particle inhaled pulmonary drug development, allows a greatly expanded range of services on both fee-for-services and developmental partnership terms. The company has deep expertise in particle engineering, both in the generation and characterization of nanocrystals and polymer-encapsulated microspheres utilized in ophthalmic suspensions, intranasal sprays, pulmonary dry powder inhalation systems and general injectable dosage forms.

Additionally, the company provides assistance to construct the CMC sections of IND and ANDA submissions.

About Integral BioSystems

Integral BioSystems is a specialty drug delivery contract research organization that offers an integrated, practical approach to formulation development projects for both small molecule and large molecule drug candidates. Offering contract services to pharmaceutical companies to develop drug products through its CMC offerings in analytical method development, formulation development, process development, scale-up and technology transfer, the company also partners with pharmaceutical companies to co-develop products based on its proprietary pharmaceutical delivery systems.

The Company has developed numerous dosage forms for most delivery routes and many indications, including those for ophthalmic use. Integral BioSystems has a translational approach to drug

development, customizing delivery systems to achieve the biologically effective objectives of the therapy. Dosage forms are customized to achieve sustained release or targeted, tissue-focused delivery or fast-release/instant delivery, depending upon the desired product attributes.

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