



## SUMMARY

Integral BioSystems is based in the Boston area, with its corporate headquarters in Bedford, MA, and laboratories in Littleton, MA.

Our business model is based on the following corporate objectives: (a) to be a collaborating partner in formulation development / drug product design for start-up companies, taking concepts from the laboratory to the clinic, (b) to re-formulate approved drugs for better efficacy and safety profiles, (c) to be a collaborating partner with API synthesis companies to develop generic drug product formats and (d) offer corporate legal services such as contract development/ negotiations, patent filings and assessment of IP portfolios.

Integral BioSystems' niche is in drug delivery, in the development of biocompatible formulations that are compatible with physiological fluids and tissues. We have developed formulations in ophthalmic, oral, sublingual, intranasal, IV and transdermal routes. Integral BioSystems has a translational medicinal approach to drug development, customizing delivery systems to accomplish the biologically effective objectives of the therapy. From this perspective, delivery systems are customized to achieve sustained release or targeted, tissue-focused delivery or fast-release/instant delivery, depending upon the desired product attributes.

Once the drug-containing formulations are tested in preclinical models, we develop an integrated CMC plan to systematically transition the project to scale up and product development. As part of product development, Integral BioSystems specializes in efficiently developing a dosage form to manufacture and test in Phase I/Phase II first-in-man trials for proof-of-concept. We have a network of manufacturers / analytical houses for pharmaceuticals, that can fast-track the manufacture and release of the sterile dosage form for first-in-man trials.

Integral BioSystems works with collaborating companies that specialize in clinical development and IND submissions for Phase I/II trials. Additionally, Integral BioSystems also specializes in corporate legal services such as contract development/ negotiations, incorporations, IP strategy, positioning and assessment of existent IP portfolios.

## DRUG DELIVERY R & D SERVICES

Our Drug Delivery researchers focus on the delivery of drugs to the target tissues. We design research scale delivery systems based on its desired attributes and characterize these systems in-vitro. These in-vitro systems may be membrane permeation, or in-vitro release, or in-vitro compatibility with cells and physiological fluids. These initial data provide the basis for full scale formulation development of a drug product.

### Delivery Functionalities

- a. Microencapsulation and Nano-encapsulation in biodegradable polymers systems
- b. Micronization and Nano-ization of Active Pharmaceutical Ingredient
- c. Dispersed systems, such as suspensions, emulsions, creams, liposomes
- d. Lyophilized / freeze-dried dosage forms
- e. Tablets, Capsules
- f. Nasal Sprays
- g. Sublingual Fast-Release Films
- h. Solubilization of insoluble drugs
- i. Hydrogel Depots
- j. Cell-Targeted Delivery Systems
- k. Eye-Drops, Ointments

**Molecules**

- a. Small Molecule
- b. Proteins/ Peptides
- c. Nucleic Acids

**In-Vitro Testing (IVT)**

- a. Release testing of sustained release dosage forms
- b. In-vitro flow-through compatibility
- c. Compatibility with cells

**Routes**

- a. Ophthalmic
- b. Transdermal
- c. Small Volume and Large Volume IV
- d. Sublingual
- e. Oral

**DRUG DEVELOPMENT SERVICES****Drug Characterization (API)**

- a. Polymorph Screening
- b. pka, log P, crystallinity, tap density, particle size distribution

**Pre-Formulation**

- a. Solubility Matrices
- b. pH solubility profiles
- c. pH stability profiles
- d. Drug-exciipient interactions
- e. Forced Degradation

**Analytical Method Development**

- a. Specificity
- b. Accuracy and Precision
- c. Spike-Recovery
- d. Forced Degradation

**Toxicology Samples**

- a. Toxicology Sample Preparation
- b. Sample Preparation Reports

**CMC Development**

- a. Scale-up of formulations from 5 ml to 50 Liters.
- b. Drug Product Specifications Development
- c. Technology transfer for CTM manufacturing
- d. Planning and writing CMC sections for IND submissions for Phase I and II
- e. Writing of Clinical Pharmacy Protocols

**LEGAL SERVICES****Intellectual Property**

- a. Fast, Affordable Provisional Filings and Patent Applications
- b. Copyrights and Trademarks
- c. IP Assessments and Review

**Contracts**

- a. Contracts