

LOCALIZED / TARGETED DRUG DELIVERY

Integrative Drug Delivery Optimization and Development Studies

Targeted drug delivery localizes exposure to the site of action, overcoming physiological barriers. Novel excipients and modes of administration have synergized with biocompatible materials and biological agents to optimize bioavailability and open new therapeutic strategies.

Relevant examples include:

- Controlled-release therapeutics
- Combination drug-device products
- Localized tissue and organ-specific chemotherapies
- Biologics and cell-based (regenerative and growth factor release)
- Microparticle and nanomaterial-based delivery

CBSET's Multi-Disciplinary Approach

Understanding the complexity of localized/targeted therapies requires expertise in a broad array of preclinical studies, from *in vivo* studies to physical characterization, complex pathologies and pharmacokinetics. We collaborate with sponsors by integrating in-life procedures and *ex vivo* analyses, along with materials characterization and computational modeling, into a cohesive regulatory path.

Quantify tissue response of delivery paradigm

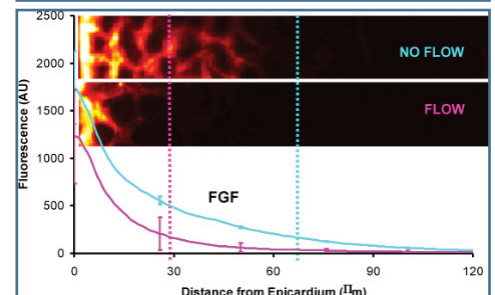
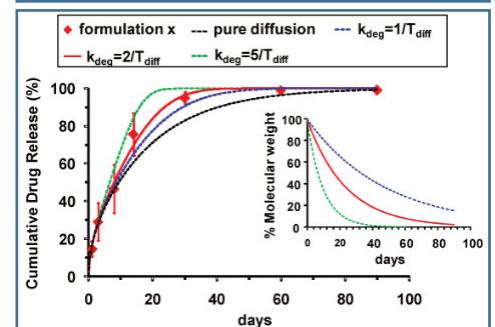
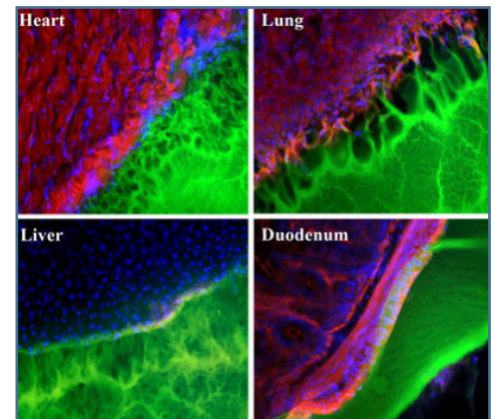
- Correlate device geometry with patterns of drug distribution
- Evaluate local and systemic PK and TK

Characterize material-drug interaction

- Understand interplay of drug properties with device materials, such as polymer type
- Correlate drug distribution with binding interactions, mixing conditions, as well as the composition of release media particles, matrices, coatings or synthetic polymers

Apply computational modeling to bridge anatomic-pathologic effects with material and drug perturbations

- Morphometry and quantitative scoring paradigms
- Create intuitive 3-D visualizations, integrate anatomic and image data (e.g., OCT)
- Develop predictive models of efficacy, safety, and distribution



ABOUT CBSET

CBSET is a state-of-the-art translational research institute located in the greater Boston area of MA.

Our mission is to advance biomedical research, through innovative, high-quality services. We combine top-tier research with operational expertise. Since our inception, CBSET has continued to develop technical and scientific acumen through collaborative projects in the medical device, pharmaceutical and academic communities.

Our 40,000 square foot, GLP-compliant, AAALAC- accredited facility includes vivaria, procedure rooms, catheterization / imaging labs, surgical and necropsy suites, histopathology, SEM, and a range of other technologies.

Why CBSET?

- **Credibility.** We are recognized as unbiased experts, bringing independent credibility to your regulatory filings.
- **Culture.** Our culture is based in science; we value new models and creative collaboration.
- **Mission.** Our motivation is to enable your success; your product is our mission.
- **Integrated resource.** Our multidisciplinary team includes board-certified veterinary, quality, biological and quantitative sciences expertise, as well as board-certified pathologists – all in one facility.

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Surgical and imaging modalities

- Use small and large animal models and surgical methods to allow precise testing of any paradigm
- Use full catheter lab to enable interventional methods such as TACE
- Incorporate anatomic information through imaging modalities such as CT and EC

Histopathology

- Overlay histopathology and biological endpoints via immunofluorescence and IHC
- Perform safety assessment with boarded pathologists

Regulatory guidance and compliance

- Implement a cohesive regulatory strategy and educate your stakeholders at our GLP compliant, AAALAC-accredited institute

A Multi-Disciplinary Drug Delivery Paradigm

