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Capabilities Statement

Integral BioSystems, LLC is a majority woman-owned business founded in 2009, with expertise and capabilities in drug development, specifically in R&D. Integral BioSystems is cGLP-compliant and is available to assist primary contractors and the NIH (and other appropriate government agencies) by providing the following services:

SERVICES SUMMARY

- Analytical method development (small molecules, biologics) by HPLC, UPLC
- Analytical method qualification (cGLP)
- API Characterization (XRPD, solubility, log P, forced degradation, NMR, FTIR, DSC, TGA, SEM)
- Preformulation and compatibility studies
- Formulation development
- Nanocrystalline formulations
- Emulsion, dispersion, liposomal formulations
- Sustained Release Injectable Microspheres
- Lipid Nanoparticles
- Process Development and Scale up
- Drug Binding studies
- Container Closure studies
- Syringeability studies
- cGLP ICH Stability Studies
- USP IV Flow-through IVRT studies
- Particle Size Distribution (PSD), Laser Light Diffraction
- Particle Sizing by Dynamic Light Scattering
- Surface Tensiometry, Contact angle measurement
- Osmometry
- Moisture analysis by Karl Fisher
- Rheology (Viscometry)
- pH measurement
- Residual Solvent Analysis by GC
- Toxicology clean supplies and cGLP release testing
- cGLP dose analysis
- Bioanalytical method development
- Analysis of API in tissues by bioanalytical LC/MS/MS
- Scale-up and Technology Transfer

SUBJECT MATTER AND ROUTE EXPERTISE

- Routes: Ophthalmic, Otic, Dermal, Sublingual
- Analysis and formulation development of proteins, peptide, cDNA, protein-based vaccines for injectable and ophthalmic routes.
- Analysis and formulation development of small molecules for injectable, intranasal, transdermal, pulmonary, otic and follicular formulations.
- Subject matter expertise in sustained release delivery systems (microspheres, depot systems)
- Subject matter expertise in eye-drops and ophthalmic drug delivery
- Subject matter expertise in lipid nanoparticles and PLGA microspheres
- Fast dissolving oral films to deliver vaccines

COMPETITIVE DIFFERENTIATION

- Highly innovative and focused;
- Expertise is cutting-edge;
- Complex formulations
- Trouble-shooting, problem solving various formulation issues

PAST PERFORMANCE AND CLIENTS

- Have performed and delivered on >30 complex formulations in the injectable, ophthalmic and dermal space.
- Assisted >20 companies in private sector with cutting-edge formulation development
- Companies: Novartis, Alcon, Allergan, Perfuse, Allysta, Encore Vision, Nicox, ONO, ONL Therapeutics, Endogena, FHI360, Bill and Melinda Gates Foundation, Nacuity Pharmaceuticals.

COMPANY DATA

DUNS: 786575287; Cage code-6SVP3; NAICS CODE-541714

Will Accept Credit Cards