

BRTT GLP Core

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BRTT GLP Core Objectives

- To advise and establish strategy for pre-clinical testing needs of the Nanoparticle investigator.
- To establish efficient GLP protocol designs that are compliant with current FDA requirements.
- To schedule GLP toxicology studies at Ricerca when necessary.



BRTT GLP Core Contacts

- General Questions – Core Director – Jim Ault, VP Regulatory Affairs – (440) 357-3690, email ault_j@ricerca.com.
- GLP Protocol Design – Randy Jones, D.V.M., PhD., DABT and DABVT, VP of Biology Services – (440) 357-3091, email jones_r@ricerca.com; or
Michael Watson, Executive Director of Project Management – (440) 357-3757, email watson_m@ricerca.com.

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- Standard IND studies in various animal models – 14- or 28-day studies required depending on the intended human dose – acute or chronic.
- Maintain animal colonies for most studies to enable quick turnaround, although the rate-limiting step is usually pathology reporting.
- Have extensive experience with Analytical and Bioanalytical testing to support studies.



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- Routinely consult with clients concerning the Chemistry, Manufacturing and Controls (CMC) and Pre-clinical sections of FDA IND submissions.
- Work with clients to ensure that clinical protocols and Investigator Brochures are supported by the pre-clinical studies and formulation of test articles.

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- Routinely develop synthesis routes for lead compounds and metabolites/degradants— from bench scale to Kilo Scale to Production Plant. Radiochemical synthesis is also available.
- Routinely prepare bulk clinical materials for our clients under GMP controls.
- Available full-time staff of Organic Process chemists and engineers.



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- We welcome questions and tours if any investigators are interested.
- Please contact us if you have questions or want to discuss FDA requirements for GLP, GMP or Regulatory submissions.