Flagship BIOSCIENCES
Expert insights for your tissue data.

GLOBAL REGULATORY STRATEGY AND REGULATORY SUBMISSION SUPPORT

New drugs cannot be marketed until the FDA approves them based on evidence of safety and effectiveness. This occurs during their review of data generated during the product discovery/concept phase, preclinical (animal) research, as well as clinical research. The FDA continues to review the safety and efficacy of the product once it is approved as a part of post-market safety monitoring.[1]

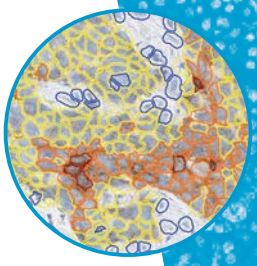
Utilizing relevant regulatory guidance, our regulatory team has assisted numerous clients with their development by providing strategic advice and preparation of regulatory submissions. Through strategic regulatory consulting and integrated regulatory submissions, we ensure that your development team is supported through every phase of your drug development life cycle.

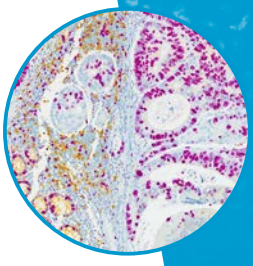
Our services and support include:

- Biomarker development strategy and regulatory pathways
- Assay development and biomarker study design
- Companion Diagnostic (CDx) planning and regulatory development
- Data review and analysis
- Regulatory meetings and interface with the FDA
- Regulatory submissions and maintenance: pre-submission background information packages, pre-Investigational Device Exemption (IDE) and IDE filings, pre-Investigational New Drug (IND) submissions and materials, and preparation of IND files

These services are amplified with the use of Flagship's proprietary image analysis platform which provides the industry's most accurate tissue data sets that cannot be obtained with manual pathology alone.

At each step in the process, our team will provide contextual tumor and immune data to ensure that the best patients as well as the most appropriate endpoints, are achieved. Due to the large volume of data that is generated, cut-point evaluation can be performed, and even adjusted. at any stage to mitigate risk.





1. National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies; Board on Chemical Sciences and Technology; Board on Agriculture and Natural Resources; Board on Life Sciences; Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System. Washington (DC): National Academies Press (US); 2017 Jun 28.

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ABOUT US

Founded in 2009 and headquartered in Westminster, Colorado, Flagship Biosciences, Inc. is a technology-driven tissue analysis services company delivering the most accurate and informative data available. We are revolutionizing tissue analysis to improve drug development and diagnostics using the power of AI with a consultative approach.

Our services and technology dramatically improve on the data and interpretation from traditional pathology methods, eliminating variability associated with typical tissue assessments, and bringing new insights to tissue analysis results.

We provide expert scientific consultation on every project. Our team interprets results, xcontextualizes tissue biology, and identifies the best course for success.

TO LEARN MORE ABOUT FLAGSHIP

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