Regulatory services at Touchlight

Our expert regulatory support team is dedicated to working closely with our clients, providing expert advice and guidance to ensure smooth transition of drug programs utilising enzymatic doggybone DNA (dbDNA™) , from pre-clinical into clinical development and commercialisation.

Regulatory status of dbDNA

Our regulatory team has broad experience in product development operations, Quality Assurance (QA) and CMC regulatory affairs and has engaged with all major regulatory agencies including the FDA, EMA, MHRA and ANSM in relation to dbDNA technology utilisation in ATMP and DNA vaccine applications.

dbDNA has been approved for First-In-Human (FIH) clinical trials in both the US and EU for AAV and mRNA therapeutics. Multiple Investigational New Drug (IND) and Clinical Trial Applications (CTAs) are ongoing for a range of advanced therapies. Additionally, the UK's MHRA has issued an ILAP passport for a dbDNA-based vaccine, which provides access to developing a product-specific Target Development Profile (TDP) with the MHRA and their partners to accelerate the time taken for an innovative product to reach the market.

Touchlight also has a Drug Master File (DMF) filed in the US for the dbDNA process, ready for cross reference in INDs.

Touchlight provides the following regulatory support services:

- Regulatory strategy for products utilising dbDNA™ either as a critical starting material or as an active pharmaceutical ingredient (API).
- Support for health authority interactions, including preparation of documentation for pre-IND or scientific advice meetings.
- IND and CTA support for all phases of the product development including IMPD authoring, and responses to regulatory questions.
- Access to the DMF for GMP grade dbDNA thereby enabling regulatory acceleration in US.
- Change control assessments and regulatory advice.
- Preparation of submission documents for IND or CTA amendments and post approval variations.

United States

2	1
INDs accepted	DMF

European Union

1	2	1
CTA accepted	CTAs ongoing	ILAP