Device Development Regulatory Support

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

When a company develops a product such as an instrument and/or consumable for use in a cell and gene therapy process, one of the steps is to get that product approved for its intended use. In this case study, a client requested regulatory guidance for assistance in achieving this step.

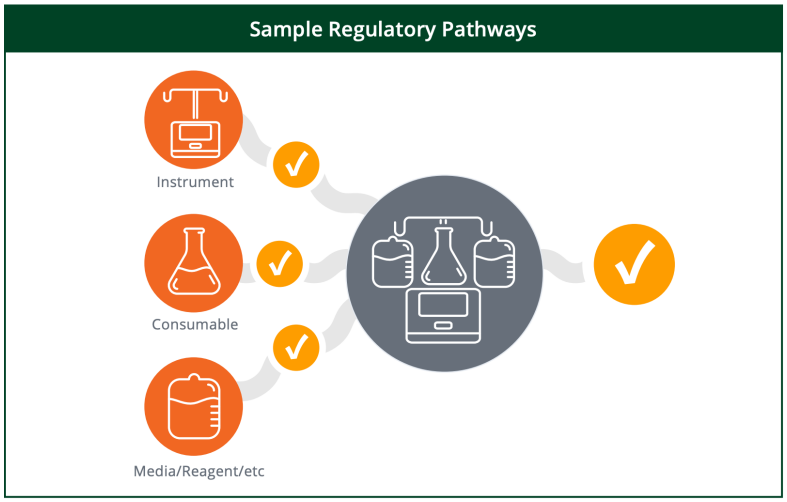
Core Capabilities

DHC's Approach

1. First, we ensured a thorough understanding of the core technologies in question by extensively reviewing technical documentation and speaking at length to the development team.
2. Then, we generated a list of regulatory references as well as a statement of intended use. This material was reviewed in tandem with the client's development team.
3. If further development or higher volume manufacturing would be required, we have the ability to assist in identifying engineering groups and manufacturing partners.
4. During #2 above, we identified the potential regulatory pathway(s) to approval, including development of the quality system that would be required for the product.
5. After identifying the types of verification testing and validation testing that would be required for the product, we wrote and executed studies on behalf of the client.
6. The next step was to meet with the regulatory agency and submit any necessary regulatory documentation. The combination of an instrument with a consumable increases the scope of regulatory requirements needed, with minimal overlap in testing and documentation (as demonstrated in the sample pathway illustrated here).

The Impact

The client cleared the regulatory hurdle(s), allowing for their equipment to be utilized in accordance with its intended use in the manufacturing process of a Cell or Gene Therapy.



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