Submission of Information on a Complex Inhaled Device to the FDA

The Situation

DLRC partnered with a global biopharmaceutical company who are developing next-generation technology around inhaled devices. The client was looking to register its inhaled device with the FDA and sought support from DLRC to compile and submit the required device information. The DLRC CMC and MedTech experts worked with the client over a six-month period. The DLRC regulatory experts and the DLRC Inc. team also acted as the US agent for the filing.

The challenges were significant in that neither the client nor DLRC had submitted this type of application to the FDA previously, hence the level of information and the level of detail required was uncertain at the onset of the project.

DLRC's Solution

DLRC adopted a highly collaborative approach with the client and set up a project team, including the key personnel from both companies, working on the project. The team produced a high-level timeline and reviewed it regularly during project meetings. A clear deadline for the submission date was agreed at the outset of the project. With a strong PM infrastructure in place, the following describes the sequence of events for the project:

- The first steps taken by DLRC were for the CMC and MedTech experts to research the available device guidance in the USA. The team carried out this work to understand the technical and regulatory requirements for the submission.
- The next steps were to create a template in the eCTD format to initiate the submission compilation process with the client.
- The client then provided a European submission for the inhaled device with some of the required information. DLRC used this to populate the submission template and identify any gaps.
- DLRC and the client then identified the information needed to fill the gaps, and the client gradually provided that information over time.
- The client then reviewed the now-complete submission file and received approval from senior management. Regular comments resolution meetings were held at this stage of the project.
- DLRC then published the submission and filed it via the FDA's CDER NextGen Portal. An acknowledgement letter was received shortly afterwards.

The team submitted the application exactly on time. The next step is to await comments from the FDA.

The Outcome

DLRC delivered a robust device submission for the client, on time and within budget. This enabled the client to further progress their project in line with their long-term strategy for this inhaled device.

DLRC's experienced team of CMC, MedTech and regulatory experts were able to provide a high-class service to the client at all stages of the project using their global team with the UK team doing the bulk of the CMC, MedTech and regulatory work and the US team providing seamless support acting as the US agent for the client and advising the UK team at the outset of the project and as the project proceeded.

If you, too, seek the support and expertise of DLRC in your regulatory endeavours, we invite you to reach out to us at hello@dlrcgroup.com. Together, we can turn your regulatory challenges into successes.

DLRC Group
hello@dlrcgroup.com
www.dlrcgroup.com