Submission of Information on a Complex Inhalation Device to the FDA

The Situation

DLRC partnered with a global biopharmaceutical company who are developing next-generation technology around inhalation devices. The client was looking to register its inhalation 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 for over a year with support from the DLRC regulatory experts and the DLRC Inc. team, who acted as the US agent for the filing.

The challenges were significant in that, as both the client and the DLRC team had limited experience in submitting this type of application to the FDA previously, 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. A high-level timeline was produced and reviewed at regular project meetings, with a clear deadline for the submission date 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 in order to understand the technical and regulatory requirements for the submission.
- The next steps were to create a FDA compliant template in the eCTD format to initiate the submission compilation process with the client.
- The client then provided a European submission for the inhalation device with some of the required information. DLRC used this to populate the submission template and identify any gaps.
- DLRC, along with the client, then established what information was required to 'fill' the gaps, and the client supplied that information over the course of time.
- The submission file was reviewed by the client and approved by the client's senior management. Several comments resolution meetings were held to finalise the submission files.
- DLRC then published the submission and filed it via the FDA's CDER NextGen Portal.
- The DMF submission was then acknowledged by the FDA.
- DLRC also supported maintenance activities following the initial filing.

The Outcome

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

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