Case Study:

Regulatory assessment, compilation & submission of dossier in eCTD for cardiovascular generic drugs

Client

USA based generic manufacturers.

Products

A Cardiovascular Drug

Product Categories

Generic Drug

Countries of Interest

USA

Services offered

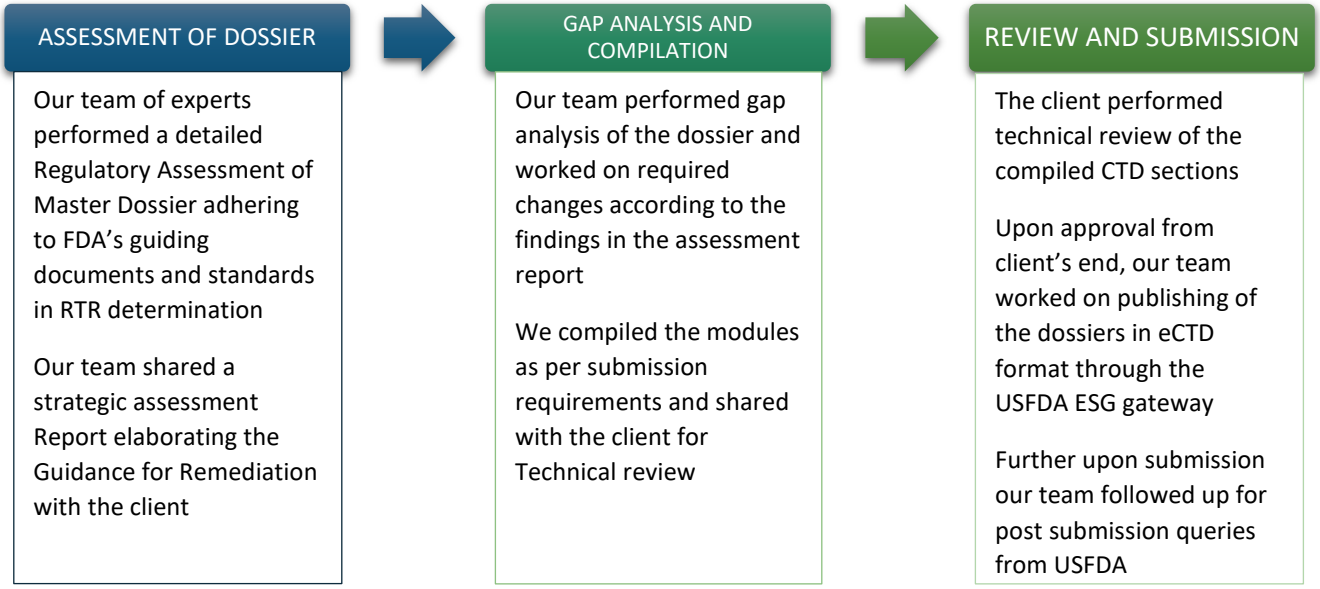
ANDA RTR Response

Client Situation

The Client is a US based pharmaceutical company focusing on generic cardiovascular, Oncology and Respiratory therapeutic drugs. They had filed an ANDA for one of their Cardiovascular generic drugs but unfortunately their ANDA Filing had caused FDA to Refused to Receive (RTR). They had to respond within a short timeframe as suggested by USFDA and hence were seeking a partner to support them with regulatory assessment of their documents by finding gaps and help with the dossier submission to USFDA with a quick Turnaround Time (TAT).

Aariya's Solution

Aariya's team brings decades of experience with preparation of ANDAs, we have our team of regulatory experts and project managers in USA and our deep knowledge and expertise standout as a partner of choice for Generic pharmaceutical companies. We understand that under the enactment of the Generic Drug User Fee Amendments of 2012 (GDUFA), the Office of Generic Drugs (OGD) issues RTR action to an organization whose ANDA has not sufficiently permitted information required for approval. Aariya conducted strategic assessment of client's dossiers and did an end-to-end Gap Analysis pertaining to insufficient information. Our team of experts worked diligently on the remediation planner to achieve the goal of submission to USFDA with a quick TAT. We meticulously planned and managed each step considering the response timelines given by USFDA by providing comprehensive strategic inputs enabling ANDA approval with USFDA using following process:



Key Highlights

- Client had a stringent timeline as it had received RTR from the USFDA, our team of experts supported them in achieving the same
- Client could benefit from Aariya's approach of right Planning, timely Execution, and conclusion (PXC Strategy)
- A one-stop-solution for all of Client's needs driven by Client focus and ownership
- The client received the approvals for their generic drug within stipulated timelines