Publishing – Marketing Campaign in US, EU, CA & CH

A global pharmaceutical company specialising exclusively in the research, development and marketing of medical solutions for dermatology recently entrusted to BlueReg the publishing of an initial Marketing Authorisation Application (MAA) dossiers for Europe, Canada & Switzerland + Responses to Questions for United States, Europe, Canada & Switzerland.

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Challenges

The Publishing Team had to face multiple Challenges

1.EU Dossier :

- o **Two weeks** to build the entire dossier with full new Module 3 – Only Modules 4 & 5 were kept from US NDA Dossier
- o Set all hyperlinks in Modules 1, 2 and 3
- o Build Module 1 for decentralised procedure (DCP) submission (14 Countries)

2. CA NDS Dossier :

- o **Four weeks** to build the full dossier with entire new Module 3
- o For Technical Reasons, re-set of all hyperlinks pointing from Module 2 Clinical Sections to Module 5
- o Build Module 1 for CA submission
- o Reformatting of Module 4 nonclinical reports and Module 5 clinical reports in order to make them fully compliant with Canadian Electronic Submission Requirements.

3. CH MAA Dossier :

- o Publish the dossier in Client's Environment with CH DTD 1.3 before the CH DTD 1.4 becomes Mandatory (very short timelines)
- o Publish the D106 EU first set of responses in parallel of the CH Initial Submission (facing technical hyperlinking issues with client's publishing tool related to file re-use in parallel submissions)
- o Implement numerous last-minute changes (i.e. inclusion of full Active Substance Master File (ASMF) open part with separate M3 documents)

4. Technical Aspects :

- o Working in Client's Environment (Tools & Processes)
  - Publishing Tools
  - Formatting Tools
  - EDMS System
  - Procedures and Supportive Documents
  - Others (Sharepoint; Virtual Machine, Validators, ...)

BlueReg Support

BR put in place a team of highly experienced consultants with solid expertise in publishing to meet the specific project needs within short timelines.

1. BlueReg provided experienced Publishers with the client's tools & Processes

o Publishing /Electronic Document Management
  - Publishing Software
  - Electronic Document Management System
o Formatting / Document Compliance
o Back-up Solutions
  - BlueReg Publishing Environment

2. Specific zone expertise and support for this project

o US FDA
o CA Health Canada
o SwissMedic
o EU DCP

3. Project Management

o Planning, managing and ensuring on-time Published dossiers to meet tight submission timelines
o Provide advice to optimise client's process in terms of efficiency and quality
o Reactivity implementing last minute changes requested by the client, managing /resolving technical issues with client's publishing tool, ensure high quality publishing service (identified missing sections, formatting issues etc)

Achievements

• US Dossier

o All response sequences submitted on time with no Technical invalidation

o Approval received as per client's expectations

• EU Dossier

o All response sequences submitted on time with no Technical invalidation

o Approval received as per client's expectations

• CA Dossier

o All response sequences submitted on time with no Technical invalidation

o Approval received as per client's expectations

• CH Dossier

o Initial Dossier Submitted on time

o Assessment still on going

In conclusion :

The BlueReg Publishing teams was able to submit the initial registration for Europe and Canada in accordance with the deadlines provided by the client and in a complicated framework (challenging timelines, customer environment and tools, etc ...).

The team then handled the entire question and answer period for all countries in parallel, including the initial submission for Switzerland. Again, all sequences were submitted on time and within the deadlines provided by the agencies without any technical invalidation. To date the US, Canada and Europe have registered the drug to the great satisfaction of the Client.