Case Study

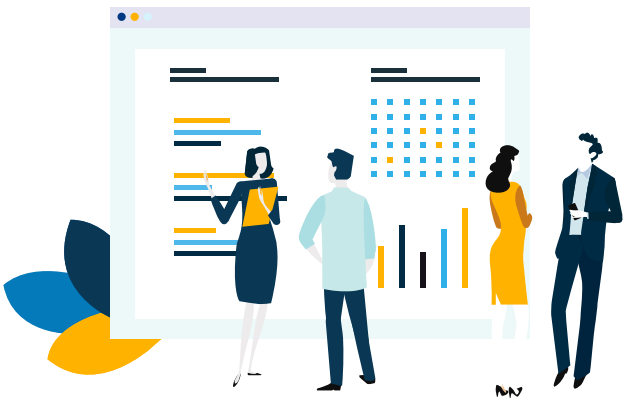
Central coordination of promotional material review through a dedicated software.

Scope :

BlueReg supported a US based client with its promotional launch campaign in Europe for their new medicinal product. BlueReg provided full coverage for all aspects of setting up and coordinating the global and local reviews of the various promotional items of the launch campaign.

Challenges :

BlueReg experts assisted the client with the regulatory reviews through a professional software specifically designed to allow the creation, review, and management of compliant items.



The challenges associated with this project were :

- Coordination of the global and local reviews of many promotional items involving several reviewers, which were both internal BlueReg consultants and worldwide partners.
- Deadline management. BlueReg was faced with expedited reviews involving multiple partners from multiple countries and different time zones.

BlueReg support :

Thanks to a well-structured outsourcing platform, BlueReg put in place a team of consultants and partners with solid expertise in promotional regulatory review to meet the client's needs.

The Software

- The software allows pharmaceutical companies to easily outsource the review of promotional materials to BlueReg. Indeed, specific workflows simplify the distribution and allows the medical, legal, and regulatory (MLR) experts to review in parallel and approve faster the promotional items. The client can assign tasks to BlueReg experts who can directly access the item to review and comment.
- The software allows you to associate other documents with the promotional item to be reviewed (e.g. related documents, attachments, etc.). In order to facilitate the review, it also allows references to be anchored directly in the promotional item (linked documents).
- Promotional review through appropriate software enables compliant management and monitoring of the different versions of items and their status.

Development of global promotion campaign

The BlueReg consultants who performed the global promotional review are experts in European promotional regulations and requirements and have excellent command of the review software.

The Regulatory Affairs Consultants:

- Provided global review of all types of promotional items (e.g. presentations for congresses, visual aids, website, etc.) against the applicable regulations and codes (e.g. IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), EFPIA (European Federation of Pharmaceutical Industries and Associations)).
- Delivered a high-quality regulatory review, on time, through the review software:
    - Commented directly on the items to be reviewed in the software and affixed a "tag" to each one (in particular, #mandatory or #optional).
    - Collaborated with other reviewers (MLR reviews in parallel).
    - Assigned a verdict to the task ("Approved", "Approved subject to changes" or "Revise and resubmit").
    - Performed additional round of review if previous verdict was «Revise and resubmit». At that time, through the software, the client can reply to comments made by the regulatory consultant during the previous review and/or provide further information.

Coordination of local reviews :

The Regulatory Affairs Consultant:

- Oversaw the local deployment of the promotional campaign for review.
- Acted as the main contact person for an optimal coordination of reviews.
- Received from the software the promotional tasks to be reviewed, recorded them in a tracking table, and dispatch them to the relevant local partners.
- Provided regular updates on the project's progress to the client (e.g. weekly meeting, summary emails).
- Acted as an intermediary between the client and local partners when further information is needed for the review.
- Ensured that deadlines were met by liaising with local partners if necessary.
- Received feedback, comments and verdicts from local partners and shared them with the client through the review software.

The local partners:

- Provided local expertise on domestic promotional regulation and requirements.
- Delivered a high-quality, on time, regulatory review for every promotional item received.
- Acted as local representative responsible for promotional activities when needed (e.g. Information Officer in Germany).

Achievements :

With its outsourcing platform dedicated to the review and validation of promotional materials, BlueReg provided high-quality support by coordinating and handling the global and local item reviews on time. BlueReg gave relevant recommendations and reviews through the software which resulted in efficient approval of items. The client appreciated BlueReg's contribution to their launch promotional campaign and the valuable regulatory expertise provided which allowed a great improvement in promotional items quality.