CASE STUDY

OUTSOURCING PLATFORM ON PROMOTIONAL MATERIAL SERVICES

Review and assessment of a chatbot interactive tool available on an Internet website, among European regulations

A pharmaceutical company contacted BlueReg experts on promotional material for review of a non-promotional website and associated chatbot. The chatbot is an interactive tool with which the user can interact. Different information, in relation with the website on which the tool can be found are available on the chatbot. The chatbot will ask questions to the user and the user will have different possibilities of answers.

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Challenges

A pharmaceutical company contacted BlueReg experts on promotional material for review of a non-promotional website and associated chatbot. The chatbot is an interactive tool with which the user can interact. Different information, in relation with the website on which the tool can be found are available on the chatbot. The chatbot will ask questions to the user and the user will have different possibilities of answers.

BlueReg support

BlueReg is the strategic partner to meet your goals for worldwide promotional material review and validation for drugs and medical devices. We provide a broad range of services linked to the review of promotional material for international congresses and local compliance.

These flexible solutions range from an integrated package of services, to adapted ad-hoc regulatory and technical support. Our goal is to explore innovative approaches and provide relevant advice to ensure you maintain your competitiveness in this complex and changing regulatory environment.

The client gave BlueReg experts access to an interactive version of the chatbot, which reflects the one they intend to be made available to the user and an Excel file compiling the information given by the chatbot section by section.

In this written document, all the sequence of questions raised by the chatbot to the user, possibilities of answers for the user and information given by the chatbot were given, together with a link to access the gifs included in the chatbot whenever they will appear during the conversation on the chatbot.

With this information BlueReg experts could review consistency of the entire information given in the chatbot and test it in real use.

It is important to mention that the availability of both types of data, i.e. demonstration version of the chatbot and written version of all sections, is necessary for the review.

Regulatory comments about the tool (e.g. relevance of the information given as per the regulatory guidelines, inadequate gif based on the information given in the tool...) have been made on the Excel file and provided to the client.

In addition, in parallel the client asked for regulatory review of the website so consistency between the website and the chatbot has also been assessed by BlueReg experts.

Achievements

- Perform regulatory review of an interactive tool which offers multiplicity of possibilities depending on the user's answers
- Customer's recognition of Blue-Reg's expertise for non-promotional & promotional review

How BlueReg can support you ?

Outsourcing Platform on Promotional Material Services "OPPROS"

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Our Services

- Regulatory and medical review and validation of all advertising and promotional materials at the global and local level:
- Clear, concise market feedback provided on alternative options and risks associated with the promotional materials for decisions to be undertaken for each piece / market
- Worldwide network of local partners, providing the services of local signatories / person responsible as required in line with local requirements (e.g. The Association of the British Pharmaceutical Industry (ABPI) signatory in the United Kingdom, Information Officer (Informationsbeauftragter) in Germany, Regulatory Scientific Services in Italy and Responsible Pharmacist in France)
- Submission of materials to regulatory agencies as required at a national level
- One identified project manager as your central contact point and campaign oversight co-ordinating all worldwide activities
- In addition, BlueReg can support throughout the full set up, training and validation of your procedures: Write or review Standard Operating Procedures (SOPs) and working instructions on a global and national level
- Provide advice on the software workflow for each market taking into account the local requirements for review, approval and signature of promotional items

Various types of materials

Compliance tools

We manage material according to local market requirements but a broad list of applicable codes of practice include International Federation of Pharmaceutical Manufacturers and Associations (IFPMA code), WHO Resolution Ethical Criteria for Medicinal Drug Promotion, European Federation of Pharmaceutical Industries and Associations (EFPIA code), Medical Device Regulation 2017/745 and local regulations such as the Association of the British Pharmaceutical Industry (ABPI code), French National Agency for the Safety of Medicines and Health Products (ANSM) recommendations, Medicines Australia Code of Conduct, the Brazilian National Health Surveillance Agency (ANVISA) and the Federal Food, Drug and Cosmetic Act.

Our clients

Our clients range from start-ups to global pharmaceutical companies, requiring a temporary or permanent need for support with activities concerning promotional material review and validation.

BlueReg Expertise

BlueReg utilises experienced team members to review each material for compliance against international and local market specific codes / guidance. In addition, the expert reviewers provide further guidance based on their local experience to guide companies through the complex and diverse local requirements which are often challenging for global project teams to align campaigns and/or materials.

For more information please contact us

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