



#### Client:

- 🌐 A world leader in the Pharmaceutical Sector, International Department of Regulatory Affairs

#### Context:

- 🌐 Delay in treating variations of several hundred international Marketing Authorization Application variation dossiers (MAA).

#### Objective pursued:

- 🌐 Make up this delay in order to assure the continuity of the industrialist's regulatory obligations with regard to control authorities of exporting countries.

#### Organization of the mission:

- 🌐 Compiling the elements requested in each variation (documents, samples, packaging, legalizations, etc)
- 🌐 Posting elements to every country concerned (83 total)
- 🌐 Enriching the centralized follow-up data base of regulatory activity.

#### Means of implementation:

- 🌐 4 in-sourcing people for 4 months, all university graduates in foreign languages.
- 🌐 Setting up the mission lasts only 5 weeks in a complex profession context.

#### Results:

- 🌐 Objective completed on time.
- 🌐 The client is satisfied with the service and is favourable to making new requests for assistance.

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**Client:**

- 🌐 A world leader in the Pharmaceutical Sector, Department of Clinical Operations.

**Context:**

- 🌐 Appreciable and regular growth in administrative work in the Department, as well as its variations submissions over time. This growth is not compensated by an equivalent growth in internal resources.

**Objective pursued:**

- 🌐 Respond to the increased work load and its variability, through a new administrative resource organization, including setting up outsourcing. Therefore optimizing administrative efficiency and flexibility of the Department of Clinical Operations.

**Organization of the mission:**

- 🌐 Advising the client in the framing, organization and setting up of the outsourcing project.

**Means of implementation:**

- 🌐 1 consultant specialized in organizing the administrative outsourcing process.
- 🌐 1 consultant specialized in the pharmaceutical industry and profession organization risk management.

**Results:**

- 🌐 Mission in progress.

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#### Client:

- 🌐 A world leader in the Pharmaceutical Sector, R&D Department (Regulatory Affairs).

#### Context:

- 🌐 Respond to the obligations arising out of the new European Paediatric Regulation on the paediatric effects of drugs.

#### Objective pursued:

- 🌐 Assuring the conformity of the customer's operations with a significant regulatory evolution.

#### Organization of the mission:

- 🌐 In the framework of achieving conformity with the European Paediatric Regulation and adhering to the implemented methodology and using all tools and computer applications necessary, the mission was the following :
  - establish an inventory of the clinical studies
  - verify if these studies were subject to submission to competent regulatory authorities
  - verify if the mention paediatric exists in the summaries of the product's characteristics
  - make a link between these mentions and studies.
- 🌐 This for all the customers' MAAs in the 30 countries concerned.

#### Means of implementation:

- 🌐 2 people, university graduates in foreign languages and scientific training in in-sourcing for 6 months.

#### Results:

- 🌐 Mission in progress.

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#### Client:

- 🌐 A world leader in the Pharmaceutical Sector, International Department of Regulatory Affairs.

#### Context:

- 🌐 Setting up a centralized follow-up data base of regulatory activities and regulatory processes on a global level. A real group project, involving all the client's subsidiaries and international representatives in 110 countries. The objective pursued by the client and improving information accessibility, being able to respond in a simpler, faster and reactive way to the requests coming from control authorities.

#### Objective pursued:

- 🌐 Identify and collect all follow-up information on regulatory activity concerning all the products sold in all the countries up to 2006.
- 🌐 Validate this information and input the data into a new central data base developed to this effect.

#### Organization of the mission:

- 🌐 A test phase of 4 months in order to frame the mission accurately and put a process, controls, metrics and reporting tools in place.
- 🌐 An operational phase of 15 months, to collect, control, validate and capture information from 110 countries around the world.

#### Means of implementation:

- 🌐 1 pharmacist in charge of the project + 6 people, university graduates in foreign languages or scientific training in in-sourcing for 19 months.

#### Results:

- 🌐 Mission in progress.

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#### Client:

- 🌐 A world leader in the Pharmaceutical Sector, International Department of Business Regulations.

#### Context:

- 🌐 Setting up the format e-CTD for legacy MAA dossiers and subsequent variations, simultaneously with their migration into an Electronic Document Management System (EDMS).

#### Objective pursued:

- 🌐 Improve the consultation and accessibility to information of the client's products.
- 🌐 Allow future submissions access to the e-CTD format.
- 🌐 Eventually, implement a real life-cycle document management.

#### Organization of the mission:

- 🌐 Identify the existing computer contents in the present file system for the MAA files of 7 drugs, presenting them in e-CTD format, and then transferring all of them into the new EDMS system. Make the necessary controls and corrections to the integrity of the content finally stored in the EDMS.

#### Means of implementation:

- 🌐 1 person, university graduate in foreign languages and scientific training in in-sourcing for 6 months.

#### Results:

- 🌐 Mission in progress.

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