



CASE STUDY

Project in the pharmaceutical industry
Solution and workflow

SCENARIO

→ THE CLIENT

An international group with Italian roots, specializing in the development and production of Active Pharmaceutical Ingredients

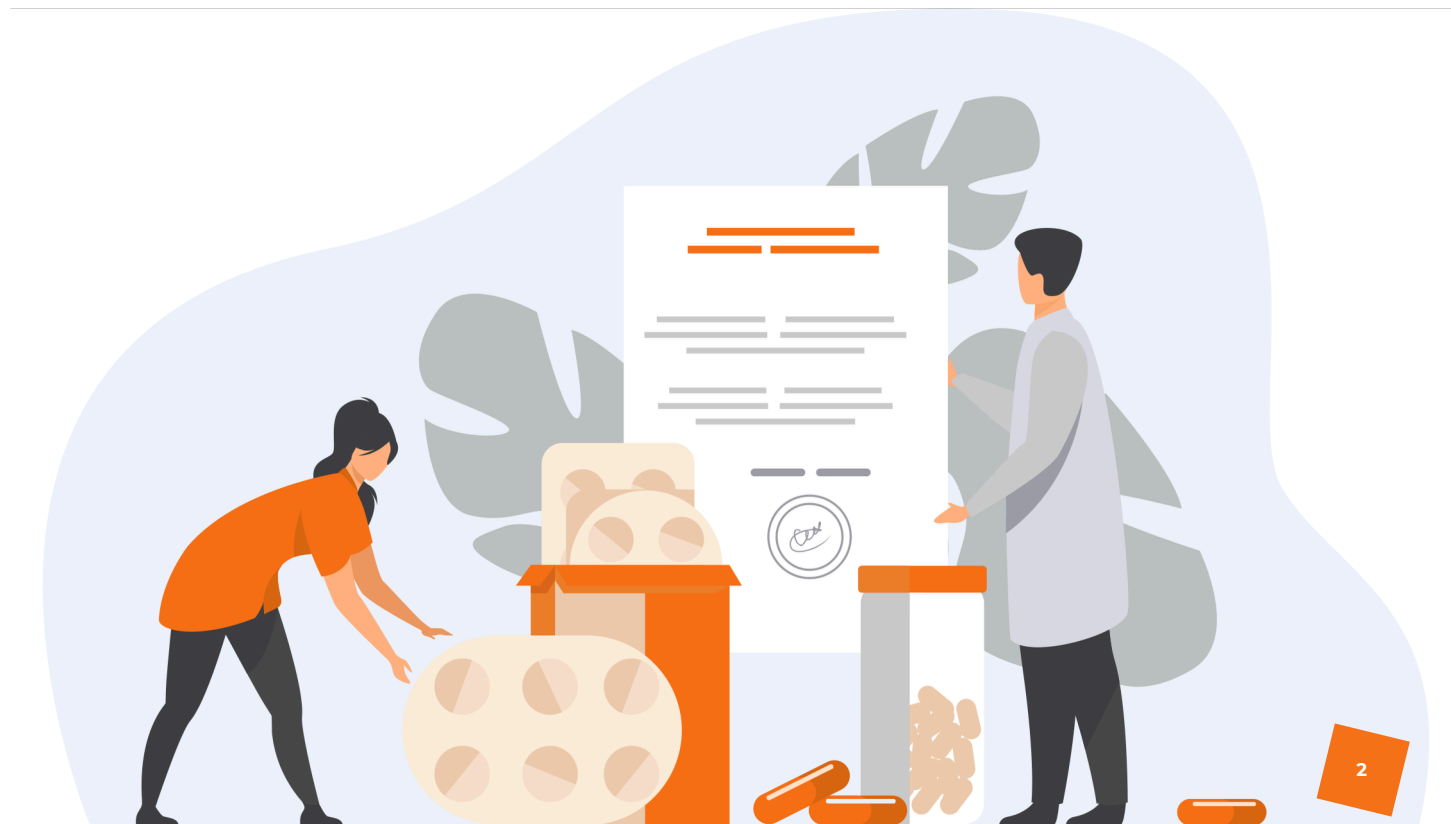
→ THE DEMAND

They have won a significant contract in Canada and must submit all the documentation related to the AIFA inspection of their quality system to Health Canada.

The Corporate Regulatory Affairs Manager is seeking a certified partner to translate large volumes of documents from Italian to English on a very tight schedule. Some of the translated documentation will also be used for a GMP Clearance procedure with the Australian Department of Health (TGA).

→ TYPE OF DOCUMENTATION

- Inspection Report
- CAPA Plan
- Site master file



CHALLENGE

→ **280,000 WORDS TO BE TRANSLATED FROM ITALIAN TO ENGLISH**

→ **9 BUSINESS DAYS TO DELIVER THE PROJECT**

→ **NON-EDITABLE DOCUMENTS**
handwritten in the original and scanned, necessitating **extensive Desktop Publishing work** by our editors

→ **ISO CERTIFICATIONS FOR THE TRANSLATION INDUSTRY**

UNI EN ISO 17100:2015

for translation

UNI EN ISO 18587:2017

for post-editing of machine translation

TIMELINE

✓ **November 9th**
Initial contact and prompt delivery of the quotation

✓ **November 14th**
Start of work

✓ **November 23rd**
Completion of delivery

✓ **November 23rd**
Presentation of the client to Health Canada



SOLUTION



DEDICATED INTERNAL TEAM FOR THE PROJECT

to organize, execute, and meticulously track the progress of work on schedule (Project Manager, Vendor Manager, Editor, Linguists, Quality Specialist, Technology Specialist)



POOL OF TRANSLATORS WITH APPROPRIATE SKILLS AND EXPERIENCE

selected after a detailed evaluation of their profiles, availability, and capacity



DETAILED SCHEDULE

of translator deliveries, staggered to allow reviewers to promptly address their portions of the project, in order to optimize delivery times



SHARED REPOSITORY AMONG INTERNAL TEAM, TRANSLATORS, AND CLIENT

for managing translation assignments, delivery schedules, real-time progress tracking, translator guidelines, shared memory, and a query sheet for addressing translators' terminology questions and concerns



FINAL ADDITIONAL MANUAL CHECK

of target texts against source texts, with particular attention to dates, tables, and handwritten sections

WORKFLOW

SEAMLESS INTEGRATION OF PROCESSES AND PEOPLE

The project's complexity demanded a precise and timely workflow, detailed in this graphic.

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- 1 FORMATION OF A DEDICATED INTERNAL TEAM
 - 2 DEFINITION OF THE TRANSLATOR POOL
 - 3 CREATION OF A SHARED REPOSITORY
 - 4 FILE PREPARATION
 - 5 PROJECT SETUP IN THE CAT TOOL
 - 6 ASSIGNMENT OF TASKS TO TRANSLATORS
 - 7 TRANSLATION
 - 8 HUMAN REVIEW
 - 9 FINAL AUTOMATED REVIEW
 - 10 ADDITIONAL MANUAL CHECK
 - 11 DELIVERY TO THE CLIENT
 - 12 FEEDBACK COLLECTION AND MANAGEMENT



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