EU Release and the Importation of IMPs in the European Union

CASE STUDY:
EU BATCH CERTIFICATION OF A BIOLOGICAL PRODUCT MANUFACTURED IN CHINA FOR USE IN A EUROPEAN CLINICAL TRIAL

European regulations require that a qualified person (QP) to certify that every investigational medicinal product (IMP) entering the EU has been manufactured in accordance with all applicable laws and regulations. This case study outlines how CSM helped one sponsor's contract manufacturing organization (CMO), located in China, import a biological product for use in a clinical trial in the EU. This was the first time the CMO had sent IMPs to the EU, so it required an especially high level of guidance to be sure the CMO complied with all required standards.

CHALLENGES

EU regulations require the QP to issue a batch certificate confirming the IMP was manufactured, packaged and labeled in accordance with current good manufacturing practices (cGMPs) and the product specification file.

This trial presented three major challenges:

1. Although the sponsor planned to conduct the clinical trial in Europe, they chose to organize production of the IMP, a biological peptide, in China with a contract manufacturing organization (CMO). Thus, in addition to the problems of day-to-day communication, only a small portion of the manufacturing documentation was available in English. This created an issue for the timely delivery of the appropriate, complete and translated documentation to the authorities.

2. Because the medicinal product was produced in bulk, it was necessary to perform a secondary packaging and labeling operation before distribution to six EU countries, each with a different national language. Furthermore, the IMP itself was sensitive to temperature (+2-8°C) and light, so it had to be handled accordingly.

3. To import the IMP for use in a clinical trial in European countries, a QP declaration must be signed by a European Qualified Person. An onsite audit had to be arranged to verify the site complied with GMP rules that were at least equivalent to EU cGMPs.

"This project was a specific challenge as the CMO had never manufactured a product to be distributed in Europe before and therefore had to be coached through the process," said Martine Fouarge, Qualified Person at CSM Europe SA. "Added to this was the complex nature of the manufacturing process and the huge volumes of documentation to be reviewed and evaluated."

The generation of the batch certificate was a particular challenge due to the complex manufacturing process of these biological peptides and the large volume of documentation to be reviewed, evaluated, and approved.

CSM'S SOLUTION

- Using its network of qualified auditors, CSM was able to go onsite in China quickly to verify the CGMP compliance of the producer and provide the sponsor with the QP declaration needed. To overcome challenges related to the language, an onsite audit report and IMP documents were rapidly translated from Chinese into English and reviewed by our QP.

- Packaging and labeling production was completed at CSM.
  - Temperature-monitored labeling at 2-8°C with light filters to protect the product was provided.
  - Multi-language booklet labels were produced to maximize flexibility and minimize costs. Thereafter, our QP could generate the final batch release certificate of the packaged and labeled IMP.

- Verification of regulatory authority approval of the clinical trial application and ethics committee approvals were obtained prior to the distribution to sites. This solution ensured that each site had the regulatory green light and could receive IMPs.

RESULTS AND OUTCOMES

The IMP was certified on time so that the clinical trial could be carried out in full compliance with European and local regulations. This was especially impressive because this was the first time this biological product had been released for use in a clinical trial within the EU.

CSM's two established sites in the post-Brexit EU (Belgium and Germany) and in-house QPs make your clinical trial risk free of any Brexit issues.

- CSM's track record of thousands of IMPs being QP released and dozens of audits performed by CSM qualified auditors make CSM the solution to facilitate your clinical trials.
- CSM's combined QP expertise and knowledge of more than 20 years supports clinical trials you can trust, conducted wholly or partially within Europe.
- CSM will provide you with impeccable guidance, support and technical expertise for complex projects with challenging timelines.

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