SYNER-G BioPharma Group

CASE STUDY

Syner-G BioPharma's Strategic Leadership in Regulatory Conformance Checks

How Syner-G BioPharma Facilitated Regulatory Submissions for a Major U.S. Biopharmaceutical Company to Japan's Pharmaceuticals and Medical Devices Agency (PMDA)

ABOUT

Syner-G partnered with a leading, globally recognized biopharmaceutical company, known for providing cutting-edge health solutions. The company's diverse portfolio includes prescription medicines, vaccines, biologic therapies, and animal health products.

CHALLENGE

The client's Japan subsidiary committed to the PMDA and Japan's Ministry of Health, Labour and Welfare (MHLW) to conduct periodic quality conformance checks after on-site inspections revealed gaps between manufacturing documents and submission dossiers, which are legally binding in Japan. These gaps, in violation of the Pharmaceutical and Medical Device (PMD) Act, led to a product recall in Japan. Following the 2016 MHLW notification after Japan's Kaketsuken Raid, regulations tightened, and unannounced health authority inspections increased. In response, the client introduced a stand-alone review process to mitigate nonconformances and protect the quality, safety, and efficacy of its products.

The root cause was identified as errors in manufacturing site documents due to insufficient quality checks, transcription mistakes, mistranslations, and errors in regulatory documents. These issues stemmed from poor communication and inconsistent interpretation of Japan's regulatory requirements.

RESULTS

Syner-G was selected to lead the stand-alone review process from the project's inception. The Syner-G team quickly integrated with the client, understanding their workflows and effectively collaborating with internal and external stakeholders globally. Over four years, Syner-G successfully led approximately 40 projects for products registered or pending registration in Japan, including prescription medicines, biologics, and vaccines. Syner-G also contributed to establishing internal procedures and best practices for the client.

This process involved comprehensive project and resource planning, precise execution, and time management. Syner-G negotiated with CDMOs and manufacturing sites while reviewing a wide range of documents, such as batch records, automation recipes, lab raw data, protocols, validation reports, and more, ensuring alignment with the submission dossiers legally binding in Japan.

THE IMPACT

1. The conformance check centralized site-level documents in a repository, streamlining responses to PMDA inspection requests.
2. Data integrity was ensured by mapping submission dossiers to corresponding manufacturing documents.
3. All site-level documents (e.g., batch records, procedures) were kept current and QA-verified.
4. The process ensured accurate transcription of lab data into dossiers through thorough chemical analysis.
5. Transcription errors between site documents and regulatory submissions were identified and corrected early.
6. Translation errors between local language manufacturing documents and English versions were addressed.
7. Foreign manufacturing sites were confirmed to be accredited by MHLW at the time of submission.
8. Manufacturing documents were aligned with Japanese Pharmacopeia (JP), or updated to ensure compliance where necessary.

> *Syner-G's thorough and detailed checks have supported many successful submissions in Japan. Attentiveness and excellent collaboration were provided for each conformance check completed. It has been a pleasure to work with Syner-G over the past few years.*

9. Syner-G resolved 15% of the gaps identified through the conformance check process.