propharma

CASE STUDY

# Ensuring Compliance: QP Declaration as Your First Step Towards Successful QP Batch Certification

**The radiopharmaceuticals market is rapidly evolving, offering promising new diagnostic and treatment options for cancer and other life-threatening diseases.**

## Challenge

A U.S.-based start-up was preparing to initiate a late-stage clinical trial in Europe for a novel radiopharmaceutical therapeutic targeting Gastroenteropancreatic neuroendocrine tumors (GEP-NETs). These rare and potentially aggressive tumors affect approximately 200,000 patients in the United States alone, with metastatic disease present at diagnosis in 40–76% of cases.

Given the significant unmet need and therapeutic resistance in this patient population, the innovative treatment approach offered a considerable market opportunity.

The sponsor had built a vertically integrated organization to support clinical development but faced critical challenges meeting EU GMP requirements—for example the need for a Qualified Person Declaration (QPD) as part of the Investigational Medicinal Product Dossier (IMPD).

A strong partner was needed for navigating the complex process not only for routine QP certification of the clinical trial material following IMPD approval but for overcoming all obstacles on route towards becoming a Marketing Authorization Holder (MAH).

## Solution

Recognizing the regulatory complexities and time-sensitive nature of the trial, the sponsor partnered with ProPharma in Spring 2022 to leverage ProPharma's fully electronic MIA (Manufacturing and Importation Authorization) services.

With deep expertise in the radiopharmaceutical landscape, ProPharma provided tailored support through a dedicated team of Qualified Persons (QPs) and senior QA consultants.

In June 2022, a ProPharma QP conducted an on-site qualification audit of the CDMO and worked closely with the sponsor to fine-tune the IMPD and ensure GMP compliance. A QPD was rapidly issued, enabling timely submission of the IMPD in Q4 2022. ProPharma's integrated MIA services—designed to streamline both clinical and commercial product pathways—positioned the sponsor to move efficiently through QP certification.

Following EMA approval of the IMPD in late Q3 2023, the first patient dose was certified for use in the European arm of the trial just weeks later.

## Results

ProPharma's involvement enabled the sponsor to accelerate trial initiation, minimizing delays, and significantly shortening time to first-patient dosing.

The high-quality, regulatory-compliant approach fostered confidence in the sponsor's development program and attracted investor interest, further supporting future growth.

With momentum building, the sponsor is now preparing to expand its production capabilities through a dedicated manufacturing facility—continuing its collaboration with ProPharma to support GMP compliance, QMS development, and inspection readiness efforts as the company matures toward commercialization and MAH approval.