propharma

CUSTOM SOLUTIONS FOR COMPLEX NEEDS

scalable.
nimble.
transparent.

EU and UK Batch Release through ProPharma's Manufacturing and Importation Authorisations

Navigating both general and country-specific regulations and requirements to supply medicinal products to the European markets can be a complex challenge for Marketing Authorisation Holders (MAH).

MAHs must create tailored supply strategies per country and establish a legal entity with a Manufacturing and Importation Authorisation (MIA) and a named Qualified Person (QP) in the region, which can be extremely difficult for even the most experienced organizations. The QP is responsible for ensuring each individual batch has been manufactured and checked for compliance with laws specific to the country where certification takes place, in accordance with the Marketing Authorisation (MA) and Good Manufacturing Practice (GMP) requirements. Partnering with ProPharma's industry-leading compliance experts will help unravel these complexities to improve business efficiency, shorten timelines, and reduce overall costs, allowing companies to focus on product development and commercialization to support patient needs and safe outcomes.

ProPharma holds both EU and UK MIA licenses which allows us to help clients overcome the complexities of supplying to the EU and UK markets, such as creating tailored strategies to navigate country-specific and national regulations. MAHs can utilize ProPharma's MIA license and QP in the region to ensure products are released to patients in need across the EU and UK in a quick and flexible way. It can take more than 1 year to obtain their own MIA license, but MAHs can greatly accelerate their timelines to get products listed within 3-4 months utilizing ProPharma's licenses.

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Learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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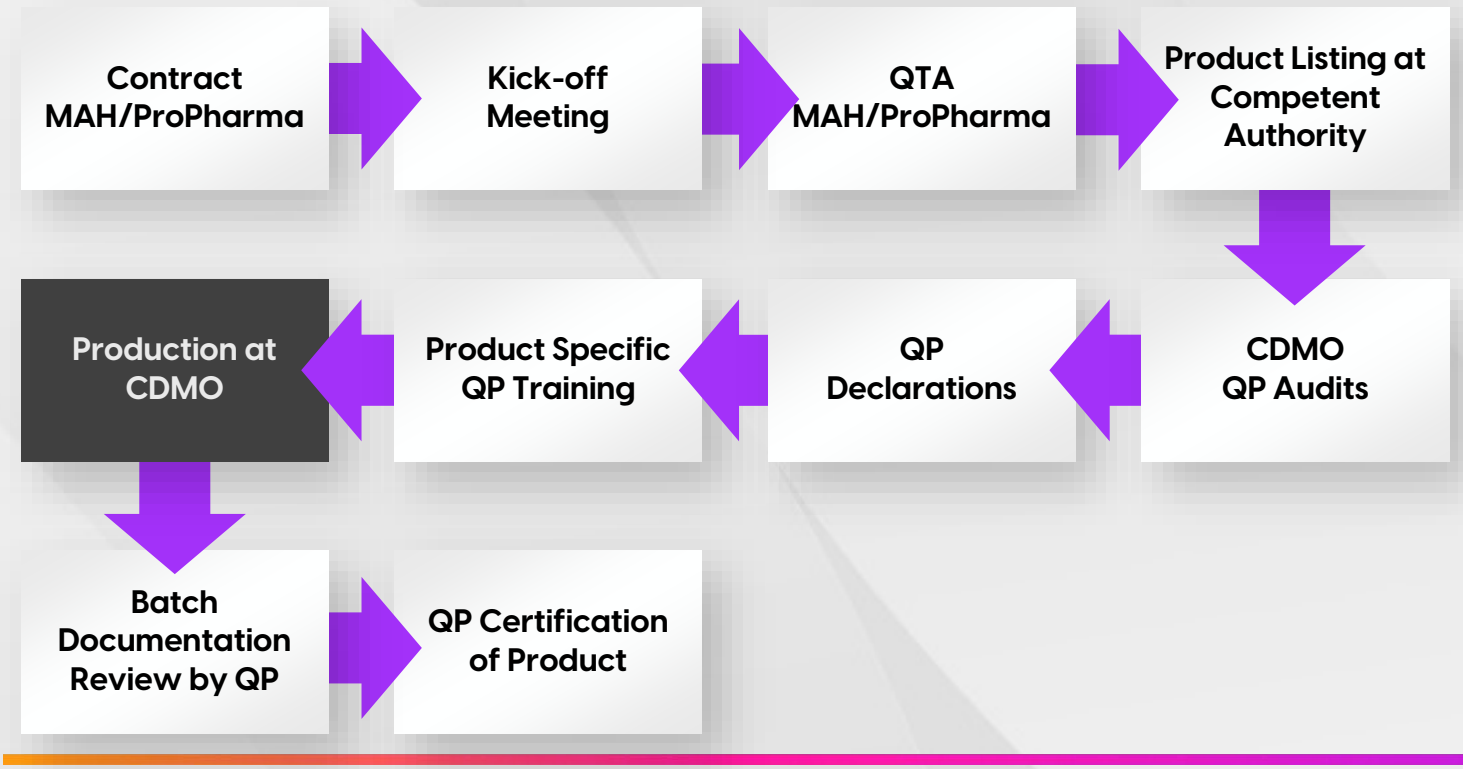
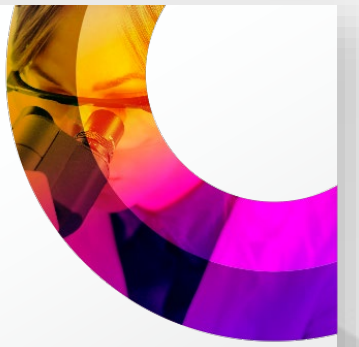
QP declaration of a product's API-sites is a critical factor in your Marketing Authorisation Application or variations to the Marketing Authorisation (MA). The QP declarations can be signed by a ProPharma QP. Through ProPharma's global network of auditors and QPs, we can quickly coordinate and execute audits worldwide as a basis for your QP declarations.

ProPharma can perform QP Batch Certification services under its own MIA licenses for pharmaceutical and biotech clients launching products to the European and UK markets, as well as release for export from EU (e.g., to the United States). This applies to both new and existing products. Listing your products on the ProPharma MIA licenses gives you access to skilled and experienced QP's for multiple types of products/formulations including biologics, ATMPs, vaccines and small molecules.



Improving Patient Health and Safety

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.



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