propharma

Assess Your Progress:
A Quiz for Companies Supplying Pharmaceutical Product to EU/UK/EEC for Clinical Trials or Sale.

For companies seeking to supply their pharmaceutical products in the European Union (EU), United Kingdom (UK), and European Economic Community (EEC) for clinical trials or sale, there are critical factors they must consider.

This 13-question quiz, designed as a progress self-assessment, aims to help you evaluate readiness and compliance with essential requirements.

By addressing key aspects such as project management, legal entities, systems, personnel, supply chain, and importation/distribution, this assessment serves as a valuable tool for ensuring success.

By taking this quiz, you can evaluate your progress and address any shortcomings, ensuring compliance, quality, and successful navigation of the regulatory landscape when supplying pharmaceutical products in the EU, UK, and EEC.

Failing to properly address these items can result in regulatory non-compliance, compromised patient safety, compromised safety, quality issues, distribution problems, supply chain vulnerabilities, and inefficiencies. Therefore, it is important to consider each of these questions carefully and address any areas of weakness or uncertainty to ensure patient safety and regulatory compliance. Good luck!

QP & MIA Self Assessment

Read through each of the questions and mark the appropriate answer.

		Yes	No	Don't Know
01	**Project Management:** Do you have a proactive project management structure to oversee the completion of your Clinical Trial Application or Marketing Authorization Application?	○	○	○
02	**Legal Entity:** Do you have a legal entity in EU/UK/EEC that can act as the Clinical Trial Sponsor or Marketing Authorization Holder (MAH)?	○	○	○
03	**Legal Entity:** Does your legal entity have a Quality Management System appropriate for a Sponsor/MAH?	○	○	○
04	**Resources:** Do you have appropriate resources to handle Post Market Surveillance in regard to Product Quality Complaints, Pharmacovigilance, and Medical Information??	○	○	○
05	**Resources:** Do you have access to a Qualified Person for Pharmacovigilance (QPPV)?	○	○	○
06	**Supply Chain:** Have you identified, contracted, and audited all parts of the supply chain including contract manufacturers, laboratories, and critical service providers?	○	○	○
07	**Licenses:** Are you in the possession of a Manufacturing Importation Authorization (MIA) to enable batch certification inside the EU/UK/EEC or have you found a partner that can provide batch certification services?	○	○	○
08	**Resources:** Do you have access to a Qualified Person (QP) who can release your batches, perform the final batch certification and sign your QP declarations?	○	○	○

QP & MIA Self Assessment (continued)

Read through each of the questions and mark the appropriate answer.

		Yes	No	Don't Know
09	Site: Do you have access to a physical site of importation with a valid MIA-license that can import and quarantine your products until QP-certification?	○	○	○
10	Licenses: Do you have a Wholesaler Distribution Authorization (WDA) in the countries you are planning to store/sell/own/distribute Pharmaceutical Products?	○	○	○
11	Resources: Do you have access to a Responsible Person (RP) or Responsible Person import (RPi) for the UK overseeing your distribution activities?	○	○	○
12	Resources: Do you have appropriate resources to handle Post Market Surveillance regarding Product Quality Complaints, Pharmacovigilance, and Medical Information?	○	○	○
13	Supply Chain: Do you have your supply chain mapped out and risk assessed?	○	○	○

How many 'Yes' responses did you have? TOTAL ☐ ☐ ☐

< 4 Less Than Ideal: Meet with an expert to discuss how best to move forward.
5 – 9 Getting There: Let's chat to discuss how you can effectively support this program.
> 10 Impressive: This is better than most companies. Our experts are happy to be another set of eyes to ensure program is running effectively.

Readiness and compliance are critical components to supplying pharmaceutical products to Europe. ProPharma's industry-leading quality assurance and compliance experts are here to help. Contact us today to schedule a call.