PROPHARMA GROUP®

Improving Patient Health and Safety

Progress Self Assessment

Supplying Your Pharmaceutical Product to EU for Clinical Trials or Sale

Use this readiness questionnaire to assess the current state of your progress. Good luck!

	Yes	No	Don't Know
Do you have a proactive project management structure to oversee the completion of your Clinical Trial Application or Marketing Authorization Application?	○	○	○
Do you have a legal entity in EU/EEC that can act as the Clinical Trial Sponsor or Marketing Authorization Holder?	○	○	○
Does your legal entity have a Quality Management System appropriate for a Sponsor/MAH?	○	○	○
Do you have appropriate resources to handle Post Market Surveillance in regards to Product Quality Complaints, Pharmacovigilance, and Medical Information?	○	○	○
Do you have access to a Qualified Person for Pharmacovigilance (QPPV)?	○	○	○
Have you identified, contracted, and audited all parts of the supply chain including contract manufacturers, laboratories, and critical service providers?	○	○	○
Are you in the possession of a Manufacturing Importation Authorization to enable batch certification inside the EU/EEC or have you found a partner that can provide batch certification services?	○	○	○
Do you have access to a Qualified Person (QP) who can release your batches, perform the final batch certification and sign your QP declarations?	○	○	○
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?	○	○	○
Do you have a Wholesaler Distribution Authorization in the countries you are planning to store/sell/own/distribute Pharmaceutical Products?	○	○	○
Do you have access to a Responsible Person (RP) overseeing your distribution activities?	○	○	○
Do you have appropriate resources to handle Post Market Surveillance regarding Product Quality Complaints, Pharmacovigilance, and Medical Information?	○	○	○
Do you have access to a Qualified Person for Pharmacovigilance (QPPV)?	○	○	○
TOTAL SCORE			

How many "Yes" responses did you mark?

< 4
Uh-oh!

We need to meet immediately to discuss strategy.

5 - 9
Getting There!

Let's chat to discuss how you can effectively support this program.

10 +
Great Job!

Keep up the good work and contact us if you need any help.

Schedule a call with our team to discuss your results!

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