Consultancy Insights:
Interview Series

The significance of QP Services for Product Importation to support development programmes

In our consultancy insights interview series, we review the 'the significance of QP Services for Product Importation to support development programmes''. This interview aims to address the considerations necessary for UK-EU product flow. The interview aims to help pharma and biotech companies understand why QP support is necessary, what it involves, and what benefits can be achieved by involving QPs early in supply chain planning and execution.

Introduction

Mark Dignum is the Founder of Copea Pharma Ltd and Copea Pharma Europe and is a qualified QP. Mark has over 25 years of experience in both operational and quality focussed roles ranging from multi-national organisations to SME's in the UK. His breadth of experience helps to support clients not only with quality challenges associated with batch release but also with the alignment of the commercial challenges in meeting project milestones or supply chain commitments.

The role of the QP

1. **What is a Qualified Person (QP), and what is their legal responsibility?**

   A Qualified Person (QP) is a statutory role in the UK/EU responsible for certifying each medicinal product batch before release. They ensure compliance with GMP, the Marketing Authorization, and legal standards. QPs hold personal legal accountability, including potential criminal liability, prioritizing patient safety over company interests.

2. **Why is a QP needed for product importation into the EU (and export from UK to EU)?**

   A QP is required to certify imported medicines meet EU GMP and Marketing Authorization standards. They ensure products made outside the EU are equivalent in quality and safety, safeguarding patients. For UK–EU trade, post-Brexit, QP oversight is mandatory for regulatory compliance and legal batch release.

3. **How does the QP role differ between the UK and the EU (if at all)?**

   The QP role in the UK and EU is largely the same: certifying batch compliance with GMP and Marketing Authorizations. Post-Brexit, however, the UK and EU require separate QPs for product release into their respective markets, meaning dual certification may be necessary for cross-border supply.

Considerations for Import and Export

4. Please can you explain how the regulatory landscape has changed since Brexit in terms of importing and exporting medicines between the UK and EU?

Since Brexit, the UK is a "third country" to the EU. Medicines moving between the UK and EU now require additional regulatory steps: EU imports need EU-based QP certification, while UK imports need UK QP certification. Separate Marketing Authorizations are required for UK and EU markets. Mutual recognition of QPs no longer applies, meaning dual testing, certification, and pharmacovigilance oversight may be necessary. Northern Ireland follows the EU regulatory framework under the Windsor Framework, adding complexity. Overall, Brexit introduced duplication, extra costs, and administrative burdens for medicine supply between the two regions.

5. What are the practical implications when performing clinical trials where either a comparator product or trial material must cross borders for use?

When clinical trial materials or comparators cross UK–EU borders, dual regulatory requirements apply. Each region requires local QP certification, import licenses, and compliance with GMP. This can cause delays, added costs, and duplicate testing. Sponsors must manage separate supply chains, regulatory submissions, and documentation. Northern Ireland complicates logistics further.

6. What are the implications if a company does not have QP oversight in place when moving products between the UK and EU?

Without QP oversight, products cannot be legally certified or released for use in the UK or EU. This means medicines may be stopped at borders, leading to supply chain disruption, trial delays, regulatory non-compliance, and potential product recalls. Companies risk financial penalties, reputational damage, and patient safety concerns.

7. What does the typical process look like when a QP certifies a batch for import into the EU?/ What documentation and information does a QP typically need from a biotech company?

For EU import, the QP reviews full batch documentation, including the Batch Manufacturing Record, Certificates of Analysis, stability data, and GMP compliance evidence from the manufacturing site. They also need the Marketing Authorization/CTA details, supply chain traceability, and import license. After verifying compliance with EU GMP and regulatory requirements, the QP certifies the batch for release.

8. How does the QP coordinate with CMOs/ CDMOs and logistics partners?

The QP liaises closely with CMOs/CDMOs to review manufacturing, testing, and quality documentation, ensuring compliance with GMP and regulatory requirements. They coordinate with logistics partners to confirm supply chain integrity, import/export licenses, and temperature-controlled transport. Effective communication ensures timely documentation flow, issue resolution, and compliant, secure product release across borders.

The benefits of early QP oversight.

9. Some companies traditionally try to keep QPs at the end of the supply chain. Can you share any examples where the absence of early QP support caused major delays or issues with product release?

Delaying QP involvement can cause significant setbacks. For example, some biotech firms faced EU import refusals because documentation from CMOs lacked critical GMP evidence or Certificates of Analysis. In another case, clinical trial shipments were delayed weeks due to missing QP certification and unresolved deviations, halting patient dosing. Early QP engagement helps anticipate regulatory gaps, coordinate batch testing, and streamline cross-border logistics, preventing costly delays and compliance risks.

11. At what stage in development or commercialization do you think a biotech company should engage with a QP service provider when considering their supply chain?

A biotech company should engage a QP service provider early in development, ideally during process scale-up or before first clinical trial material production. Early involvement ensures GMP compliance, regulatory alignment, and robust supply chain planning. It allows proactive identification of documentation, import/export, and certification requirements, reducing delays during clinical trials and commercial launch, and ensuring smooth cross-border product release.

12. What should biotech companies look for when selecting a QP service provider?

Biotech companies should seek QP providers with proven GMP expertise, EU and UK regulatory knowledge, and experience across clinical and commercial supply chains. Key factors include a strong track record with cross-border imports, robust documentation review processes, proactive regulatory guidance, and effective coordination with CMOs/CDMOs. Providers should offer scalability, reliability, and clear accountability, with independent judgment and legal responsibility for batch certification. Familiarity with both early-stage trials and commercial launch requirements ensures seamless support throughout product development.

13. What questions should a biotech company ask a potential QP provider before engaging them?

A biotech company should ask a potential QP provider:

- Do you have experience with EU and UK GMP and regulatory requirements?
- Have you certified batches for both clinical trials and commercial products?
- How do you coordinate with CMOs/CDMOs and logistics partners?
- Can you manage cross-border imports/exports and dual-market releases?
- How do you handle deviations, inspections, or regulatory audits?
- What is your availability and turnaround time for batch certification?
- Can you provide references from similar biotech clients?
- These questions ensure competence, reliability, and regulatory compliance.

Additional Strategic Benefits of QP Support

14. In addition to importation and product release, what other value can a QP bring to project/programme delivery?

Beyond importation and batch release, a QP adds value by providing regulatory guidance, identifying potential compliance risks early, and supporting supply chain strategy. They help optimize documentation, ensure consistent GMP adherence, and streamline audits and inspections. QPs can advise on clinical trial material planning, deviation management, and risk mitigation, improving timelines and reducing delays. Their oversight fosters cross-functional coordination between manufacturing, quality, and logistics teams, ensuring smoother project delivery, enhanced patient safety, and confidence in regulatory compliance throughout development and commercialization.

15. What are the long-term benefits of building a strong relationship with a QP provider?

A strong QP relationship ensures consistent regulatory compliance, smoother batch releases, and reduced risk of delays or recalls. Long-term collaboration fosters deep understanding of a company's processes, supply chain, and product portfolio, enabling proactive guidance and faster problem-solving. It improves planning for clinical and commercial supply, supports audits and inspections, and enhances overall quality culture. Reliable QP oversight also strengthens regulatory credibility and investor confidence, while providing continuity and efficiency as the company scales, launches new products, or expands into multiple markets.

Conclusion:

16. If you had one piece of advice for a biotech company planning to move products between the UK and EU, what would it be?

Engage a QP early in the planning process—before manufacturing or clinical trial material production. Early QP involvement ensures compliance with both UK and EU GMP, streamlines import/export certification, anticipates regulatory gaps, and coordinates supply chain logistics. This proactive approach minimizes delays, reduces risk of non-compliance, and safeguards patient safety, ultimately saving time, cost, and resources while ensuring smooth cross-border product movement.

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