

Getting your product to the right patient at the right time

Your clinical trial supply chain can be a complex network of manufacturers, logistics companies and storage warehouses in multiple countries around the globe. This can cause a real logistical headache for biotech and virtual pharma companies. How do you coordinate your supply chain? How do you ship to multiple countries with different rules, regulations, and languages? How much product do you need to manufacture? It can be common to over manufacture, leading to unnecessary stockpiling, wastage, and product attrition.

At Quotient Sciences, we understand the challenges of managing clinical trials at numerous sites, in multiple countries. We can ease the headache of global product supply logistics and accelerate your proof-of-concept timeline. We'll develop and manufacture your drug product, and then seamlessly integrate into a flexible packaging, labelling & distribution strategy, tailored to your clinical trial.

Customized packaging, labelling and distribution services

Quotient can manage the packaging, multi-language labelling and door-to-door logistics. Our clinical trial supply team works with you to design the most efficient process for drug product supply to your central hub or direct to clinical sites including the provision of bulk drug product or individual patient kits.

Benefits of a flexible packaging, labelling and distribution strategy

- Flexible product get the product delivered as bulk, Brite Stock in primary package, or as bespoke patient kits - the choice is yours.
- > **Global supply** ensure distribution where it's needed, anywhere in the world, when it's needed.
- Avoid stockpiling and product attrition at clinical sites through Brite Stock Inventory Management and just-in-time [JiT] labelling and distribution – only ship product when it's required by a named patient.
- The JiT labelling strategy can be further extended to include JiT manufacturing enabling for full flexibility in dosage form design to meet patient and clinical trial supply needs.
- > **Protect precious API** and drug product develop a logistics strategy that reduces waste.
- Access in-depth knowledge on best practice from local rules and regulations, through to managing import and export licencing.
- Benefit from flexibility in cross protocols through drug pooling – maximize flexibility by JiT labelling to allow distribution of drug product across multiple clinical protocols.

Manufacturing strategies

The traditional route is still a suitable route for many clinical trials but where your trial and/or clinical trial supplies need increased flexibility there are alternative strategies we offer through Brite Stock manufacturing and personalised real time manufacturing routes. You can achieve significant savings in terms of API consumption and overall product wastage, which will have a positive impact on your development budget.

Quotient offers a clinical trial manufacturing, testing and certification service designed to meet your individual requirements. We understand the time and cost pressures you face during early phase evaluation and work with you to ensure a rapid, seamless path from development to clinical trial supply. We have extensive experience developing and manufacturing drug products with a focus on oral dosage forms.

Manufacturing and clinical supply considerations

	Personalized 'real-time' Manufacturing	Bright-Stock Manufacturing	Traditional Batch Manufacturing
Batch size	Small	Large	Large
Dose flexibility	High	Medium	Low
Labelling / Shipping	Per patient / Country	Per patient / Country	Bulk product
Shelf-life / Stability	Short-term	Long-term	Long-term
API consumption	Low	Low	High
Product overage / Waste	Low	Low	High
Cost	Low	Low	High

Product packaging and labelling services

We combine customized packaging with flexible label design technology in accordance with your clinical design. Product packaging is scalable, from bulk product, to Brite Stock in primary package, and patient kits designed to support clinical design, patient needs and storage requirements. Labelling is available as multilanguage flexible design to meet 1°, 2° and 3° packaging needs.

Summary

Detailed consideration of clinical trial supply strategy is essential to ensure delivery of product in the right format, at the right time in the right place. Each clinical trial is different, so multiple strategies may need to be employed to suit the needs of different products, clinical trial designs and patients.

Quotient has vast experience in global clinical trial supplies, having delivered thousands of drug products to hundreds of unique clinical sites in hospitals and contract research organizations worldwide.

Connect with us to learn how we can help support your global clinical trials.

