

Outsourcing your clinical supply chain and optimizing internal operations

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Role of Clinical Supply Chain

CMC

Clinical Operations

Regulatory

Finance

Clinical Supply Management
Demand Planning &
Supply Chain Readiness
Right Drug, Right Place, Right Time

Packaging and Labeling
(Internal /External)

Drug Substance/Drug Product
Manufacture

Distribution (Internal/External)

IRT

Components/Comparator
Sourcing

Label Translation

Role of Clinical Supply Chain

- Within organizations having a fully integrated clinical supply team can be vitally important.
- An effective clinical supply team can provide input into early protocol development to identify potential issues with supply, provide innovative solutions and speed up manufacturing and production timelines.
- Communication between the clinical needs, regulatory changes and the CMC team are essential to ensure success and clinical supply provides this flow of information.
- A lack of understanding how protocol design will affect the clinical packaging operations can have significant impact on how quickly a study can be initiated.

Challenges of Managing a Clinical Supply Chain In-House

- **Limited expertise/resources:** Smaller biotech companies may lack the internal expertise and infrastructure needed to manage all aspects of the supply chain effectively.
- **High costs:** Building and maintaining the necessary infrastructure can be expensive, especially for early-stage companies.
- **Regulatory complexity:** Navigating the ever-changing regulatory landscape can be a daunting task for in-house teams.

Challenges of Managing a Clinical Supply Chain In-House

- **Time constraints:** Delays in the supply chain can significantly impact clinical trial timelines and ultimately slow down the drug development process.
- **Scalability:** Difficulty scaling operations to meet changing demands.
- **Distribution:** Global logistics and distribution challenges.

Different Models of Outsourcing Your Clinical Supply Chain

Full Outsourcing

- Provider manages the entire clinical supply chain, from drug substance manufacturing to global distribution.

Functional Sourcing

- Outsource specific functions, such as packaging, labeling, or clinical trial management.

Selective Sourcing

- Outsource only highly specialized or complex tasks

Hybrid Sourcing:

- A combination of full and functional sourcing, tailored to your specific needs.

Benefits of Outsourcing Your Clinical Supply Chain

- **Cost reduction:** Access economies of scale and expertise offered by specialized providers.
- **Increased efficiency:** Leverage the provider's infrastructure and processes to streamline operations.
- **Access to expertise and resources:** Outsourcing partners have the specialized knowledge, experience, and infrastructure to ensure efficient and compliant supply chain management.
- **Reduced regulatory burden:** Your outsourcing partner can take on the responsibility of navigating complex regulatory requirements.

Benefits of Outsourcing Your Clinical Supply Chain

- **Faster time to market:** Reduce operational bottlenecks and accelerate clinical development timelines.
- **Increased focus on core competencies:** You can free up your internal resources to focus on your core strengths, such as drug development and research.

Partnering with a Clinical Supply Vendor

- **Experience and expertise:** Look for a provider with a proven track record in your therapeutic area and relevant regulatory experience.
- **Quality and compliance:** Ensure the provider has a strong quality management system and adheres to the highest regulatory standards.
- **Communication and collaboration:** Choose a partner with open communication channels and a collaborative approach to working with you.
- **Flexibility and scalability:** Select a provider that can adapt to your changing needs and scale its operations as your clinical trials progress.
- **Financial stability and reputation:** Partner with a financially stable and reputable organization to minimize risks.
- **Expertise in your therapeutic area:** Choose a partner with experience in your specific therapeutic area, as regulatory requirements and processes can vary.

Ensuring a Successful Outsourcing Partnership

- When choosing a vendor be open and honest on your expectations and how you want to work with your project manager.
- Have regular scheduled meetings to discuss packaging campaigns, distribution activities and timelines. Clearly define roles and responsibilities.
- Implement robust quality and appropriate oversight.
- Understand that things will go wrong and that successful relationships are built on mutual trust and respect. Prioritize work appropriately.
- Ensure that a suitable escalation pathway to discuss issues and to make both parties accountable if they deviate from agreed upon timelines.

Summary

- Clinical supplies is not a one size fits all approach.
- Depending on company size, product type, operating regions, dosage form, therapeutic areas and protocols design there can be a large degree of variability in supply chain.
- What works for one product may not make sense for another. For smaller companies with few products a product specific approach may work best.
- When developing internal SOPs and processes try to keep things general so you have flexibility to work with multiple vendors and can quickly adapt to organizational changes.
- Outsourcing your clinical supply chain can be a strategic decision that optimizes your pipeline, reduces costs, and accelerates your path to market. By carefully considering the benefits and challenges, and choosing the right outsourcing partner, you can leverage this strategy to achieve your development goals and bring innovative therapies to patients faster.