

COMMERCIAL SUPPLY CHAIN
READINESS FOR BIOPHARMA
ORGANIZATIONS

For emerging biotech and biopharma organizations, ensuring commercial supply chain readiness is critical to achieving success, and there are key strategies and business decisions you will need to make that [set the groundwork for your commercial launch](#). As a company prepares to move from clinical to commercial production, supply chain leaders especially will need to evolve their approach and leverage their knowledge to scale production to meet a whole new set of demand.

As an organization, you understand the science. You are deeply invested in the key milestones for your clinical trials and regulatory filings. The challenging piece is [building a roadmap](#) that ensures you are developing a business model that is viable, scalable, and sustainable, and one that puts the organization in a position to be commercial-ready.

One of the first steps an organization can take is creating a multi-year supply chain roadmap, building out a holistic, inter-related view of the required supply chain capabilities and business decisions – including the organizational shifts, processes, and technology that will be needed, both short- and long-term – to support a commercial operation (See Figure 1). Ideally, this would begin two to three years ahead of filing and approval, with key milestones for indication of progress over time.

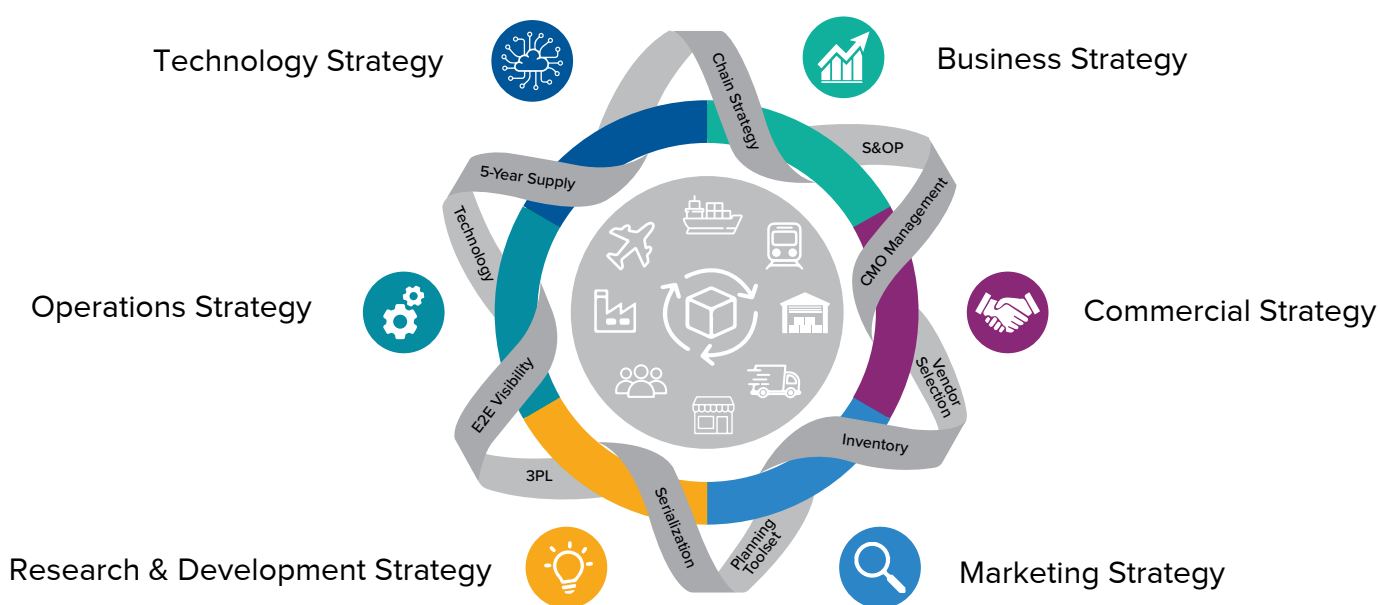


Figure 1

EVOLVING SUPPLY CHAIN CAPABILITIES

In advance of a regulatory commercial filing, i.e. New Drug Application (NDA) or Biologics License Application (BLA), an organization should apply its focus to evolving its supply chain capabilities to support a commercial operation. An organization's supply chain roadmap should encompass people, process, and technology components. Regulatory and quality requirements will drive necessary changes in your commercial operation, leading to a need for more rigorous processes around supply

chain execution and [real-time visibility](#), change control, supplier management, track and trace capability, labeling practices, trade compliance, and product recall.

Commercial readiness also requires scaling up the organization's capacity. Manufacturing, supply chain planning, and inventory management will be most impacted as the company prepares to move from clinical to commercial and scale up production. These processes start to require formalized standard operating procedures, tighter cross-functional collaboration, and alignment with those in finance, quality, and commercial operations. An additional benefit to ensuring processes are properly documented is organizational scale; these documents can be key for training and onboarding new employees.

In this report, we dig a bit deeper into three important capabilities for any commercial organization as it builds a supply chain to sustain the future: supply planning, supplier management, and serialization.

SUPPLY PLANNING WILL BE AT THE HEART OF YOUR COMMERCIAL OPERATION.

Organizations should first evaluate the basic fundamental components of supply chain planning, such as [part numbering](#) and bill of materials. This will set the stage for efficient cross-functional collaboration on planning demand, planning supply, and managing inventory. Determining the optimal amount of supply for product launch can come with challenges, especially if the product launch will expand into multiple regions and countries. Establishing a robust commercial supply plan and supply planning process, with clear cross-functional accountability, will be key to success and ideally documented in standard operating procedures that allow for tighter control.

Since pre-commercial companies are typically managing most of their business on spreadsheets, it's vital to ensure this type of [supply planning tool](#) can be scalable and sustainable. As the organization grows and product numbers and complexity increase, ensuring these fundamental components of your planning process are in place will only help streamline the implementation of a more robust supply chain planning solution in the future.

Sales & Operations Planning (S&OP) should also be designed, implemented, and established to support commercial launch activities and enhance collaboration between various departments and functions. Aside from establishing a framework to balance your demand with supply, the [S&OP process](#) is essential to ensure the organization is putting together a framework that allows it to be agile in its decision-making, especially those decisions that will have the greatest impact on the success of its commercial launch. Injecting the supply plan into the S&OP process will help the organization avoid a supply disaster (over/underproduce for its commercial launch).

SUPPLIER MANAGEMENT, ESPECIALLY IN A VIRTUAL MANUFACTURING ENVIRONMENT, IS VITAL.

The move to commercialization will require more [robust supplier management](#), especially for companies operating in a virtual manufacturing environment, where Contract Manufacturing Organizations (CMOs) represent the heart of the supply chain. CMOs own the production schedule, capacity, and responsibility to produce quality products, so you will need to have rigorous processes to manage and communicate with them on a regular basis. Well-documented agreements, expectations, and performance management metrics are vital. Establishing a relationship based on communication and trust will serve both parties well, especially as commercial volumes rise. Organizations will also want to consider building redundancy and resiliency into their supply chain, which may include second-source strategies, to ensure proper CMO capacity.

In the pre-commercial stage, it's common to see procurement and supplier management reporting to the finance or engineering organizations because purchases have primarily been for R&D or indirect expenses and not inventoried or tracked beyond receipt and payment. However, in order to support a commercial operation, a common organizational shift would be for these functions to report into the supply chain and include heavy collaboration with the quality team. This is important to ensure a supply chain that can deliver product at the right cost, time, and quality. When CMOs are at the center of this, supply chain leaders will want to have supplier management competency in their organization.

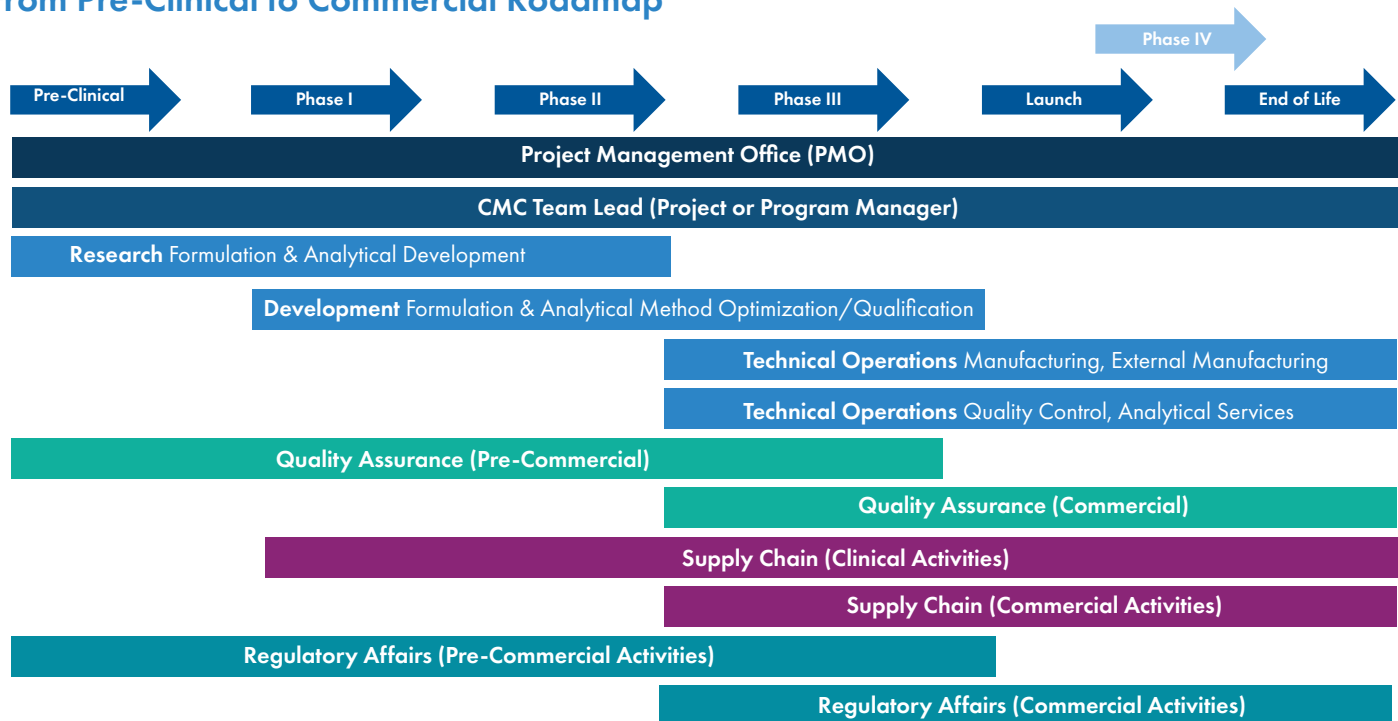
SERIALIZATION AND THIRD-PARTY LOGISTICS (3PL) MANAGEMENT WILL BE A TOP PRIORITY.

One of the most significant capabilities for a supply chain leader to build is serialization, which allows their organization to track an individual unit of drug product through the supply chain and back to the origin of manufacturing, making it easier to provide authenticity of the product, track product expiration, and accelerate the product recall process, if ever needed. The U.S. and other countries are requiring [product serialization](#) as part of final regulatory submissions and approval.

A central, global corporate serialization system will most likely be required to provide [serialization services](#) for contract packaging sites and 3PLs. As part of a [vendor selection process](#), an assessment and understanding of the serialization requirements for each market the organization intends to distribute its products in should be performed first. This will allow for a knowledgeable selection of the appropriate serialization technology for your current and future business strategy.

In conjunction with serialization, 3PL management is also important. [Selecting the right 3PL](#) is vital at this stage, and organizations should look for a 3PL that has a history of supporting order management, fulfillment, and serialization at scale; a robust ERP system and reporting capability; and a willingness to collaborate on track and trace solutions.

From Pre-Clinical to Commercial Roadmap



Credit: Linda Plumley

WHAT ABOUT TECHNOLOGY?

Many organizations wonder where technology should fit into their commercialization roadmap. The technology chosen is dependent on the speed and extent of commercialization and volume to be produced. Implementing the necessary technologies to plan, transport, and track the product is vital. Prioritizing systems that remove manual tasks and allow for efficiency gains as well as technology that supports important areas of quality and compliance is critical. By focusing first on people and process, you will get a strong foundation to which to apply the right technology. Timelines and financial budget are often underestimated, so planning technology early in the roadmap will allow for proper resourcing down the road.

While certain technologies such as ERP and [supply chain planning solutions](#) can be critical during the various stages toward commercialization, the decisions to implement these types of solutions can largely depend on the suite of technologies that already exist within the organization, expected product volume, and level of control needed. As mentioned, serialization is a space where the risk outweighs the reward, and implementing a solution earlier proves to be beneficial.

THE JOURNEY TO COMMERCIALIZATION REQUIRES DECISIONS.

Depending on where the organization is on its commercialization journey, many important decisions will need to be made along the way. It's important to understand the [capabilities required](#) to effectively support the business at various stages and how to develop these capabilities as foundational pieces for commercialization. The roadmap to get there will be dynamic and consistently reassessed to consider new information and data points. Milestones and stage gates allow leaders to [track progress](#) and continue to assess the gaps that exist between current and future capability, and the impact on people, process, and technology to get there.

If you're looking for a trusted advisor to partner with during your [commercialization journey](#), reach out to Clarkston today.

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