Argos Therapeutics is a biopharmaceutical company focused on the development and commercialization of fully personalized immunotherapies for the treatment of cancer and infectious diseases. Based on the initiation of a Phase 3 clinical trial of their leading candidate product, Argos was starting to look ahead towards commercial launch planning. Autologous immunotherapy has unique challenges, including a supply chain process which ensures the chain of identity of patient materials throughout manufacturing through to treatment.

Argos engaged Clarkston to help them define and prepare their business processes and systems to support commercial operations and reduce risks novel to their technology platform.

Personalized cell therapy models are extremely complex to commercialize because of the complications related to:

- Chain of Identity Management
- Coordination with the Clinics and Apheresis Centers
- Complex Billing and Evolving Reimbursement Processes
- Revenue Recognition Timing and Cash Management Implications
- Patient Enrollment Process
- Logistics and Materials Transportation (inbound/outbound kits, labeling)
- Manufacturing Capacity Allocation and "Reservations"

At the time of this project, Argos was starting their Phase 3 trial for their leading candidate based on their Arcelis platform, a precision immunotherapy technology that captures both mutated and variant antigens that are specific to each patient's individual disease. While supporting clinical manufacturing and awaiting trial data results, the company was preparing for commercial operations. The purpose of this project was to help Argos define, plan, and implement their commercial systems and processes.
INDUSTRY: Biotechnology

PRODUCTS & SERVICES: Focuses on the development and commercialization of individualized immunotherapies for the treatment of cancer and infectious diseases in North America

PRIMARY OBJECTIVES:
Clarkston was working with this pre-commercial biotechnology company to help them build their commercial readiness. Preparing for commercial launch for a precision immunotherapy product introduces new challenges to a highly complicated product launch process. Some key areas where Clarkston helped the client included:

- Conducting a formal risk assessment for the FDA on chain of identity throughout the product lifecycle, including risk mitigation through defined process and system controls
- Identifying systems and process requirements for product launch, including a gap analysis between traditional biopharma best practices and requirements for personalized medicine manufacturing
- Modeling the locations and best business partners to support capacity planning related to the complexities of the supply chain model

RESOLUTION:
With Clarkston’s help, Argos was able to create a unique vision for their commercial needs. As part of their strategic planning activities, the team:

- Developed a recommended systems roadmap for commercialization, including a custom physician / patient collaboration platform, with defined phases for efficient development across a multi-year plan
- Facilitated a chain of identity risk assessment, which articulated the planned use of processes and systems. This risk assessment was part of a response to the FDA
- Identified critical processes and system integrations which would be required to support the unique business processes of an autologous therapy

KEY BENEFITS:
This project provided Argos with a first-of-its-kind analysis for an emerging autologous therapy biotechnology company, including: a robust risk assessment on chain of identity for the FDA. The roadmap developed by Clarkston Consulting defined a sustainable, long-term, and scalable commercialization of existing and future cell therapies, tailored for the unique complexities of autologous immunotherapy treatment. This roadmap was further bolstered by a comprehensive computer system landscape definition to ensure a technological environment that could support and evolve with the commercialization of the cell therapy.