

# Creating a CMC Playbook for a Cell and Gene Therapy Company

A cell and gene therapy company engaged Clarkston's operations experts to create a Chemistry, Manufacturing, and Controls (CMC) playbook. Beyond the CMC playbook, the project was to create and accelerate the adoption of the "Client's Way" for Technical Operations.

Employees new to the client organization, early in their career, and in unfamiliar roles, coupled with new technology, added complexity to project management. This led to the need for clarification on roles and responsibilities (R&R) for the CMC Team. There was also a need to define how CMC at this company would work and how the process would be executed, taking into consideration the experience team members had from previous companies.

The lack of a process to document risks and decisions made, as well as a lack of tools to make periodic project updates to management and leadership, was ineffective, inefficient, and created opportunities for miscommunication. Stage gate reviews with acceptable risk (project timeline or science) needed to be defined to ensure research teams transferred potential clinical programs to the development team and enabled the research team to work on new candidates.

The CMC playbook would serve as the guiding document that the technical operations team would use for all product candidates to ensure business objectives were met.



# Life Sciences Case Study

## PROJECT OVERVIEW



### INDUSTRY:



Life Sciences

### PRODUCTS AND SERVICES :



Cell and Gene  
Therapy Operations

### PRIMARY OBJECTIVES:

- Develop a CMC playbook to document the overall process with tools to support an effective and efficient structure to deliver clinical-stage drugs to patients
- Include product candidate baseline plans, timelines and milestones, and assumptions and risks in CMC playbook
- Establish the standard ways of working for the technical operations team for current product candidates and future ones
- Ensure effective decision-making occurs with appropriate escalation throughout the execution of development of drug candidates

### RESOLUTION:

- Interviewed stakeholders to identify existing tools and gathered them into an easy-to-access location
- Recommended how to make the tools easier to use and harmonized into a single template
- Held working sessions with functional area stakeholders to develop the outline for the CMC playbook
- Provided a single reference point for the CMC teams to ensure consistent execution
- Identified CMC team and sub-team structures and determined which levels were authorized to make decisions
- Documented responsibilities for each level in the CMC team and for each functional area
- Added a Glossary of Terms (local dictionary) to the CMC Playbook to create the "Client's Way," ensuring key terms were understood across all functional areas
- Established meeting best practices for the CMC playbook to set expectations for meetings, leading to better communication and knowledge management
- Included requirements for TCP (*Target Candidate Product*), TPP (*Target Product Profile*), and QTPP (*Quality Target Product Profile*) in the CMC playbook
- Worked with early career team members and those in new positions on PowerPoint presentation best practices

### KEY BENEFITS:

- Improved communication and transparency with a common dictionary, eliminating confusion with terms that have more than one meaning or unique ones that weren't industry standard
- Gathered and revised available tools, allowing them to be fit for purpose for the CMC team
- Identified quick wins, like assigning the responsibility to the CMC project lead to save all information in the appropriate SharePoint site or providing instructions for consistent use of the Project Executive Summary template, ensuring all stakeholders received the status updates needed

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