DPT Thought Leadership
Issue 8

PARTNERING WITH YOUR CDMO FOR CMC PREPARATION

INTRODUCTION

Collaborative partnering between Contract Development and Manufacturing Organizations (CDMO) and the drug product submission applicants (Applicant) is becoming increasingly important with the emphasis on product design by regulatory agencies. The CDMO can provide the appropriate resources to build the scientific knowledge base for the product and the depth of science-based information for the drug design and development that are required in the CMC sections of the application.

Partnering with a CDMO offers several benefits, including:

1. CDMOs can provide the essential scientific, manufacturing and quality control module preparation and review services.
2. CDMOs can provide the scientific basis for the Pharmaceutical Development Report
3. CDMOs have the unique product and process knowledge
4. CDMOs are most knowledgeable about their components equipment and processes

Finding the right CDMO relies on each CDMOs knowledge, experience with report preparation and the level of support they can provide the applicant. With the right partner, leveraging the product knowledge base of the CDMO for the preparation of the CMC sections can significantly improve the quality of the submission.

RATIONALE

In addition to the other development and manufacturing benefits for pharmaceutical companies, CDMOs can provide valuable chemistry, manufacturing, and controls (CMC) module preparation and review services for the regulatory submission, potentially saving time and money, and possibly reducing regulatory delays. A majority of the documentation to support the CTD Module 2 Quality Overall Summary (QOS) and the Module 3 Quality will be provided by the CDMO. *This includes:*

1. component and product specifications and justification
2. the methods and method validations
3. the process and process design and/or
4. validations, and stability data.

More importantly, the CDMO will provide the scientific basis and understanding for the pharmaceutical development elements of the Pharmaceutical Development Report which is incorporated into the application. The CDMO has developed the specifications, methods, and process, validated the methods and process, and determined the critical quality attributes and critical process parameters.

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The development and validation of analytical methods that provide for the assessment of the identity, strength, quality, purity, and potency of the drug substance and drug product, and specifically, stability-indicating assays for the drug substance, must be diligently monitored by the applicant and the CDMO during the drug development process. In addition to the inclusion of the method and validation documentation in the CMC, the regulatory agency will often independently evaluate the method and validation during the application review process.

The CDMO has the unique product knowledge and process understanding from statistically-designed, multivariate experiments to understand the product and process, to define the design space, and to describe the relationship of the design space to the control strategies. This understanding provides the basis for the critical process parameters that are required for the process qualification. Successful execution of a validation protocol with these parameters is essential to confirm that the process design is capable of providing a reproducible manufacturing process.

In addition, the CDMO can provide the justifications for the drug product and component specifications based upon its supplier and materials knowledge.

The CDMO is most knowledgeable about their components, equipment, and processes and, for example, can provide the understanding of how changes in active pharmaceutical ingredients (APIs) and excipients attributes can affect the manufacturing process or how the critical process parameters can affect the product attributes. The CDMO will have the experience with the design space of other products to increase the efficiencies of processes and subsequent changes to processes or components.

SOLUTION

The important factors to consider when identifying the experienced CDMO include whether the CDMO has

1. The knowledgeable in-house personnel to provide the services
2. Whether the personnel have worked on similar types of submissions, and
3. Whether the in-house personnel will provide support for the submission both during preparation and during the regulatory review process.

The CMC modules should be prepared by a team of persons directly involved in the development and manufacturing processes and knowledgeable about the regulatory requirements for the specific dosage form. The CDMO team will be familiar with the CDMO procedures, processes, documentation and systems and can assure that they align with the application commitments. Since the CDMO will have had experience with the preparation and review of many applications, the CDMO is in a unique position to guide the Applicant along the most appropriate regulatory and scientific path.

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CONCLUSION

The effectively-managed alliance between the CDMO CMC preparation team and the Applicant can help meet the regulatory agency expectations for the submission in a timely and efficient manner and ensure that consistent information is being presented to the agency. Integrating the preparation of the CMC into the CDMO development process can streamline the process for both and provide a system for addressing issues as they arise. In addition, the CMC collaboration between the CDMO and the Applicant can serve as preparation for the Pre Approval Inspection (PAI) since CDMO persons involved on the CDMO submission team will likely be involved in the PAI or preparation for the PAI. The increased knowledge of the product submission will facilitate the PAI questions that may arise.

Increased emphasis by FDA on pharmaceutical development to build quality into a product requires close communication and partnership between the Applicant and the CDMO. By utilizing the CMC preparation services offered by the CDMO, the quality and efficiency of the submission preparation process can be greatly enhanced.

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ABOUT DPT LABORATORIES:

DPT is a contract development and manufacturing organization (CDMO) providing companies the best solutions to their sterile and non-sterile pharmaceutical development and manufacturing needs through innovation, technology, and service. Specializing in semi-solid and liquid dosage forms, DPT has a reputation for quality, unmatched technical expertise, extensive manufacturing capabilities, and an exemplary regulatory compliance record. With five cGMP facilities in San Antonio, Texas, and Lakewood, New Jersey, DPT offers full-service outsourcing solutions, including stand-alone development, site transfers, state-of-the-art manufacturing, packaging, and worldwide distribution.

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