VERISTAT

Helping a Sponsor Overcome a Partial Clinical Hold and Seamlessly Steer Multiple Products Through Development

Veristat Helps Small-Sized Biotech Company Resolve Critical Regulatory CMC Deficiencies to Meet FDA Requirements

Background

A small-sized biotechnology company engaged Veristat in mid-clinical development for help with a novel cell therapy/immunotherapy product platform targeting several cancers. Due to several chemistry, manufacturing, and control (CMC) deficiencies, one of the products was placed on a partial clinical hold, which further resulted in several information requests from FDA for all products across the platform. To help the sponsor move forward, Veristat's regulatory experts stepped in to provide tailored CMC support.

Study Demographics

Indication
Cell therapy/immunotherapy product platform targeting multiple cancers

Phase
IND

Regulatory Agency
FDA

Primary Services Provided:
- Regulatory Consulting
- Chemistry, Manufacturing, & Controls (CMC) Consulting

SOLUTION

Our team of regulatory CMC experts supported the sponsor to:

- Work with and advise CRO/CMO to ensure proper implementation of the stability program and analytical program development, method troubleshooting and feasibility testing, validation, and transfer of methods.
- Optimize methods for sensitivity and robustness required for late-phase development, including viable cell count, plasmid copy number, plasmid retention, and cell clumping.
- Resolve stability program deviations.
- Work with and advise CMO for screening and manufacturing of a new working cell bank.
- Respond to FDA information requests related to analytical methods and process validation.

IMPACT

Veristat was able to help move the program forward from the partial clinical hold and steer the manufacturing and analytical programs for all products across the platform through development, preventing any further clinical delays.

ABOUT VERISTAT

Ensure a Successful Submission for Your Biologic

Without a sound strategic CMC plan tailored to your biotherapeutic, your IND submission risks being delayed. To give you an advantage, Veristat's team of regulatory experts is experienced in helping sponsors establish CMC strategies designed to meet FDA requirements.

Lessons Learned

- Developing and validating assays in early development may not have adequate range, sensitivity, or robustness for the variability of a biological product.
- Utilizing secondary methods to troubleshoot or substantiate a method may not successfully transfer and invalidate the original method.
- Sponsors must ensure that assays with limited load capabilities and sensitivity are not at the lower limit of detection, especially with biotherapeutics, including cell and gene therapies, which have inherent variability.

Contact Veristat Today

To learn more about Veristat or how we can assist you, reach out to us today.

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