MANUFACTURING COMPANY, CALIFORNIA

CASE STUDY

Regulatory and Quality Consulting, Operational Readiness Services

WHEN YOU NEED TO MEET A HIGHER STANDARD®

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Why CAI?

CAI was chosen for our broad range of experience in FDA regulated industries and ability to align quality and compliance with risk to users. Cell cultured food production is a novel technology and the FDA is still evaluating the best way to regulate and monitor this unique food production method. Since CAI's consultants have a broad breath of experience in all phases of FDA regulation and can interpret and implement current regulations while remaining at the forefront of current agency thought, we are able to implement programs that are both compliant and flexible enough to allow for changes as agency feedback is received by the client and as the guidances for this novel technology is created and implemented. In addition, our focus on speed to market helps balance compliance and quality with manufacturing excellence driving value for our clients' stakeholders.

Project Overview

CAI were initially approached to assist in writing several high-level program documents. The project became a full-time staff role as head of quality performing all quality functions as well as participating in facility registration, FDA documentation review, Hazard Analysis and Critical Control Point (Food Safety Plan) review and implementation, training development, supplier qualification program implementation, and day to day quality and regulatory activities. A second project was initiated for Operational Readiness for the development of raw material specifications, standard operating procedures, master batch records, and other required quality management system documentation.

CLIENT:
CONFIDENTIAL

LOCATION:
CALIFORNIA, USA

TIME FRAME:
1 YEAR

CONTRACT SIZE:
~$600K

Challenges

As this is a new industry, the challenge is to understand and implement food regulations (21 CFR 117) while using elements of pharmaceutical production and controls (e.g., for equipment qualification and process controls) within a controlled way to promote a level of control that is required in food production without overburdening the processes with unnecessary regulatory requirements intended for pharmaceuticals. Working with key stakeholders on decision making is critical. It is also important to create systems that are flexible and can grow and adjust as the company moves from R&D through product development through commercialization.

Solution

CAI provided industry thought leadership and solutions that merged the food regulations with biopharmaceutical technology allowing for a quick turn start up of converting a small R&D facility into a GMP compliant facility to allow for study materials to be manufactured following cGMP processes. This information was subsequently used to grow and refine the systems and processes for larger scale manufacturing and long-term success.

Results

The cultured meat product is currently under final regulatory review with approval expected soon.