



September 1st, 2019

Vitti Labs is a registered tissue bank with the U.S. Food & Drug Administration's Human Cell and Tissue Establishment department. Our establishment is registered to recover, package, research, process, store, label and distribute products and materials within the guidelines of 21 CFR part 1271.

Vitti Labs extensive standard operating procedures were developed by scientists and doctors using legal counsel from the national healthcare legal firm Lathrop Gage, whom we continue to use, and highly regarded consultants experienced with FDA, GTP (Good Tissue Practices) and AATB (American Association of Tissue Banking) regulatory policies and procedures including best practices for donor eligibility. Vitti Labs intends to continue maintaining strict adherence to all applicable regulatory agencies and dynamically respond to any new clarifications and classifications that are updated by the FDA, AATB, and GTP. In the event new regulatory guidelines are implemented, Vitti Labs will consult immediately with legal and regulatory counsel to constantly stay in compliance and make any necessary standard operating procedure manual, facility, and/or protocol updates, including but not limited to any product labeling or product registrations.

We strive to make innovative therapeutic products that are intended for homologous use only, and work within all applicable FDA, AATB, and GTP guidelines. It is our mission to follow the highest regulatory standards and prioritize public safety and quality assurance.

If you have any questions please contact your Vitti Labs representative.

Sincerely,

A handwritten signature in black ink, consisting of a large, stylized initial 'P' followed by a series of sharp, vertical strokes that resemble a barcode or a stylized signature.

Regulatory Affairs Department, Vitti Labs