DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	7/17/2017-7/26/2017* FEI NUMBER 3008307548

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anthony Dudzinski , Chief Operating Officer

FIRM NAME	STREET ADDRESS
American CryoStem Corporation	7 Deerpark Drive, Suite C-7
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Monmouth Junction, NJ 08852	Biologic Drug and HCT/P manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, the aseptic processes used to manufacture stromal vascular fraction (SVF) and the ATCell expanded mesenchymal stem cells (MSCs) biological drug product, such as but not limited to SVF isolation from adipose tissue and (b) (4) of MSCs, have not been validated to ensure that these products can be consistently manufactured in a manner that prevents microbiological contamination.

OBSERVATION 2

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the processes used to manufacture your SVF and ATCell products have not been validated to ensure that each batch can be consistently produced with the identity, strength, quality and purity that they purport or represent to possess.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Cody D Rickman, Investigator Kip J Hanks, National Expert	X Cody D. Rickman Investigator Signed By: Cody D. Rickman -S Date Signed: 7/26/2017	7/26/2017

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Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, a program for environmental monitoring for microorganisms in aseptic processing areas has not been established since beginning operations in 2011. To date, approximately (b) (4) batches of your ATCell expanded MSCs biological drug product have been distributed to physicians across the US.

OBSERVATION 4
Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

For example, components used in manufacturing such as but not limited to (b) (4) and (b) (4) are received with certificates of analyses from the supplier. However, at least one specific identity test is not conducted and the reliability of the suppliers' analyses has not been established through appropriate validation of the suppliers' test results at appropriate intervals.

OBSERVATION 5
Written procedures are lacking which describe in sufficient detail the sampling and testing of components.

Specifically, there are no written procedures that address the sampling and testing upon receipt of components used in manufacturing SVF and ATCell, such as but not limited to (b) (4) (b) (4) and (b) (4).

OBSERVATION 6
There is no written testing program designed to assess the stability characteristics of drug products.

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Specifically, a testing program has not been developed in order to determine appropriate post-processing storage conditions and expiration dates for your ATCell expanded MSCs biological drug product.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the cleaning and disinfection of aseptic processing areas has not been validated to show that cleaning and disinfection practices can consistently perform as expected.

OBSERVATION 8

The production area air supply lacks an appropriate air filtration system.

Specifically, aseptic processing is conducted in and out of biological safety cabinets, which are located in production areas that have no Clean Area Classification/ISO Designation for air classification.

OBSERVATION 9

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, in-process materials and drug products and to prevent contamination.

Specifically, the biological safety cabinets used for research and development are located directly adjacent to biological safety cabinets used for production of biological drug products.

***DATES OF INSPECTION**

7/17/2017(Mon),7/18/2017(Tue),7/19/2017(Wed),7/20/2017(Thu),7/26/2017(Wed)

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X Kip J Hanks
National Expert
Signed By: 1300135856
Date Signed: 7/26/2017

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