DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	12/1/2025-12/4/2025
	FEI NUMBER 3030478415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Douglas Harsy, CEO	
FIRM NAME Cryo-Dynamics, Inc.	**STREET ADDRESS** 910 S Kimball Ave # 100
CITY, STATE, ZIP CODE, COUNTRY Southlake, TX 76092-9005	**TYPE ESTABLISHMENT INSPECTED** Initial Importer and Specification Developer

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 I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm's procedure 820.100, Corrective and Preventive Action, Rev 00, no effective date, lacks essential operational details regarding Corrective and Preventive Action (CAPA) implementation. The procedure fails to address two critical elements: how the firm manages CAPAs throughout their lifecycle, and the identification of events, conditions, or triggers that would initiate a CAPA.

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, your firm has not established procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Your firm provided a complaint log during the inspection, however, the lack of established procedures means that there is no defined process for handling complaints received through email and oral communications, or for determining whether complaints constitute reportable events.

OBSERVATION 3

Written MDR procedures have not been developed and implemented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Elizabeth A Krolczyk, Investigator	X Elizabeth A Krolczyk Investigator Signed By: ELIZABETH A KROLCZYK Date Signed: 12-04-2025 11:12:25	12/4/2025

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Specifically, your firm has not established procedures for Medical Device Reporting as required by 21 CFR 803.17, which mandates that importers develop, maintain, and implement written procedures for the identification, investigation, evaluation, and reporting of events that may be subject to medical device reporting requirements. Additionally, your firm does not have an eSubmitter account to submit reportable events.

OBSERVATION 4

Quality audits have not been performed.

Specifically, your firm's procedure 820.22, Rev 00, effective 9/21/2023 sets forth requirements for internal audits of your firm and external audits of suppliers and vendors. While Section 6 mandates that internal Quality Audits occur annually, your firm has failed to conduct any internal audits as required by both your established procedure and the regulation.

OBSERVATION 5

Software validation activities and results for computers or automated data processing systems used as part of the quality system have not been documented.

Specifically, your firm has not validated Microsoft and cloud storage systems as required by 21 CFR 820.70(i), which mandates that computer software used as part of production or the quality system shall be validated and documented according to an established protocol for their intended use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Elizabeth A Krolczyk, Investigator	X Elizabeth A Krolczyk Investigator Signed By: ELIZABETH A KROLCZYK Date Signed: 12-04-2025 11:12:25	12/4/2025

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Annotations to Observations

Observation 1: **Promised to correct**

Observation 2: **Promised to correct**

Observation 3: **Promised to correct**

Observation 4: **Promised to correct**

Observation 5: **Promised to correct**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Elizabeth A Krolczyk, Investigator	X Elizabeth A Krolczyk Investigator Signed By: ELIZABETH A KROLCZYK Date Signed: 12-04-2025 11:12:25	DATE ISSUED 12/4/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."