DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
San Francisco District 1431 Harbor Bay Parkway, Alameda, CA 94502-7070 510-337-6700 Industry Information: www.fda.gov/oc/industry	5/12-14/2015
	FEI NUMBER 2971884

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Garan K. Ito, P.A., M.T., (ASCP) M.B.A., Director, Diagnostic and Interventional Services

FIRM NAME	STREET ADDRESS
Hamamatsu/Queen's PET Imaging Center, L.L.C.	1301 Punchbowl Street
CITY, STATE AND ZIP CODE Honolulu, Hawaii	TYPE OF ESTABLISHMENT INSPECTED Positron Emission Tomography Manufacturing Facility

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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The following observations pertain to the manufacture of [redacted]

OBSERVATION 1

Your firm lacks adequate production and process controls to ensure the consistent production of a PET drug that meets the applicable standards of identity, strength, quality and purity.

Specifically, Form FM-Q-008: [redacted] used to document media fills for [redacted] and [redacted] did not describe [redacted] including but not limited to, the [redacted] Furthermore, SOP Q-008: [redacted], Rev. 1, Effective 10/27/14 does not require the completion of a media fill batch record. The proper documentation of media fills is necessary to assess the ability of personnel to perform aseptic processing.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 2

You did not have master production and control records that document all steps in the PET drug production process.

Specifically, your master production and control records do not include sufficient detail of critical steps in your manufacturing process. For example, the [redacted] Production Batch Record for Lot# [redacted] manufactured on 5/12/2015, lacks sufficient detail including, but not limited to, [redacted]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Lance M. De Souza, Investigator	05/14/2015

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[redacted] and assurance that critical steps were performed to make the clean room suitable for production. Instead, the Production Batch Record states, "Perform according to [redacted]" (Master Formula for [redacted].

THIS IS A REPEAT OBSERVATION.

OBSERVATION 3

You did not follow appropriate written procedures that describe the storage and handling of components and closures.

Specifically, SOP M-006: [redacted] Rev. 0, Effective 7/25/14 describes the procedure for depyrogenating glass and other heat-stable materials for use in the production of [redacted] Injection. Section 6.1.1 states in part: "[redacted]. Section 6.1.2 states in part: "[redacted]. After execution of the depyrogenation cycle, Section 6.2.10 states in part: "[redacted].

On 5/13/2015, during my inspection of the cyclotron laboratory and the manufacture of [redacted] Injection Lot [redacted] I observed a metal tray on top of a shelf containing approximately [redacted] pieces of glassware that were depyrogenated on 4/30/2015. The glassware included multiple sized vials and glass beakers whose mouths were not [redacted] and were exposed to the environment. Some glassware was used in production to contain critical reagents, such as [redacted]

Depyrogenation of glassware is important in the production of PET drugs as residual pyrogens could be ultimately be injected into a patient resulting in an adverse reaction.

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OBSERVATION 4
All equipment used to perform the testing is not suitable for its intended purposes.

Specifically,

Your firm's current [redacted] Injection Final Product QC Release Specification for pH i[redacted] The [redacted] pH Test Strips (Lot[redacted] is currently used for pH Final Product QC Release Testing. However, these strips only have a pH range of [redacted] and can only measure pH by whole number increments by comparing a [redacted] These strips do not have the necessary resolution to measure pH to the nearest tenths place, as is required in the release specification.

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