

DSIME INS-0001114717

## **Inspection Report**

WuXi AppTec Inc.

2540 EXECUTIVE DRIVE SAINT PAUL, MN 55120

Customer ID: 15690

Certificate: 41-R-0061

Site: 001

WUXI APPTEC INC

Type: FOCUSED INSPECTION

Date: 12-SEP-2024

#### 2.32(a) Critical

#### Personnel qualifications.

During inspection the following personnel qualification issues were found:

- On 23 February 2024 an incident was self-reported to the IACUC committee regarding a guinea pig on an IACUC approved activity. A guinea pig wrapped for an IACUC approved activity on 8 February 2024 was found dead on 9 February 2024. Pathology indicated the cause of death was compromised breathing likely due to wrapping the guinea pig too tight.
- On 22 February 2024 an incident was self-reported to the IACUC committee regarding a rabbit on an IACUC approved activity. On 22 February 2024 a rabbit jumped from its primary enclosure located in the top row during provision of feed, water and enrichment by animal care staff. Upon veterinary examination the rabbit had suffered a small laceration its upper left lip and a mild contusion. Adequate veterinary care was provided until the rabbit healed from 22 February to 1 March 2024.
- On 6 December 2023 an incident was self-reported to the IACUC committee regarding a guinea pig on an IACUC approved activity. On 6 December 2023 a guinea pig was found deceased by animal care staff after being wrapped following the approved protocol. On 4 December 2023 and 5 December 2023, the animal was observed normal. Pathology performed on the guinea pig indicated hemothorax, suspected due to the wrap being too tight.
- On 6 October 2023 an incident was self-reported to the IACUC committee regarding 3 rabbits on an IACUC approved activity. On 6 October 2023 a technician performing sedation for a euthanasia procedure in accordance with the IACUC approved protocol indicated she administered Euthasol subcutaneously instead of the ketamine/acepromazine sedation that should have been administered. The technician contacted the veterinarian who administered the ketamine/acepromazine sedation and subsequently euthanized the animals with Euthasol administered intravenously.

The facility was unable to ensure that all personnel involved in the care, treatment and use of the above documented animals were qualified to fulfill their responsibilities and be familiar with the procedures for these IACUC approved activities, resulting in negative impact on the health and wellbeing of these animals. Develop and maintain a program of training and instruction to all scientists and all personnel involved with research activities that ensures that all personnel and members of research teams are trained and qualified to perform their duties and to follow procedures in IACUC approved activities so that research animals receive proper care.

All incidents documented above were investigated by the IACUC. Corrective measures had been implemented prior to inspection, to remain corrected from 16 September 2024 forward.

Prepared By:	DEBRA SIME		Date:
		USDA, APHIS, Animal Care	16-SEP-2024
Title:	VETERINARY MEDICAL		

Received by Title: IACUC Representative Date:



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2.38(f)(1) Critical

#### Miscellaneous.

During inspection the following personnel handling issues were found:

- On 28 May 2024 an incident was self-reported to the IACUC committee regarding a rabbit on an IACUC approved activity. On 28 May 2024 a rabbit jumped over the shoulder of a technician while removing it from its primary enclosure located in the top bank for an IACUC approved procedure and fell to the floor. The rabbit was observed bleeding from the mouth. The rabbit was observed by the veterinarian and found be very anxious and to have a contusion between the two front incisors. The rabbit was provided pain medication and received adequate veterinary care through recovery on 31 May 2024. The rabbit was provided a primary enclosure on the bottom bank and noted to animal care staff to be an anxious rabbit.
- On 8 March 2024 an incident was self-reported to the IACUC committee regarding a guinea pig on an IACUC approved activity. On 26 February 2024 a guinea pig was observed struggling during an IACUC approved procedure. Afterwards the guinea pig was observed bleeding from the left nostril and crackling sounds when breathing. After examination from the veterinarian, the guinea pig was euthanized due to poor prognosis. Cause of clinical signs was determined to be due to the head and chest being compressed too tightly during restraint.
- On 4 March 2024 an incident was self-reported to the IACUC committee regarding a guinea pig on an IACUC approved activity. A guinea pig was dropped while being handled by a technician. The guinea pig hit the side of the primary enclosure and a garbage bin before landing on the ground where bleeding from the mouth was observed. The guinea pig was examined by the veterinarian and noted an injury to the nasal philtrum. The guinea pig was provided adequate veterinary care.
- On 18 December 2023 an incident was self-reported to the IACUC committee regarding a rabbit on an IACUC approved activity. On 18 December 2023 a rabbit was discovered bleeding from the nose and having respiratory distress after being removed from the primary enclosure to be shaved for a procedure outlined in a IACUC approved protocol. Examination by the veterinarian determined clinical signs were consistent with likely pulmonary contusions and/or pulmonary likely due to animal over handling resulting in the veterinarian euthanizing the rabbit.

The facility was unable to ensure that all personnel involved in the handling and use of the above document animals were able to handle animals in a manner to prevent physical harm. Develop and maintain a program of training and instruction to all scientists and all personnel involved with research activities that ensures that all personnel and members of research handle animals as carefully as possible and in a manner that does not cause behavioral stress, physical harm, or unnecessary discomfort.

All incidents documented above were investigated by the IACUC. Corrective measures had been implemented prior to inspection, to remain corrected from 16 September 2024 forward.

#### 3.28(a)(1) Critical

#### Primary enclosures.

On 12 September 2023 an incident was self-reported to the IACUC committee regarding a guinea pig on an IACUC approved activity. On 12 September 2023 a guinea pig was found on the floor of a guinea pig room. It was determined that the guinea pig had escaped through a space near the auto-water area of the auto-water caging and fell to the floor. The guinea pig was examined and assessed to have mild trauma to the left upper lip.

The primary enclosure was not structurally sound to contain the guinea pig and protect it from injury. Place all guinea pig primary enclosures in a condition that is structurally sound and prevents escapes. Corrective action at the facility has

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included acquiring new guinea pig primary enclosure racks where there are no gaps at the auto-water area. The incident documented above was investigated by the IACUC. Corrective measures had been implemented prior to inspection, to remain corrected from 16 September 2024 forward.

3.30 Critical

#### Watering.

On 9 February 2024 an incident was self-reported to the IACUC committee regarding 2 guinea pigs on an IACUC approved activity. On 9 February 2024 2 guinea pigs were discovered in a water bottle primary enclosure that was thought to have been an auto-water primary enclosure rack and did not have access to water. The enclosure was changed on 7 February 2024 and the water error was not discovered during water check on 8 February 2024. Animals were provided water and examined by the veterinarian. The veterinarian assessed the 2 guinea pigs to be dehydrated and thinner, likely due to lack of water. The animals received veterinary care until fully recovered. Lack of potable water in sufficient quantity to guinea pigs can negatively impact their health and well-being by resulting in dehydration, and possibly death. Ensure potable water is provided in sufficient quantity to every guinea pig housed at the facility, as often as necessary, to ensure their health and well-being.

The incident documented above was investigated by the IACUC. Corrective measures had been implemented prior to inspection, to remain corrected from 16 September 2024 forward.

This inspection and exit interview were conducted with Facility Representatives.

End of report.

Prepared By: DEBRA SIME Date:

USDA, APHIS, Animal Care 16-SEP-2024

Title: VETERINARY MEDICAL

**OFFICER** 

Received by Title: IACUC Representative Date:

16-SEP-2024



Customer: 15690

Inspection Date: 12-Sep-2024

# **Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
15690	41-R-0061	001	WUXI APPTEC INC	12-SEP-2024

Count Scientific Name Common Name

000000 NONE NONE
000000 Total