



USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT			
Complaint No. AC20-028	Date Entered: 23-Oct-19	Processed By: AVB	
Referred To: Forbes / Snow		Reply Due: 24-Nov-19	
Facility or Person Complaint Filed Against			
Name: AltaSciences Preclinical Seattle LLC		Customer No.: 505169	License No.: 91-R-0075
Address: 6605 Merrill Creek Parkway		Email Address:	
City: Everett	State: WA	Phone No.: (425) 407-0121	
Complainant Information			
Name: (b) (6), (b) (7)(C), (b) (7)(D)		Organization: SAEN	
Address: (b) (6), (b) (7)(C), (b) (7)(D)		Email Address: (b) (6), (b) (7)(C), (b) (7)(D)	
City: Milford	State: OH	Phone No.: (b) (6), (b) (7)(C), (b) (7)(D)	
How was the Complaint received? Email			
Details of Complaint: SEE ATTACHED			
Results: A Gottingen mini-pig died of circulatory failure resulting from cardiac tamponade during a thoracic inlet blood collection procedure on 4/8/19. Multiple unsuccessful needle insertions were attempted. The pig struggled and vocalized during the procedure. This adverse event was self-reported by the facility to Dr. McKinnie on 4/9/19. It was evaluated and put as an incentive under: Handling 2.38 (f)(1). Recommend the complaint be closed.			
Application Kit Provided: Yes: <input type="checkbox"/> No: <input checked="" type="checkbox"/>			
Inspector: Diane Forbes, DVM		Date: 29-Oct-19	
Reviewed By: William W. Snow, D.V.M.		Date: 30-Oct-19	

From: (b) (6), (b) (7)(C), (b) (7)(D)
Sent: Monday, October 21, 2019 3:44 PM
To: Gibbens, Robert - APHIS
Cc: APHIS-AnimalCare
Subject: Official Complaint -- A;tasciences



Dr. Robert Gibbens

10/21/19

Director, Western Region
USDA/APHIS/AC
2150 Center Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dr. Gibbens,

I am writing to you today to file an Official Complaint again against Altasciences Preclinical (91-R-0075), for clear violations of the Animal Welfare Act which occurred recently.

A confidential Altasciences report states:

"On 08APR2019, a Gottingen minipig (5 months old, male, approximately 9.3 kg) died unexpectedly during routine blood collection at approximately 10:00 am. . . .

The technicians were performing the blood collection from the thoracic inlet, starting on the left side of the pig, using a 23g 3/4' needle with a 12 ml syringe. . . . 3 - 4 attempts were made on the left side of the animal, and one on the right. At that point, a decision was made to switch roles . . . It was at that point that the animal went limp and became unresponsive."

The report goes on to say:

"At necropsy, 35 ml of blood was found in the pericardial sac. The pathologist stated that probable cause of death was due to cardiac tamponade (which puts pressure on the heart and keeps it from filling properly). "

It is quite apparent that this botched procedure caused the death of the animal, and that the mishandling of the procedure resulted in a seriously traumatic incident, otherwise the necropsy would not have found 35 ml of blood in the pericardial sac. The inability of Altasciences staff to draw a simple blood sample, without killing an animal, must raise questions as to their qualifications and training. Not only were they unable to obtain the blood sample, but they didn't realize that they were compromising the health of this animal until death occurred.

This incident clearly violates the Animal Welfare Act potentially violating several different code sections including:

Sec. 2.32 Personnel Qualifications (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

or

Sec. 2.38 Misc (f)(1) Animal Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

or

Sec 2.31 Institutional Animal Care and Use Committee (IACUC) (d) IACUC review of activities involving animals (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures

This relatively new facility must not be allowed to get away with unnecessarily killing this animal. Your office must establish from the outset that Altasciences will be held to the highest standards and punished severely when, as with the death of this pig, they fail so miserably in meeting those standards.

Therefore, I am filing an Official Complaint against Altasciences for a serious violation of the Animal Welfare act which resulted in the death of a pig. I am calling upon your office to open a new case relevant to this unnecessary death, and I am also calling upon your office to investigate Altasciences to ascertain whether any additional deaths have taken place.

At the conclusion of your investigation, you must prosecute Altasciences to the fullest extent of the law, assessing a penalty of \$10,000 per infraction/per animal.

expect that your office will reply to this correspondence within five business days.

Sincerely,

(b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

Attachments: 1 Confidential Altasciences non-compliance report

1081-B State Route 28 #280 Milford, OH 45150

513-575-5517

www.SAENonline.org

Altasciences Preclinical Seattle, LLC
CONFIDENTIAL

Summary and Corrective/Preventative Actions Associated With
[REDACTED] from 08Apr2019

I. Summary:

On 08Apr2019, a Gottingen minipig (5 months old, male, approximately 9.3kg) died unexpectedly during a routine blood collection at approximately 10:00am.

II. Findings:

The blood collection was performed by [REDACTED] with [REDACTED] as the restrainer, and [REDACTED] as the technician performing the blood collection. The technicians were performing the blood collection from the thoracic inlet, starting on the left side of the pig, using a 23g 3/4" needle with a 12mL syringe.

The animal was not acting any differently from any of the other animals but did struggle moderately during the attempts. The animal had 5 instances over 6 days of acclimation training prior to the attempt (2 for human interaction, and 3 for clicker/treating). Each time the animal struggled, the technician did not attempt to maintain needle insertion during the times that the animal was struggling, rather, the technician removed the needle when the animal struggled. The animal was given breaks to settle down in between attempts. The animal vocalized some, but not out of the ordinary and breathing was normal. ~3-4 attempts were made on the left side of the animal, and one on the right. At that point, a decision was made to switch roles, and [REDACTED] switched positions with [REDACTED]. It was at that point that the animal went limp and became unresponsive. The entire sequence of events took approximately 10 minutes.

III. Assessment:

Both technicians are very proficient in the procedure, and [REDACTED] is also a trainer for this procedure. This technique is routinely performed at the facility, and until now, without any incidents. On the day of the incident, an [REDACTED] who is also a lead trainer in this procedure was observing prior to and after the incident. [REDACTED] was not present at the time of the incident but had noted that the two technicians were working very well together and were very skilled at the procedure. He had no concerns about the procedure.

At necropsy, 35mL of blood was found in the pericardial sac. The pathologist stated that probable cause of death was due to cardiac tamponade (which puts pressure on the heart and keeps it from filling properly). Upon initial inspection, there was no trauma to any tissue or blood vessels found in the thoracic inlet region to indicate that the volume of blood was due to a torn vessel.

It was noted that the technicians started on the left side of the neck. According to recommendations from [REDACTED] (a vendor for research swine), the right side of the neck is the preferred side for blood collections. The nerves (vagal and recurrent laryngeal nerves) on left side of the neck are more prevalent.

CONFIDENTIAL

Altasciences Preclinical Seattle, LLC
CONFIDENTIAL

IV. Corrective and Preventative Actions:

Immediate action was taken by the study director to suspend blood collections from the thoracic inlet until an assessment could be made. Blood collections already scheduled are now collected from a peripheral vein, unless it is a terminal collection.

Preventative actions to be taken:

- The SOP for blood collections will be updated:
 - Limit the blood collection attempts to 3 per technician. Staff are currently trained to only make three attempts, but it needs to be clarified that the 3 three attempts is per technician (not per site) and will be formalized in the SOP.
 - Limit the blood collection procedure to only the right side of the pig, unless it is a terminal collection.
 - Discuss with technicians the anatomy of the area, including nearby veins, nerves and arteries.
 - Draw from the cranial vena cava only when necessary (e.g. blood volume).
- Recommended training exercise: Discuss the Time Out campaign with staff. Could this animal have used a time out? Did the blood collection need to be drawn that day, and at that time, or could it have waited?
- Review and revise the acclimation training requirements for swine prior to a blood collection in the thoracic inlet.

V. Final Animal Welfare Incident Report Signatures



Date



Date

CONFIDENTIAL