



An important announcement for Aptuit customers concerning the recent MHRA notification.

In light of the inquiries we have received following the MHRA's recent press release relating to its investigation of the bioanalytical group at our former Riccarton, Scotland site, Aptuit wants to clarify information related to the MHRA's prosecution of a former employee, Steven Eaton. Mr. Eaton was recently found guilty by Edinburgh Sherriff's Court for altering pre-clinical trial data at our Riccarton site. Here are the details:

- In February of 2009, a supervisor at Aptuit Riccarton identified irregularities in some of Mr. Eaton's bioanalytical data as part of the company's Quality Control Procedures. Aptuit representatives promptly notified the MHRA and, based on that notification, an investigation was initiated. It was determined that the irregularities in the work of Mr. Eaton began as early as 2001, when the Riccarton site was owned by Quintiles. Aptuit acquired the Riccarton site from a subsidiary of Quintiles Transnational Corp. in late 2005.
- In accordance with Aptuit corporate policies, Mr. Eaton's actions resulted in immediate disciplinary procedures and his prompt departure from Aptuit's employment. Mr. Eaton has not been associated with Aptuit for more than four years.
- Aptuit fully supported and cooperated with the MHRA during the 2-1/2 year investigation and undertook study-by-study impact assessments of Mr. Eaton's actions. Aptuit also took corrective and preventative actions, while openly communicating and cooperating with customers.
- It is important to note that the MHRA stated in its March 12th press release that "following a full assessment by the MHRA's inspection team and assessors it was concluded that the data integrity issues did not invalidate the results of the clinical trials that were affected."
- At the close of this investigation two years ago, Aptuit received a letter from the MHRA stating that the matter was concluded and that "...the investigation by the MHRA and GLPMA has found no evidence to suggest that the data integrity issues were caused as a result of actions taken by the company. The data integrity issues appear to have been caused by the independent actions of individual employees."

- GLP certification at the Riccarton facility was maintained throughout the period of this MHRA investigation. Subsequent audits conducted by the MHRA also resulted in the continued GLP certification.
- Aptuit implemented a comprehensive corrective action/preventative action (CAPA) program to address and correct the situation. All impacted customers were engaged in the process to ensure minimal impact to their ongoing projects. The CAPA program included the development and institution of new or updated SOPs and quality programs, as well as additional training for all staff.
- All customers with impacted studies were contacted by Aptuit and kept informed as the impact assessments were carried out during the period from February 2009 to December 2010. If a customer was not contacted during this time, it was not impacted.

Aptuit closed its Riccarton site in 2011 due to business reasons unrelated to the MHRA's investigation, and no longer conducts any activities for customers at the site. As an industry leader in drug discovery and development services, Aptuit recognizes the importance of data integrity and remains committed to delivering the highest quality of data and services to its clients. Aptuit reiterates that the MHRA investigation was concluded years ago at a former site and has no effect on current operations.

