

FOR THE AMES STUDY MANAGER



Ames
Archive Manager

Ames Archive Manager

The **Ames Archive Manager™** is the latest addition to our suite of software for regulatory Ames testing. The program has been developed in accordance with the OECD series on principles of GLP and compliance monitoring number 15: Establishment and Control of Archives that Operate in Compliance with the Principles of GLP.

The program offers extensive searching and filtering capabilities, helping you find specific studies for archiving quickly and easily. Once archived, a study cannot be modified in any way, yet retains accessibility for report reconstruction, auditing and verification.

- **Reconstruct archived studies**
for reporting, auditing and verification
- **Lock down study data**
whilst retaining flexibility to view or report on original data
- **Developed with reference to OECD guideline**
principles of GLP and compliance monitoring number 15
- **Easy browsing, sorting and filtering**
of all your Ames studies, past and present
- **GLP and FDA 21 CFR Part 11 compliance**
with audit trails, user permissions and database security
- **Comprehensively tested and validated**
in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 9003

PERCEPTIVE
INSTRUMENTS

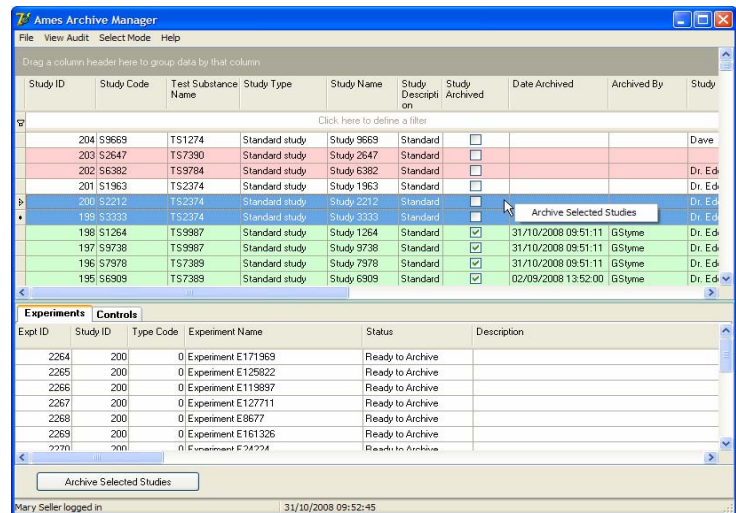


A safe and secure archiving utility *for those seeking GLP compliance*

The Ames Archive Manager is aimed at those wishing to archive their assay data in line with the OECD guideline on the 'Establishment and Control of Archives that Operate in Compliance with the Principles of GLP'. The program works in conjunction with the Ames Study Manager and its associated modules to provide the complete solution for regulatory Ames testing.

Archive studies with a single click *without the need to export study data*

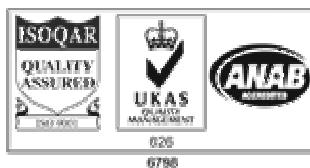
The Ames Archive Manager allows users to select individual studies or a range of studies to be archived in just one simple action. In order to maintain the integrity and accessibility of your data, the Ames Archive Manager works by simply marking selected studies as archived, and so does not remove any data from your original Ames database. This not only helps ensure the integrity of your data by avoiding any potentially dangerous export and purge operations, but also means you can still view the study and reconstruct reports for auditing and verification.



Auditing and user administration *helping you meet regulatory requirements*

The **Ames Archive Manager** has been designed and developed with reference to a wide range of regulatory guidelines and when used in conjunction with the **System Access Manager** is fully compliant with Good Laboratory Practice and the **FDA 21 CFR Part 11** final rule on electronic records and electronic signature. The program has been tested and validated in accordance with our Quality Management System which is approved to **ISO 9001:2008** incorporating ISO 90003.

Comprehensive audit trails record every action taken within the program, including both the archiving and unarchiving (where allowed) of study data. These audit events can be viewed not only from within the Ames Archive Manager itself, but also from the main **Ames Study Manager** main event log.



Perceptive Instruments have supplied image analysis and data processing solutions for regulatory genetic toxicology assays for over a decade. We have ISO 9001:2008 approval for our Quality Management system from a UKAS & ANAB accredited certification body.

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