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Industry Standard Software Supporting Whole Body Autoradiography Image Analysis.

Seescan provides an intuitive, user-friendly and comprehensive method for the analysis of Whole Body Section Autoradiographs. The program runs supports imaging file formats from Molecular Dynamics, Fuji, Biospace, and Cyclone Phosphor Imaging Systems.

- Provides an intuitive, comprehensive and user friendly method for rapid image analysis.
- Analyses image files from popular direct imaging systems including Molecular Dynamics, Fuji, BIOSPACE and Cyclone.
- Software is application specific and easy to use.
- Data can be reported as raw measured data, or calibrateddata when using standards.
- Provides a full range of tools for defining regions of interest within an image for measurement.
- GLP compliant operating mode may be selected on a studyto study basis.
- In GLP mode all actions are automatically documented making GLP compliance easy and complete.

- Software is password protected providing full user access control from the supervisory level.
- All data including study protocol are time, date and userstamped, maintaining a full audit trail.
- Supports direct data transfer of results to Microsoft[®] Excel and Microsoft[®] Word via Document Management System.
- FDA 21 CFR Part 11 Compliant.
- 'Digital' interface with Debra™ ADME LIMS.

Features

Setting up a study

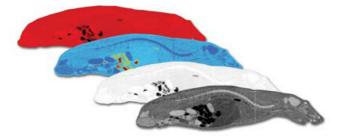
To start a study, the user defines the protocol. This provides an experimental description, defines whether the study is to be GLP compliant and defines whether the data is to be calibrated. Before starting the measurements, the user can either complete the study protocol by entering the sections and tissues to be measured, or input this during the course of analysis.

Calibration

If the study images contain calibration standards, raw measurements can beconverted into calibrated units. For each standard, the user measures andenters its nominal value. The calibration curve is calculated and displayed. Calibration algorithms include linear, quadratic, cubic, log/linear and sigmoidal. The best fit to the curve may be obtained using the different calibration algorithms. Suspect data points may be excluded from the curve but remain visible on the graph.

Image Display

A variety of image display functions are provided. These include normal, image inversion, contrast enhancing and pseudo-colouring. The software also allows four images to be montaged using the same pseudo-colour scale for comparison.



Taking Measurements

Measurements can be taken by framing the region of interest with a variety of drawing tools. These include circular, rectangular or user drawn frames of variable size. Selected areas can be defined using grey level thresholds. The image may also be zoomed and contrast enhanced to allow accurate analysis of small or poorly defined tissues.

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Results

For each measurement, the region area, the raw/calibrated result and the measurement reliability (% error) are stored. Results can either be displayed individually or as a mean for the tissue being measured. Individual resultscan be cross-referenced with the region from which they were obtained, by simply clicking on the measurement – the image appears with the measured region highlighted. All data can be reviewed and transferred to otherMicrosoft® Office applications.

The software has been designed for use at two levels, supervisor and user, both password controlled. The supervisor has the ability to; access all studies, set up and delete users, and restrict access to studies and software. Only users defined in the protocol have access to the study. All data entered, including the protocol, is time, date, and user stamped. If any data is altered or excluded, the user is forced to enter a reason, which is stored with the data in the study audit trail. All data for each study is stored in an encoded study file.

Security

Seescan[™] has a comprehensive and flexible security structure, which is used to control access to menu items andform-level functions. Given that Seescan[™] is used in a regulatory environment, it is important that Seescan[™] is able to guard against unauthorised access to data.

Debra[™] ADME LIMS Link

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Regulatory and FDA 21 CFR Part 11 Compliance

Seescan[™] is designed to fully support GLP and associated regulatory requirements and specifications for bothlaboratory operations and laboratory software design. This includes functionality to meet with the FDA 21 CFR Part 11 ruling for electronic signatures and electronic records. The system allows for System Manager control of signaturepoints on key events. Each area of the application that could require a signature is configurable. Administratorscan disable the signatures, set a silent signature which doesn't require any action on the users part, set a singlesignature or 2 signatures (the second signature normally being approval of the first). Signed electronic recordscontain information associated with the signing that clearly indicates all of the following:

- The printed name of the signer.
- The date and time when the signature was executed.
- The meaning (such as review, approval, responsibility, or authorship) associated with the signature.



Service and Support

Users of our systems can benefit from our comprehensive, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.



Validation Services

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists have years of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.



Training

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instruments and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.

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