BIOTRAX

FROM ORDER TO SHIPMENT

QUALITY MANAGEMENT SYSTEM FOR RADIOPHARMACIES.

- FDA Compliant
- Full Batch Record Management
- Stock & Instrument Management
- Electronic Document Management

BioTrax QMS combines the benefits of an electronic inventory tracking system with a batch record maintenance system, providing you with a streamlined and paperless approach to manage your PET facility's current Good Manufacturing Practice (cGMP) regulation needs. This program minimizes human error,s, ensures compliance, improves quality, and reduces costs.

BioTrax QMS integrates central document repository, raw material tracking, production, training, equipment, and ensures, in combination with **GINA X** data acquisition and evaluation, simple and automatized data collection from Quality Control and synthesis.

The centralized solution is based on an SQL database. The client/server architecture allows an easy centralization and access to the instruments and data from different PC's. With all data stored in the central SQL database, it is easy to secure the data integrity and be fully GMP and 21CFR part11 compliant.

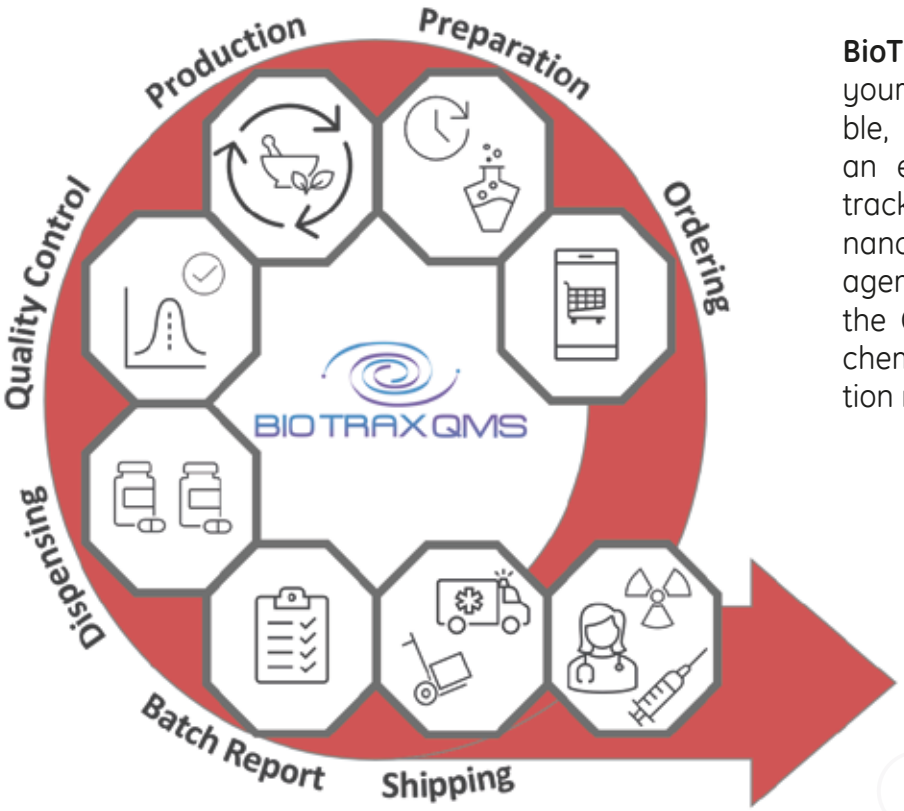
BioTrax QMS simply manages SOP's, documents, electronic batch records, user rights, trainings, instruments and facility tasks.

Official partner of :

ELYSIA RAYTEST

ec2 Software Solutions

BIO TRAX QMS

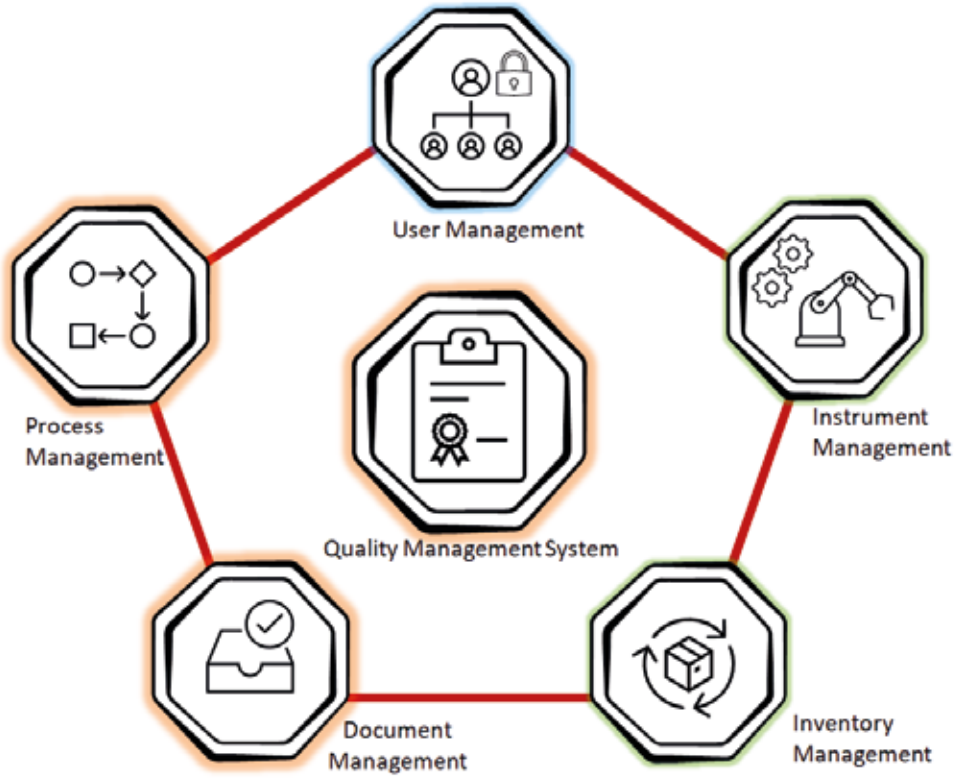


BioTrax QMS was created to provide your facility with an easily accessible, comprehensive database and an efficient system for inventory tracking and batch record maintenance. It 's covering the data management needs of the Pharmacist, the Cyclotron Engineer, the Radiochemist, the Technician, the production manager and the administrator.

Biotrax QMS is providing you with a streamlined and paperless approach to manage your facility's inventory, manufacturing and delivery needs.

BioTrax QMS has many advantages such as:

- Its customizable design provides the flexibility to convert all your compounding or manufacturing documentation into one format.
- Document management system for easy control and management of all signed-off documents and revisions with import features and a full audit trail.
- Batch record creation with audit trail capabilities.
- Document repository for SOP's and revision /version control of all SOP's, training material and specification sheets.
- An internal material identification system to manage all raw materials
- Inventory re-order messaging / warning.
- Electronic worksheets guide the user through preparation and QC of all product tasks.
- In-house preparation of materials used in production and QC
- Verify compliancy with your SOP's.
- Generate bar codes for internal tracking while maintaining a perpetual inventory.
- Force required training for designated employees.
- List and control equipments used in production and force certification requiremements.
- Generate general facility tasks and keep a log of daily user activities.



Process Management

Facility Tasks

Schedule your work easily.

The BioTrax QMS is an automated solution that simplifies facility management and reporting. The system will keep you up on track by sending messages regarding important equipment, facility and training information. Create facility tasks that are required to be completed and decide if tasks require signature to verify that they have been completed.

System Messages

All messages in one location.

Set and view reminders for sterility, document sign-offs, training needs, equipment certifications, and facility tasks. You can also view tasks due by a designated time in the future, or sort tasks into easily maneuverable sections.
The System Message Screen shows all aspects of the software requiring attention.

Regulatory

Simplify compliance.

Biotrax QMS facilitates compliance with governmental reporting regulations including: 21 CFR Part 11, 21 CFR Part 210, 21CFR Part 211, 21CFR Part 212 and USP 823 all at the click of a button!

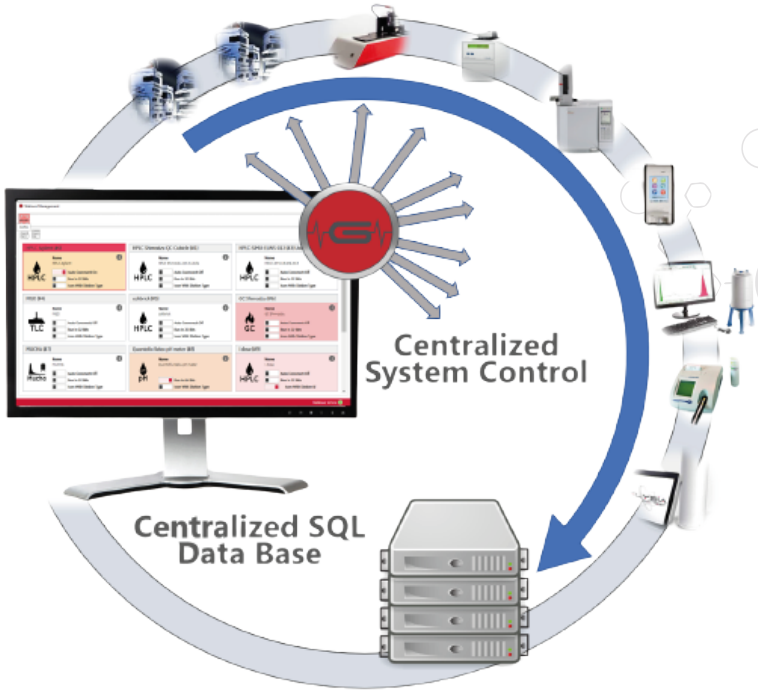
Equipment management

Manage equipment certification.

Never sort through files of papers again. Easy navigation to access equipment and other important facility information with a few mouse clicks. Force certifications to be completed for specific tasks and designate appropriate frequency for recertification. Users can also associate groups to equipment and track equipment repair. Track serial numbers, model number and other details such as maintenance, IQ, OQ or PQ.
Schedule and request a testing procedure, required service, or maintenance to be completed.
Associate equipment with one or multiple facilities and force compliance before equipment can be used in process.

Centralized Data Management

All data in one place.



Thanks to the integration of **Gina X** into **BioTrax**, you will have a fully centralized data system.
GINA X is a data acquisition and evaluation software allowing the central control of your analysis equipment.
Simply collect data from instruments such as Radio chromatographs (HPLC & TLC), Gaz Chromatographs, Multi Channel Analysers, LAL readers, ionization chambers and many more.
The client /server architecture allows an easy centralization and access to the instruments and data from different PC's. With all data stored in the central SQL database, it is easy to secure the data integrity and be fully GMP and 21CFR part11 compliant.

Stock Management

Inventory Management at Your Fingertips

Current inventory records right at your fingertips. Easily track and manage inventory and label materials' status for internal tracking.
Manage inventory by quarantining, accepting, or rejecting raw materials. Streamline your stock management by generating and printing barcodes.
Bar code stickers enable you to identify quarantined, accepted and rejected materials, tracking the use and disposal of raw materials, and monitoring the receipt of materials.
Control in-house prepared materials and print associated stickers with bar codes.
Print material receipt documents.

Electronic Document Repository

Store All Your Documents Digitally.

BioTrax QMS cuts out all the piles of paperwork. This central document repository allows you to digitally access all of your facility's documentation, for fast and easy reporting and compliance.
Store all SOPs, training materials, spec sheets and other documents in one location, and keep a record of all changes, updates and electronic signatures with full revision and version control.
A tree structure is used for organization of the documents in the repository.
Simply create documents or import different document formats to fill your repository.
Documents can be checked for editing or updating and are checked back into the track edits after modifications.
Documents can be associated with tasks. For example, quality control documents can be associated with different tasks that are needed to carry out the procedure.
Signatures required to approve document actions are specified by the system administrator and tracked.

Training management

Manage Your Employee Training Program.

Stay on top of your employee training schedule. Create trainings and ensure required employee training, establish exams with a minimum passing score requirement, associate current training media with exams, and require administrator review and approval of exams taken. Require your staff to complete training before they're allowed to do tasks, enable tasks only if defined training has been completed and exams passed.
Plan retesting schedules on daily, weekly, monthly, or yearly base.

Production/Batch Record Management

Keep Your Batch Records Connected.

- Create, connect, and manage all your batch records digitally, with one click of a button.
- Get easy access to all your important information from one convenient location.
- Force user compliance for raw material used by imple - mentation of bar code scanning.
- Force user training.
- Force valid use of equipment management.
- Gain quick access to SOPs for reference purposes.
- Attach and force required attachment of files to a batch record.
- Track deviation / non-conformance reports.
- Print consumable labels, reports, and cover pages.

Technical specification

- Client/Server configuration
- SQL database data storage
- GxP features and FDA compliant
- Audit trail
- Electronic signature
- Built-in user guide and admin Setup guide
- User management
- Instrument Management
- Stock Management
- Document Management
- Process and task Management

System Requirements

- Server: Rocky Linux 8 (Operating System Installed by Elysia)
- Server: Intel Xeon Series Processor
- Server: 16GB RAM
- Server: 1TB Hot Swap Hard Drive (Qty. 2 for RAID 1)
- Workstation: Windows 10, 64 bit
- Workstation: Intel Core i5 or higher
- Workstation: 8GB RAM
- Workstation: 500GB Hard Drive
- Workstation: Microsoft Word 2016 or newer

References.

28800001	BioTrax QMS perpetual
28800012	BioTrax QMS Annual License fee
28800023	BioTrax Web Training/Setup
28800032	BioTrax annual maintenance contract

BIOTRAX QMS

For more details on these products and services, please contact us.

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