

Biotracker™

A Laboratory Information Management System

By Ocimum Biosolutions

TABLE OF CONTENTS

1.0 EXECUTIVE SUMMARY	2
2.0 INTRODUCTION	2
3.0 BIOTRACKER™ – GENERAL FEATURES	4
3.1 LABORATORY ADMINISTRATION MODULE	5
3.2 PROJECT DATA MODULE	6
3.3 PROJECT DESIGN MODULE	7
3.4 REAL TIME WORK SCHEDULING	9
3.5 EXPERIMENT TRACKING, ANALYSIS AND RESULT ARCHIVAL	9
3.6 INVENTORY MANAGEMENT AND TRACKING SYSTEM.....	11
3.9 PLATE TRACKING	14
3.10 INSTRUMENT INTEGRATION	16
3.11 REPORT BUILDER.....	17
4.0 WHY BIOTRACKER™ FOR YOUR LABORATORY?	18
4.1 EASE OF USE AND INTUITIVENESS IN BIOTRACKER™.....	18
4.2 DATA MANAGEMENT IN BIOTRACKER™	18
4.3 DATA SECURITY AND ACCESS LEVEL CONTROL IN BIOTRACKER™	19
4.4 INSTRUMENT INTERFACING IN BIOTRACKER™.....	20
4.5 AUTOMATED DATA TRANSFER THROUGH INSTRUMENT INTEGRATION.....	21
4.6 CUSTOMIZABLE REPORTS.....	21
4.7 SCALABILITY AND EXPANDABILITY	22
4.8 COST EFFECTIVENESS	22
5.0 SUMMARY AND CONCLUSION	22

TABLE OF FIGURES

Figure 1: A screenshot of Laboratory Administration module in Biotracker™.....	5
Figure 2: A screenshot of Project Creation module in Biotracker™	8
Figure 3: A screenshot that shows an experiment with samples to be used	10
Figure 4: A screenshot displaying sample entry form.....	11
Figure 5: A screenshot of Chemical Inventory management tool in Biotracker™	12
Figure 6: A screenshot showing tree view of different physical locations of inventory...	13
Figure 7: A schematic representation of plate tracking utility for microarray design.....	15
Figure 8: A screenshot of plate tracking tool in Biotracker™.....	16
Figure 9: A screenshot of Report Building tool in Biotracker™.....	17
Figure 10: A schematic view of access level control in Biotracker™.....	19

Biotracker™

1.0 EXECUTIVE SUMMARY

This document entails a review of information management needs by laboratories engaged in life sciences research and development of software tools to fulfill such needs. Biotracker™ is a GLP compliant Laboratory Information Management System, developed by Ocimum Biosolutions Ltd.

A Laboratory Information Management System is an effective tool for improving laboratory performance. Biotracker™ allows analysts to keep track of samples, reagents, instruments, processes, and results at every stage of an experiment. Biotracker™ can help a lab to:

- § Reduce the cost of laboratory operations
- § Provide easy and timely access to pertinent information
- § Improve productivity and efficiency to meet increasing demand
- § Comply effectively with regulatory agencies' guidelines (Good Laboratory Practices compliant)
- § Report comprehensive and easy to read results

This document elucidates general features, key functionalities of Biotracker™ and how Biotracker™ is a suitable package for a life sciences research laboratory.

2.0 INTRODUCTION

A laboratory engaged in life sciences research such as microbiology, medicinal chemistry, biotechnology, pathology, biochemistry etc., has a distinct work environment. In order to understand various biological processes one must manipulate tissues, cells, compounds and biological molecules. Any such laboratory will include equipment, instruments, chemicals and samples that facilitate understanding of different processes that govern life in some way. At a broader level any life science research laboratory will include equipment such as glassware, centrifuges, a pH meter, few deep freezers and refrigerators to store samples and more than often, a voluminous list of chemicals. Further, the equipment, research methodologies and information flow varies

greatly between different kinds of laboratories based on their choice of discipline, area of research and objectives. While the output of such research endeavors is usually in the form of reports, research papers, journal articles and dissertations, these consist of information as well as knowledge. However, a vast amount of information also goes into getting such output and since it is neither a one step injection of information nor single step knowledge output, a better word might be information and knowledge throughput to indicate flow of information that a research group has to deal with in a research laboratory. A significant part of this knowledge (information) is formally recorded such as in laboratory notebooks, manuals, progress charts, user lists, vouchers, order forms etc., whereas a lot of it is committed to memory or is communicated verbally between co-workers. This collectively forms a very large volume of information to be managed by individual researchers or the entire research group. An example of varied information that a typical researcher in a life sciences laboratory has to manage during a work day may be as follows:

- § Schedule a new experiment
- § Include a new protocol or procedure in an existing experiment (that means a lot of chemicals, solutions, equipment and how to process these)
- § Collect data from ongoing experiments, record them and analyze them (data could be pictures, numbers, observations on culture tubes, petri dishes, experimental animals or lack of anything significant)
- § Read and analyze research literature
- § Keep a tab on and sign up to use a particular instrument, say a centrifuge or a microscope, scheduling these are important as there are many people in the lab who would like to use the same equipment.
- § Record usage of an instrument in the log book
- § Check for availability of chemicals in shelves and stock room, if a certain chemical has run out reorder it with the vendor. Make a note of this in the logbook, sign for the order.
- § Search and access information from online libraries, data repositories, data banks.

Aforementioned tasks are very broad areas of activity wherein certain information is managed or made use of. Any of these tasks could involve large number iterations and any of the processes could involve a lot of complexity, for example some of the DNA fingerprinting experiments can run for days, they necessitate the use of more than 50 odd chemicals, will typically involve about 8-10 major instruments and the data can be in the form of experiment log (notes), autoradiographs (X-ray films), fluorescent gel images from a sequencing machine, text files that contain DNA sequence data and so on. Similarly for an immunologist data may comprise of a completely different set of protocols, different experiment procedures and their output say about an antigen-antibody interaction.

The examples above are still simplistic views of complexity of tasks and information in a biological research laboratory. There is still one more dimension, that of volume of data. With advent of automation and progressive sophistication of diagnostic techniques, the amount of data generated is far larger than that in previous years.

Managing such magnitude and complexity of tasks and the information that is integral to it can be a daunting task, add to that core process research i.e. analyze and think. Typically routine tasks and processes consume a large part of a researcher's workday. If these tasks can be organized and the workflow synchronized to add efficiency, then it will provide a researcher with more time and resources to think and analyze.

A laboratory information management system's primary objective is to organize, synchronize and smoothen information flow in a research organization. Biotracker™ has been conceived, designed and developed by researchers and keeping in mind the requirements of biological research lab.

3.0 BIOTRACKER™ – GENERAL FEATURES

Biotracker™ is designed in a manner so that it is intuitive for the user and provides a comprehensive picture to the administrator or leader of the research group. A basic layout and functionality is discussed as follows. Biotracker™ has been

developed using advanced Java Technology and is platform independent. This allows for users who use varied operating systems like Windows, Linux, Unix or Macintosh.

3.1 Laboratory Administration Module

Biotracker™ is designed in a manner so that it is intuitive for the user and provides a comprehensive picture to the administrator or leader of the research group.

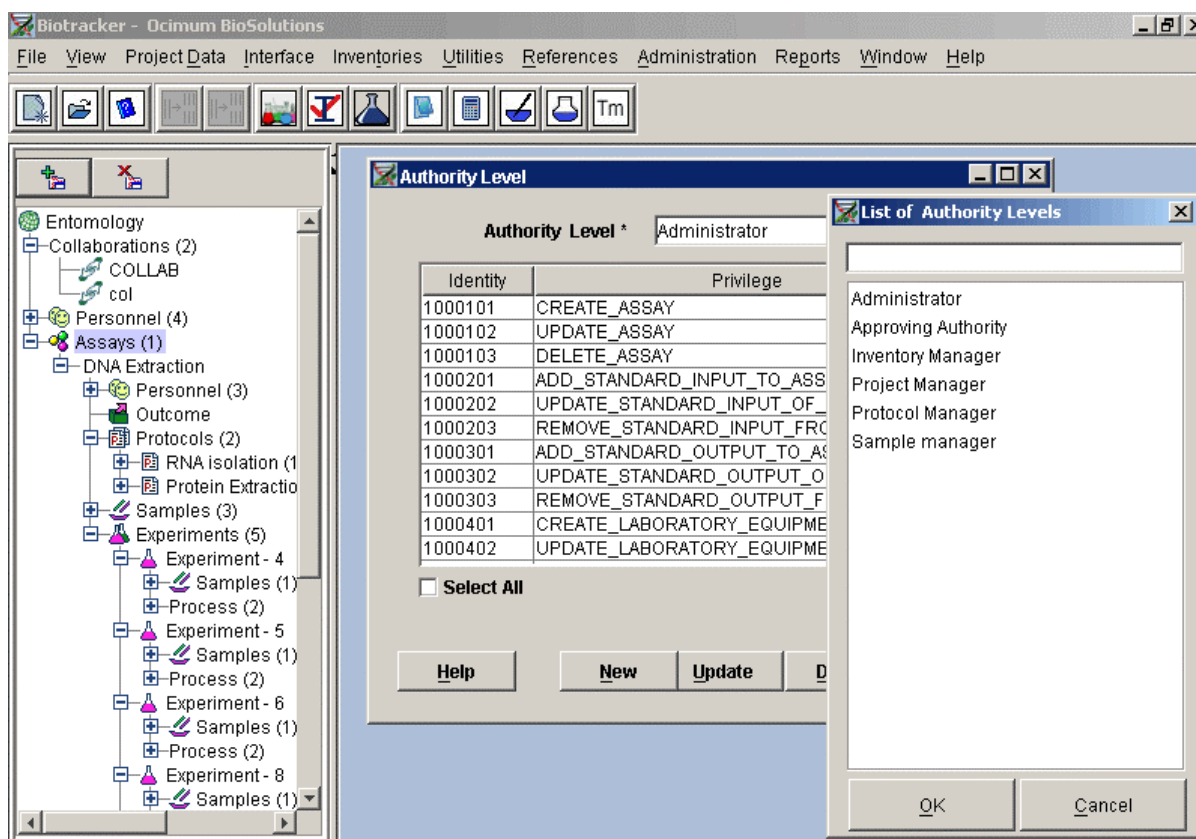


Figure 1: A screenshot of Laboratory Administration module in Biotracker™

Administration module enables security and access control to system and data. Data can be added, modified, copied or deleted only as specified in the access control settings. An administrator can configure the organizational structure and work flow in laboratory using this module. Individual users can also perform these tasks if they have an authority or access to do so. Different functions that are part of Administration module are as follows:

§ User Management

- Generate authority levels by grouping access levels and privileges that can be classified by a project, a laboratory, a domain, or parts thereof. Thereby one user can have different authority levels in different laboratories or different authority levels on different projects in the same laboratory. Any number of authority levels can be defined as per requirements of a research organization.
 - Change access and privileges of different users that meet changing requirements of a research organization.
 - Temporarily block a user account in order to prevent access of resources from the system.
 - Revoke privileges of a user that are based on changing requirements of a laboratory.
- § Domain and Laboratory Access
- Associate different laboratories to a domain whereby an organizational structure is created on the system.
 - Determine association of users to a laboratory, every user will be assigned a default laboratory when setting up the account. Further associations can be created thereafter.
 - Restructure organizational set up by changing laboratory domains and association of personnel with laboratories.
- § Contacts and Collaborations
- Associate different contacts such as research collaborations, vendors, clients with a domain or a laboratory.
 - Revoke such associations and collaborations with a domain, laboratory or a part thereof (such as a particular project).

This scheme of information flow creates a well-defined workspace and allows flexibility to reorganize the information set up.

3.2 Project Data Module

Different units of a project can be added using a Project Data module. A user can add processes, protocols and assays to the system. These serve as

individual units of information that constitute the next level of work hierarchy. Processes and protocols are classified by types, further, input required and output generated are also quantified. For example, when a user creates a process, he has to specify the input resources (skills required, chemicals, instruments, other facilities and duration for each process or a part of it) and output generation (whether an image, chromatogram, chemical output, statistical data etc.). Processes and protocols therefore become complete units of information that can be used in variable combinations in an assay or a project or they can be used as templates to create further processes and protocols.

3.3 Project Design Module

The Project Design Module in Biotracker™ allows a user to create a hierarchical model for project creation. An investigation effort is termed as “project” in system architecture, a project will consist of assays. An assay is based on one or more laboratory protocols that are executed in sequence or in tandem to investigate a particular question. A protocol consists of several procedures. Each iteration of an assay is defined as an experiment. The top level will be the project, assays and protocols can be attached to it in a tree structure.

Figure 2: A screenshot of Project Creation module in Biotracker™

A hierarchical system of work flow makes resource appraisal and result validation easy. Input and output are well quantified at the process and protocol level, a Project Manager can get a composite view of required resources, expected output and an approximation of costs involved, which can help in the decision making process. Once a project is created, samples, personnel, instruments and other resources can be assigned to it using this module. This module helps keep track of samples, assay progress and facilitates project scheduling.

Key Features of Project Creation and Execution utility are as follows:

- § Assign the project task to specified users
- § Associate samples, instruments, buffers and chemicals to experiments
- § Design new experiments on already available experiment templates

3.4 Real Time Work Scheduling

Biotracker™ Work Scheduling Module allows a user to schedule individual lab work and synchronize it with other personnel in his lab and thus streamline workflow. A daily, weekly or monthly schedule of experiments and tasks can be generated using this module for each personnel. A user can then configure and refine it to match one's own work schedule. This system helps to reschedule and redistribute tasks between lab personnel and thus ensure timely completion of projects.

3.5 Experiment Tracking, Analysis And Result Archival

Biotracker™ Execution Module enables a project leader to ensure smooth workflow for his team and allows different users to keep track of the status of their projects. An access level control facilitates flow of information as set up by the administrator. An administrator thus can monitor progress, assign tasks and redistribute tasks as required. Compartmentalization of access and various levels of access ensure security of data yet it provides ease of sharing data between personnel who have the need to work with different data sets. To facilitate this the system allows the user to enter information manually or through instrument interfaces. Analysis of results can be done by using available utilities and by interfaces through external applications. Summary of analyses and results are archived securely and backup is taken to ensure redundancy.

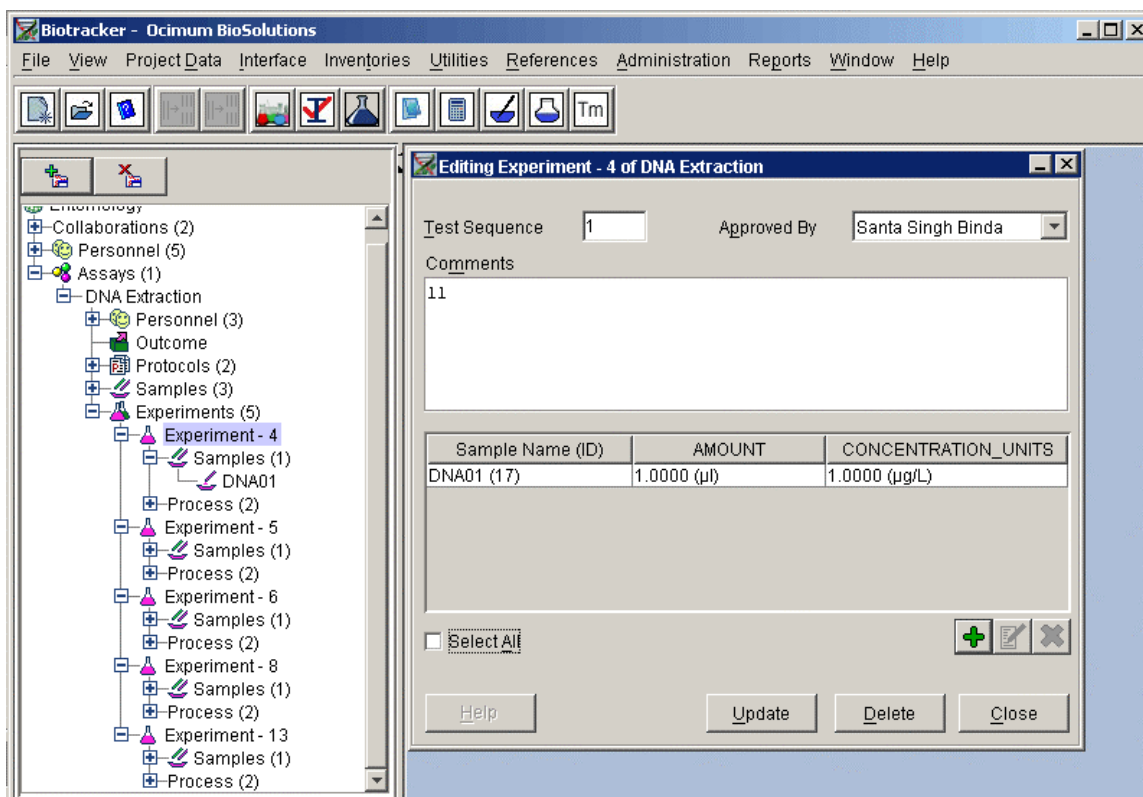


Figure 3: A screenshot that shows an experiment with samples to be used

Key Features of Experiment Tracking, Analysis and Result Archival utility are as follows:

- § Status reports can be based on time, experiments completed or samples on which analyses are complete.
- § Different calculation software (both external and those provided with the LIMS) are utilized in this module.

The screenshot displays the Biotracker - Ocimum BioSolutions software interface. The main window shows a tree view on the left with categories like Entomology, Collaborations, Personnel, Assays, DNA Extraction, Personnel, Outcome, Protocols, RNA isolation, Protein Extraction, Samples, Experiments, and Testing. The right pane is titled 'Login Samples' and contains the following fields:

- Identification: RNA-SAMP-01-COTT
- Sample Type: RNA
- Date: 7 Apr 2002
- Location: AERVG room
- Control:
- Exhausted:
- Concentration: 10.0 µg/L
- Amount: 10.0 µg
- Prepared By: jpm
- Derived From: (empty)
- Comments: RNA Sample Extracted from Cotton Leaf.

Buttons at the bottom include Help, New, Update, Delete, and Close.

Figure 4: A screenshot displaying sample entry form

3.6 Inventory Management and Tracking System

An Inventory Management and Tracking Systems form an integral part of Biotracker™. These enable user to keep track of chemicals, instruments and different buffers in the laboratory.

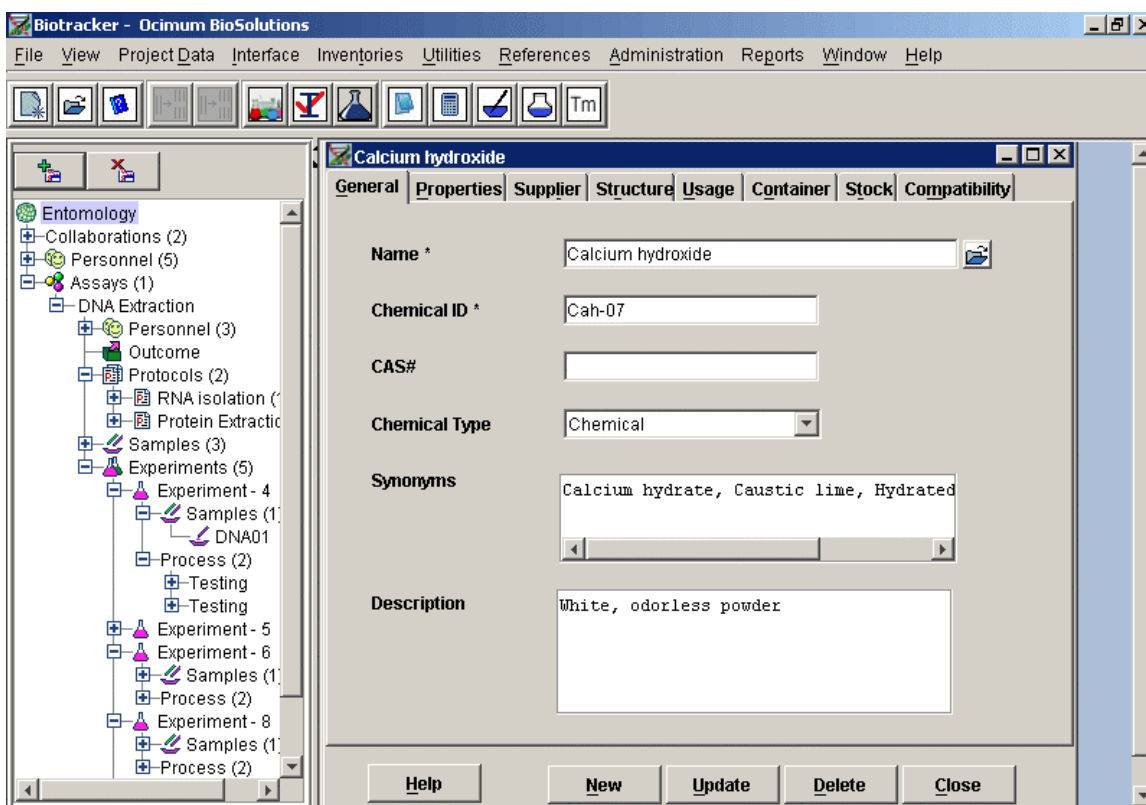


Figure 5: A screenshot of Chemical Inventory management tool in Biotracker™

It can help track the location, price, shelf life, stock and other such pertinent information about chemicals, buffers, consumables and instruments. An information about minimum level, maximum level and reorder level of inventories can be specified and the system will keep a tab on these levels. It also generates automated repurchase reminders and instrument service schedule notifications.

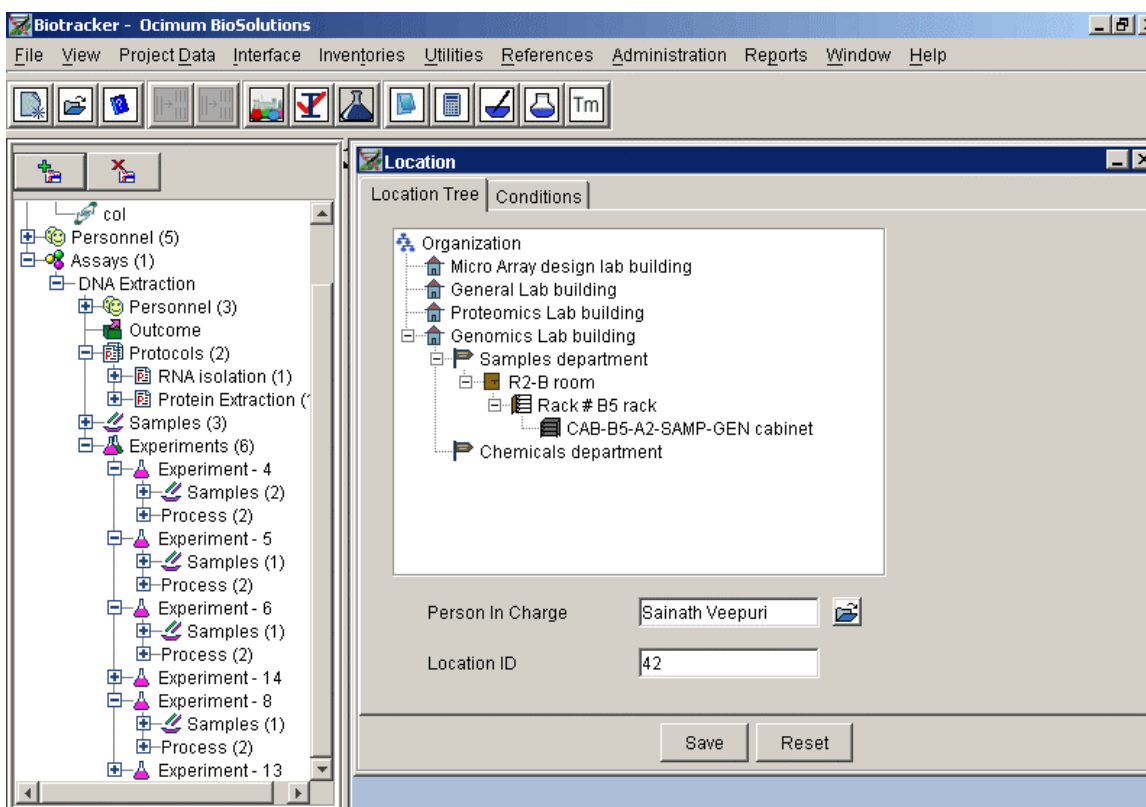


Figure 6: A screenshot showing tree view of different physical locations of inventory

Key Features of this utility are as follows:

- § Users can log in various samples individually or in batches.
- § Catalog various inventory items and furnish pertinent information about vendors, location and purchase orders.
- § Automatic update of stocks when these are used in an assay.
- § Maintain information on levels of constituent chemicals (acquired from a vendor) as well as material prepared from such chemicals in a lab (such as buffers, working solutions, stock solutions etc.).
- § Automatically generate demand sheets of chemicals and other materials for labs or users.
- § Manually enter usage of all items as well as automatic entry of usage with completion of experiments with which they are associated.

3.7 Primer Inventory

Primer library utility in Biotracker™ provides a handy tool to store information about PCR primers. Information such as primer length, sequence, vendor name, a short description of primer and its usage record can be stored and tracked through Primer Inventory. Melting temperature of primer can be calculated using Tm tool in Biotracker.

3.8 Probe Inventory

A customized inventory module for various probes that are used in microarray analysis, Southern blotting, Northern blotting and recombinant DNA experiments is provided in Biotracker™.

Information about probes such as probe type (cDNA, rDNA, genomic DNA), probe source, sequence, probe amplification primers and comments. Information from this inventory is linked to Array Design tool so that different probes that are spotted on a chip can be tracked along with pertinent data. A probe can be assigned an accession number or an identification number when it is acquired by or synthesized in the laboratory, complete information about the probe must be appended to Biotracker database. Once this is done, information about that probe whether it is incorporated on a chip or its pertinent for analysis purposes can be generated in different modules.

3.9 Plate Tracking

Plate Tracking Tool provides integration of array production information with bio-material or sample information. Array design tool integrated with analysis tools within Biotracker™ enables efficient tracking and analysis of microarray data. Biotracker™ provides features such as defining plate types, tracking plates, assigning protocols to different plates and annotation of individual wells and

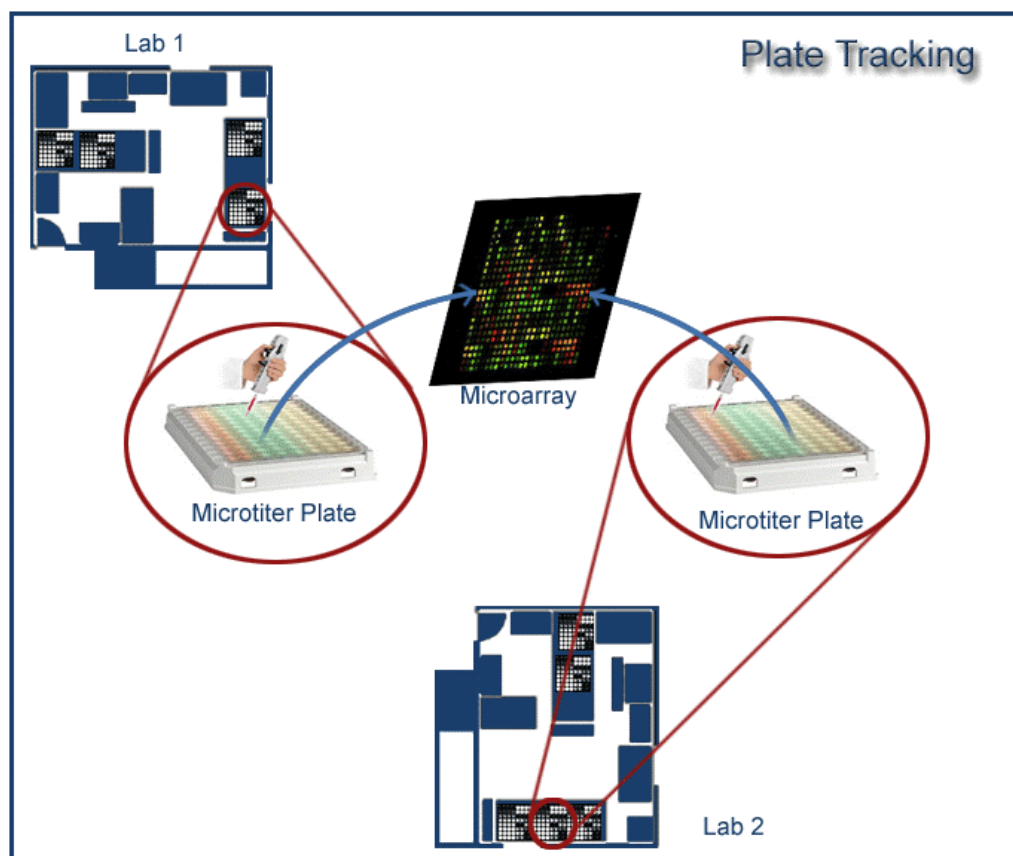


Figure 7: A schematic representation of plate tracking utility for microarray design

different probes. These design features and their tracking through experiment help with simpler data flow for analysis. Some of the salient features that Biotracker™'s Plate Tracking module offers are as follows:

- § Define array designs, print plate order, print batches, and individual arrays etc.
- § Comprehensive tracking of microtiter plates and their identities
- § Annotation with record of events, protocols and experiment conditions etc.

This tool helps track microtiter plates, probes and samples from different sections of a laboratory, different laboratories in a research organization, a deep freezer, bench or a particular rack in a particular lab. An association can be maintained between a spot on an array and particular DNA sample that can be tracked through different stages of an experiment and data analysis. This facility

coupled with Probe Inventory will be handy for customized chip design as well as for QTL mapping and SNP mapping experiments using conventional blot hybridization assays.

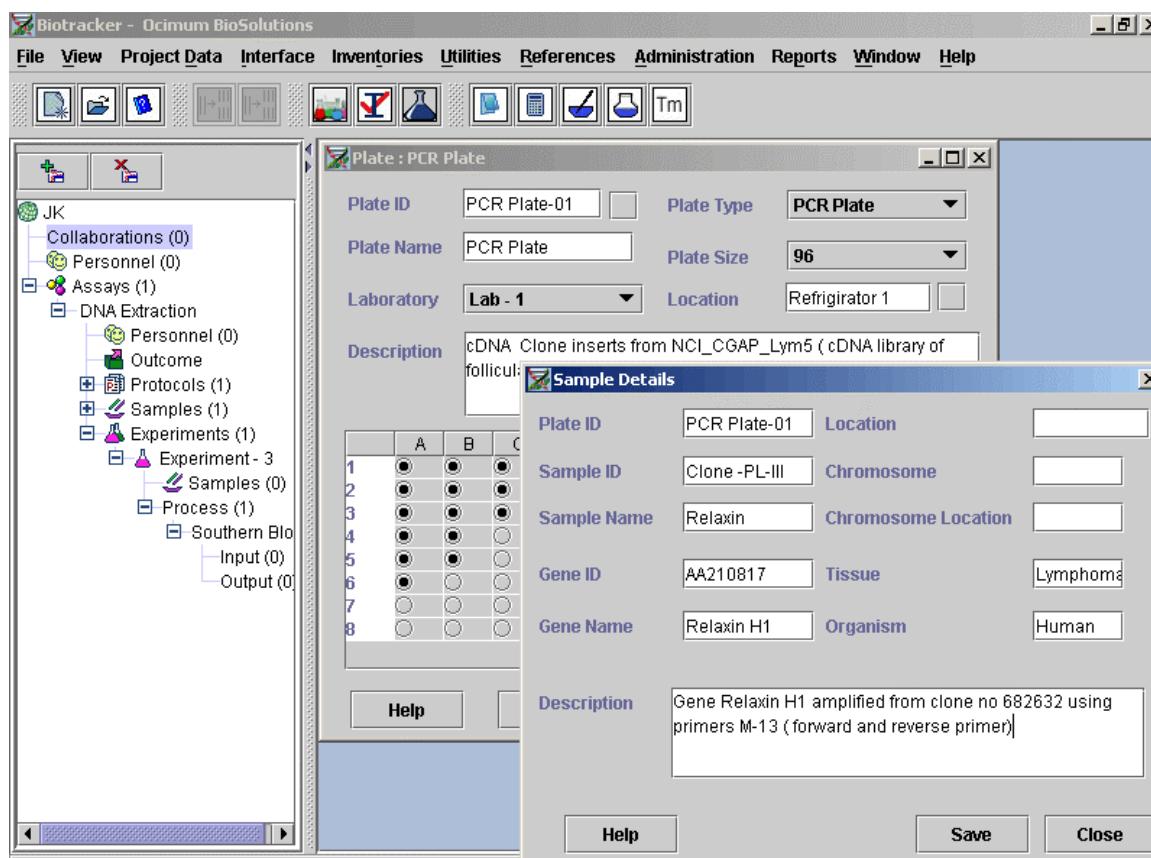


Figure 8: A screenshot of plate tracking tool in Biotracker™

Design and tracking features in Biotracker™ are highly customizable, enabling a user to define and track plates based on plate type, for example, protocols and annotation can be defined for each plate type. Further, information about a sample or a plate can be sorted by different parameters such as plate type, sample type, date of experiment, assay number etc., relevant details for each such sample can be viewed or generated in a report.

3.10 Instrument Integration

Biotracker™ provides interface for data transfer and remote operation of certain equipment; this saves time and effort invested in manually recording data

from different instruments. Better accuracy is also ensured with automated transfer of data from instruments.

3.11 Report Builder

The Report Builder module of Biotracker™ allows users to create and customize reports of various kinds. Reports can be generated based on researcher names, projects, assays and by calendar. This module provides statistical display of work and material in the laboratory. Reports can be for usage of instruments, chemicals, samples, buffers etc.

Reports can be filtered and organized based on date, experiment, user, inventory or a combination different heads. Data is primarily stored in and retrieved from the integral database, a data transfer utility facilitates import of data from local or network disks as well as export data in appropriate formats to local or network disks.

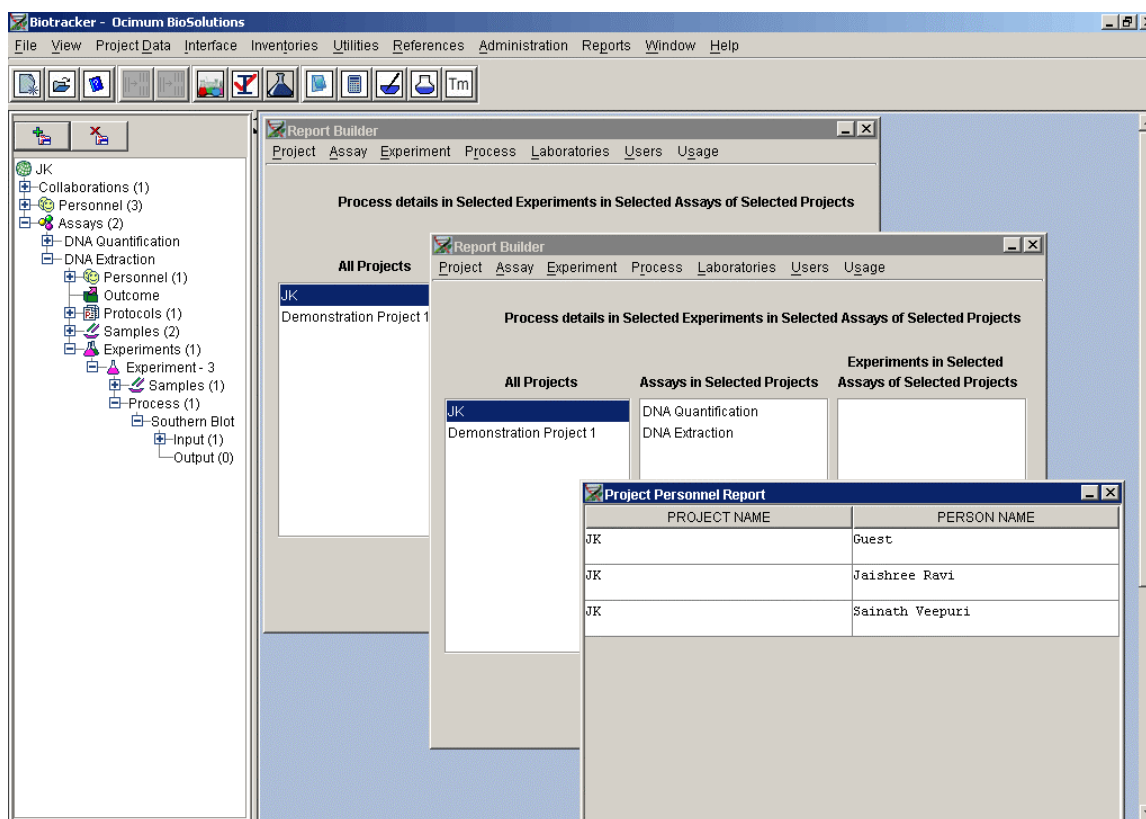


Figure 9: A screenshot of Report Building tool in Biotracker™

4.0 WHY BIOTRACKER™ FOR YOUR LABORATORY?

Biotracker™ is designed with user-friendly interface and control, yet the architecture is robust and is compatible with commonly used operating systems/platforms such as Windows 98, Windows 2000, Windows XP, Macintosh, Linux and UNIX.

4.1 Ease of Use and Intuitiveness in Biotracker™

It has very simple interfaces with minimum of software technical jargon; it has been designed by and from the laboratory researcher's perspective. A user can self-learn its features in very little time and can become proficient in its use quickly. Many features and interfaces customizable and are stored in the database as user's preference. Thus a user will find a familiar and comfortable interface after logging in.

Training and technical support are provided in form of instruction manual, user manual, systems manual, video demonstrations, visit by technical support personnel and remote support through e-mail, fax and telephone.

4.2 Data Management in Biotracker™

A database tool is integral to Biotracker™ and this works as repository of relevant information. A well laid out database architecture with different levels of access serves many purposes:

- § Centralized data storage thereby eliminating the need of multiple data storage disks.
- § Data security is taken care of by robust database architecture and backup features, a single backup operation can copy and store the entire data to a safe repository rather than taking backup of individual systems and directories therein.
- § Interpretation, analysis and report generation is easily facilitated.

Multi-user environment, another salient feature of Biotracker™ is a multi-user environment capability. Biotracker™ can be installed on a server and client machines in the network can facilitate access to several users simultaneously. In addition to an integral database, Biotracker™ facilitates easy export and import of data. Data are reported internally in XML (eXtensible Markup Language) format thereon an application can build a pdf (portable document format, xls (Excel file or spreadsheet) or a text document, thus can be recognized and read by any application. Similarly data import from XML format allows other files to be read in Biotracker™.

4.3 Data Security and Access Level control in Biotracker™

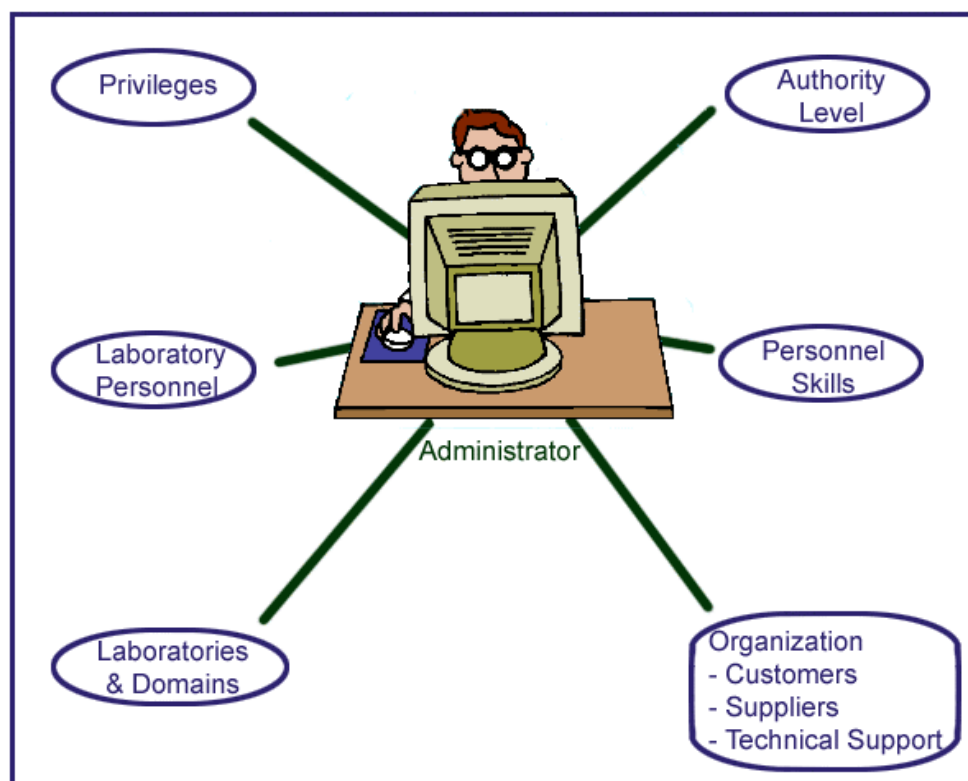


Figure 10: A schematic view of access level control in Biotracker™

Data security in Biotracker™ is ensured through client server architecture that has a multi-tiered structure for access. An administrator or a project leader has more privileges than other users. An administrator can create projects and allocate resources where as a user with limited access can't create a project.

However this user can execute a project and add research data in the system, viewing this data can be compartmentalized as decided by Administrator of research group. Copying and removal of data is also restricted based on a user's privilege.

Apart from such access level control, hardware and software measures are incorporated to ensure protection of information against intentional and unintentional loss of data.

4.4 Instrument Interfacing in Biotracker™

Following are some of the instruments that have an interface in Biotracker™; a customized interface development for other instruments is done based on different laboratory's requirements.

- **Electronic Balance:** The sample and result entry screen provides a feature that helps in calculating the strength of a solution (molarity, molality, normality, ppm, %). The quantity of chemical used in the experiment is automatically deducted from chemical database or inventory. The user can also save information on chemical assays in a database. Information such as name of researcher, amount of chemical, concentration etc., is represented in a table.
- **Electrophoresis:** This interface provides information management on electrophoresis (type of gel used, buffer used, electric field applied, destaining solution used in the experiment, duration of experiment), and molecular weight marker. Each marker details are represented in a table. The user can enter corresponding sample details (number of samples, sample name, migration patterns, ladder pattern etc.). Biotracker™ can store images of gels and autoradiographs. The information about each sample and all supporting data is represented in a table that can be edited or deleted before it is appended to database.
- **Centrifuge:** This interface enables a researcher to manage information on centrifuge usage. It can help keep track of centrifuge data such as different samples being run, rpm, duration, number of cycles per

experiment etc. The information is represented in a tabular view and the user can edit this information and save it to database.

- **Polymerase Chain Reaction (PCR):** This tool helps keep track of PCR reactions and inventory. Information on template DNA, primers, thermocycler settings (temperature and duration), concentration of different reagents used, number of cycles etc., can be easily managed using Biotracker™'s PCR interface. Information about these experiments can be saved to the database.
- **pH Meter:** This module comes in handy to manage information and data about and from a pH Meter. The information is represented in a table and it can be edited and saved into the database.

4.5 Automated Data Transfer through Instrument Integration

Biotracker™ can be integrated with instruments that have data transfer ports. Most of the contemporary diagnostic equipment and instrument such as thermocyclers, microplate readers and centrifuges come equipped with a data transfer port. These can be connected to a computer through cables and a two-way data transfer can be executed. Biotracker™ can be customized to read output files from such equipment thereby saving time and effort to transfer output data from a machine to computer. Instructions can be transferred from computer in laboratory to such equipment.

4.6 Customizable Reports

Biotracker™ provides several options and filters to view results from different experiments and about instruments, chemical and consumables inventory (test tubes, microfuge tubes, pipettes, pipette tips etc.), and makes report generation an easy task. Reports can be generated as per user's requirements such as experiment ID, sample ID, experiment status (pending, completed, approved), date of experiment, names of researchers etc.

4.7 Scalability and Expandability

Biotracker™ can grow with your laboratory's growth and its expanded requirements. While the number of users who can access Biotracker™ can be increased by the click of mouse, more software tools and analysis systems can also be built and integrated with Biotracker™. Statistical analysis tools for field and laboratory data, Genetic Linkage Analysis tools, Gel Documentation System, DNA and Protein sequence analysis tools can be seamlessly integrated with Biotracker™. Biotracker™ also works well with existing legacy systems and existing data. Proper care is taken during Biotracker™ system implementation in a laboratory to ensure smooth transition to a new information management system.

4.8 Cost Effectiveness

Biotracker™ is very competitively priced. A multi-platform capability, open source language use and our quality management ensure efficiency and prevent overruns and overheads. The basic version of Biotracker™ will cost significantly less than other commercial packages, addition of extra modules and customization is done in a very cost effective manner thus it is affordable for your laboratory. We constantly work with our customers to identify the requirements correctly, thus our customers' pay for what they require, instead of packages that may have a few required tools but costs are inclusive for those tools that are not required.

5.0 SUMMARY AND CONCLUSION

Laboratories that are engaged in life sciences research have enormous information management requirements that are growing with creation of more knowledge as well as development in technology. Increase in efficiency of information management leads to overall improved efficiency and productivity, thus researchers can focus on discovery per se rather than mundane archival and tracking tasks. Biotracker™ is a comprehensive Laboratory Information Management System developed and

implemented by Ocimum Biosolutions Ltd., India that meets standard requirements of most biological research laboratories' yet it is customizable, scalable and expandable to meet specific requirements of a particular laboratory. Biotracker™ is a multi-platform, multi-user, cost effective Laboratory Information Management System designed to meet today's and tomorrow's life sciences information management requirements