

SoftTrace Quality Module

FOR FULLY INTEGRATED, PAPERLESS
DAIRY LABORATORY OPERATIONS



SoftTrace Quality Module (QM) is a flexible, fully scalable, laboratory system purpose built on proven technology to meet the specific analysis and data integration challenges of the Dairy industry. From raw material/ingredient intake and process allocation all the way through manufacturing and product grading to finished product dispatch, SoftTrace offers Dairy manufacturers a host of functionality and the flexibility missing from generic quality management software.

Based on our in-depth knowledge of the Dairy industry, we have included critical industry-specific functionality. Our team of experts have specifically designed SoftTrace QM so Dairy manufacturers can easily configure it to meet their precise analysis needs in the following areas:

- Receiving
- Intake measurement and analysis
- Process allocation
- In-process analysis
- Average weights
- Environmental analysis
- Micro analysis
- Finished goods

SoftTrace QM offers a total solution for the effective, enterprise-wide automation and management of Dairy laboratory data and workflow processes. It delivers a paperless laboratory, enforces best practice, enhances traceability and ensures adherence to quality standards at all stages of the manufacturing process:

- Raw materials, in-process, environmental and finished product analysis.
- Raw material analytical results validation and monitoring.
- Real-time monitoring of production quality data.
- Early warning, real-time non-conformance alerts and quality incidents monitoring.
- A comprehensive quality profile of all finished goods.

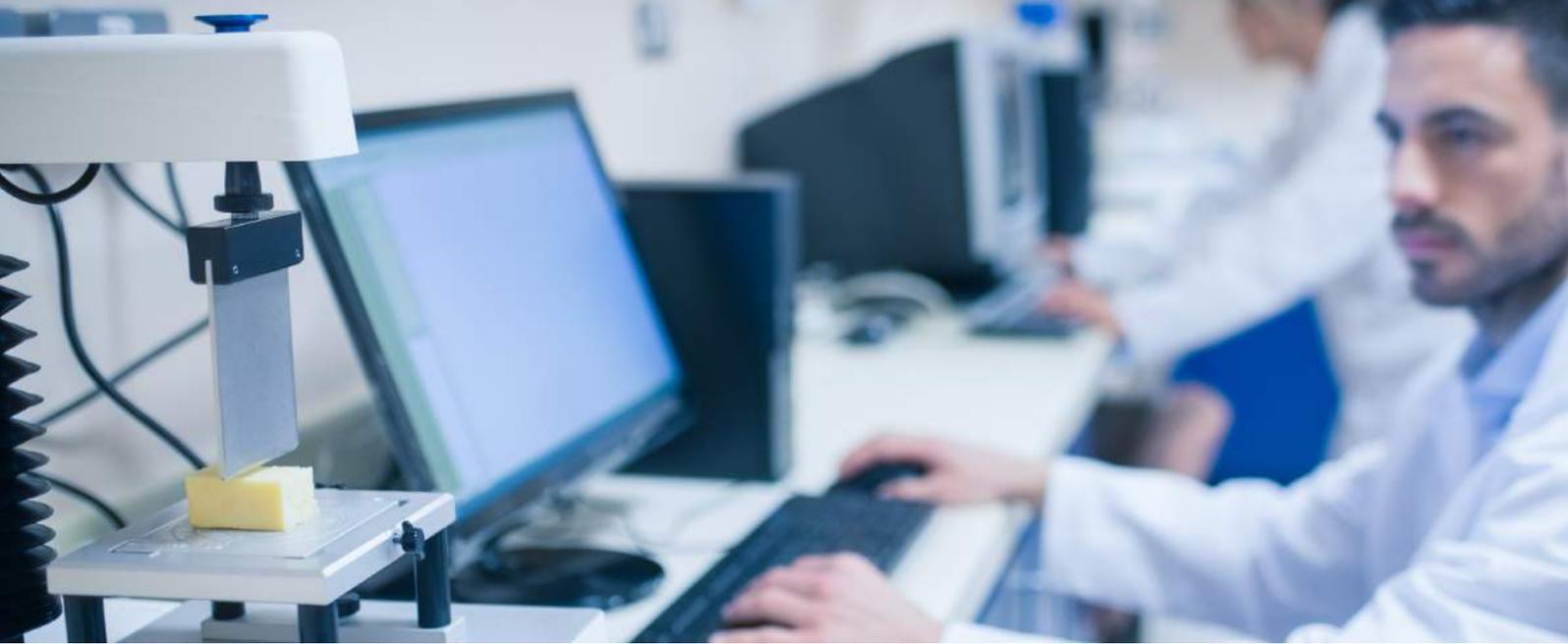
We understand the Dairy industry's quality management challenges

To meet stringent regulatory, customer and consumer demands, today's Dairy manufacturers need to achieve optimal quality data management in raw material intake and in-process manufacturing control with an associated focus on efficient data management and traceability.

SoftTrace know this means:

- Implementing an integrated laboratory management system for raw material, in-process, environmental and finished goods analysis to manage quality processes and comply with regulations, standards and statutory requirements.
- Creating an electronic link between tanker loads and silo batches.
- Defining and tracking the quality of bulk inventory, manufactured goods, purchased items and stock inventory.
- Efficiently managing the quality of processes and products throughout production.
- Real-time monitoring of production quality data and quality incidents.





Custom Configuration & Workflow

SoftTrace Quality Module (QM) has been designed to reflect distinct Dairy industry workflows. That means it is easy to use, manage and adapt to reflect existing and emerging processes.

The user-defined test database, test specifications and dynamic worksheets can be configured to reflect existing manual recording systems and work processes, as well as accommodate business change.

- **Build dynamic worksheets** to accurately reflect your working environment with variable test frequencies and test specifications.
- **Customise worksheets** for a familiar, easy-to-use interface and efficient data entry.
- **Reduce manual inputs and repetition**, while maintaining data integrity and eliminating the risk of error.
- **Automatically populate worksheet fields** with repeat results.
- **Create and store sampling schedules** and workflow plans.
- **Assign samples to worksheets** based on user defined criteria.
- **Link specification tool-tips and test method** documents to individual tests.
- **Eliminate quality bottle-necks** by incorporating a dynamic, user-defined database of products, WIP and ingredients with associated tests, test specifications, sample stages, schedules and workflow plans.
- **Convert / change units of measure and calculations** per test type and flexibly meet evolving business requirements.
- **Automatically pre-log samples** for routine sampling.
- **Avail of a full audit history** on each result.
- **Define amendment reason codes** and link these to the data entered.
- **Attach SOPs, quality documentation**, standard and free-text comments.
- **Generate certificates of analysis**, compliance documentation, and barcode labels.



softtrace
delivering traceability solutions

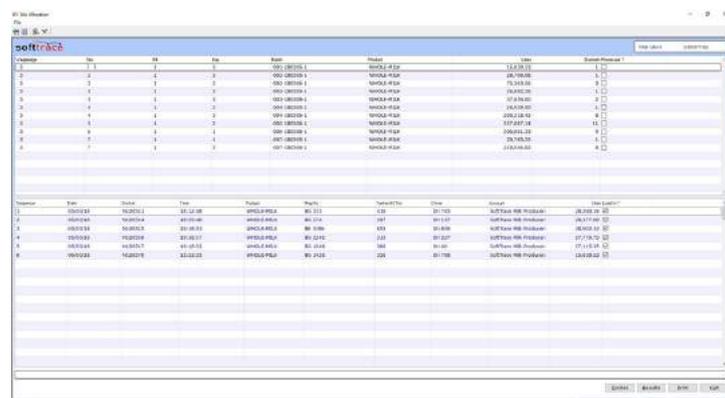
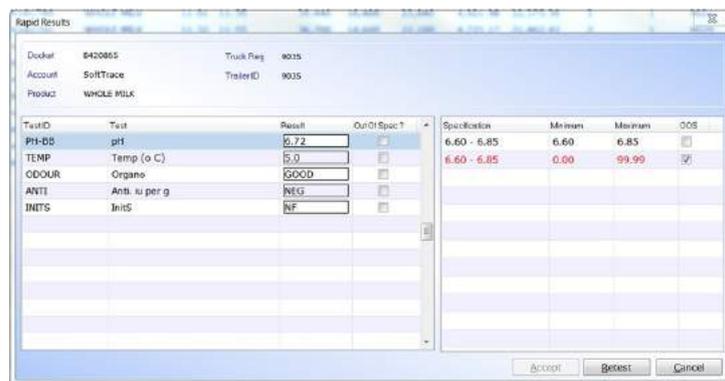
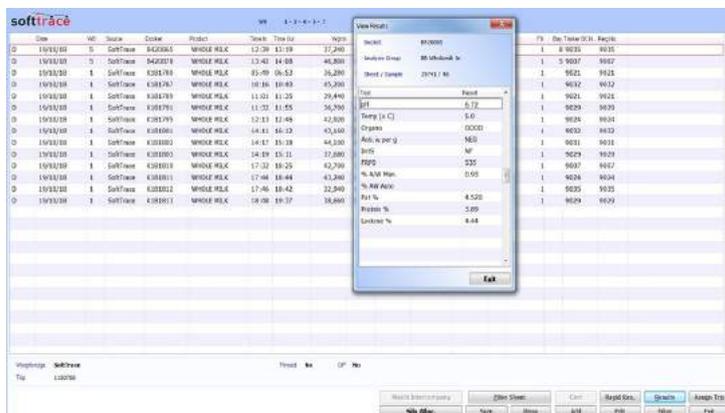


Raw Material Analysis & Process Allocation

SoftTrace QM allows Dairy manufacturers to record and track all raw materials and ingredients received into the manufacturing facility for an essential level of quality data visibility and control.

Real-time integration of SoftTrace QM with the intake measurement system, inventory records and plant automation creates an unbroken data record from the raw material and active ingredient sources to the plant, on to quality control and release to the appropriate process or holding area. **This functionality is customisable to meet individual needs:**

- Record the analysis of tanker loads including rapid intake and compositional analysis.
- Electronically track all checks and paperwork.
- Automatically highlight failures and out-of-specification results against established test specifications, red flag these and, as required, suspend tanker off-loading pending review, pass, reclassify, or reject suspended loads.
- Highlight rejected load samples on the system and generate specific rejected load analysis sheets containing the required tests and parameters.
- Automatically transfer tanker sample details to the relevant, customised SoftTrace QM worksheet for rapid acceptance analysis, compositional tanker analysis, detailed quality profile analysis.
- Rapid Testing:** rapid testing results can be captured via an interface to the analysis instrument. This facilitates efficient load management with full visibility on the status of all incoming loads. SoftTrace QM can be configured to facilitate the review of all tanker load intake analysis data for silo allocation. Out-of-specification results are flagged and unavailable for silo allocation on the system.
- Out-of-Specification Results:** tanker loads with out-of-specification, or positive results for antibiotics, are prevented by the system from proceeding from the scales to silo allocation and the manufacturing process. Out-of-specification results automatically trigger email and SMS alerts to the relevant personnel.
- Silo Allocation:** silo allocation creates/updates a silo batch. This links all tanker loads allocated to the batch for full traceability from the silo back to the tanker loads. The facility is available to split a tanker load between several silos. Creating a new silo batch number triggers a sample in the relevant SoftTrace Quality Module Silo Analysis Worksheet.
- Silo Management:** a composition record is made available for each tanker load to track the amount of protein and solids (with other components) added to the silo. In addition, a silo monitoring sample record can be automatically added to the relevant worksheet, at a frequency determined by the Quality Manager.
- Analysis by Supplier:** assign a range of supplier specific analysis groups to raw material purchases to reflect purchase agreement requirements.
- Tanker CIP:** CIP data (including CIP Type – acid or caustic) can be recorded in SoftTrace as required via the Truck Wash Interface. A SoftTrace Wash Input screen can be made available to allow the Wash Operator to manually input wash details. Alternatively, this process can be automated by interfacing with the PLC system to record the wash duration and temperature.
- Tanker Composition:** the tanker intake sample can be used to determine the protein and total solids of each load received into the plant. For compositional analysis, SoftTrace QM can interface with laboratory instruments for automatic data capture.
- Ingredients Traceability:** all associated ingredients quality control data can be recorded in SoftTrace QM to facilitate ingredient QC and release into the process. Ingredients received can be integrated and updated in your company's Inventory Management system as required, for a real-time view of ingredients and work-in-progress inventory.





Micro / Pathogen Testing

SoftTrace QM facilitates full microbiological, chemical and physical analysis of incoming materials and packaging, in-process bulk product analysis, finished product analysis, and environmental conditions analysis (swabs, air plates etc.):

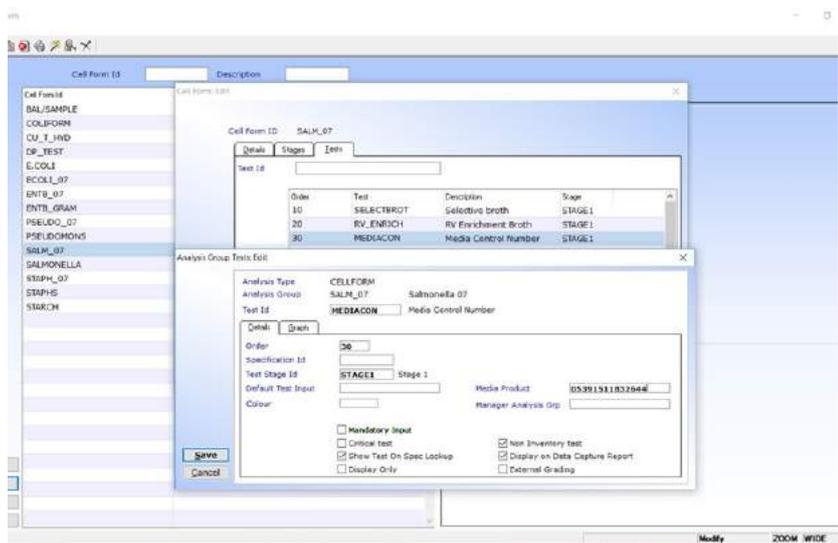
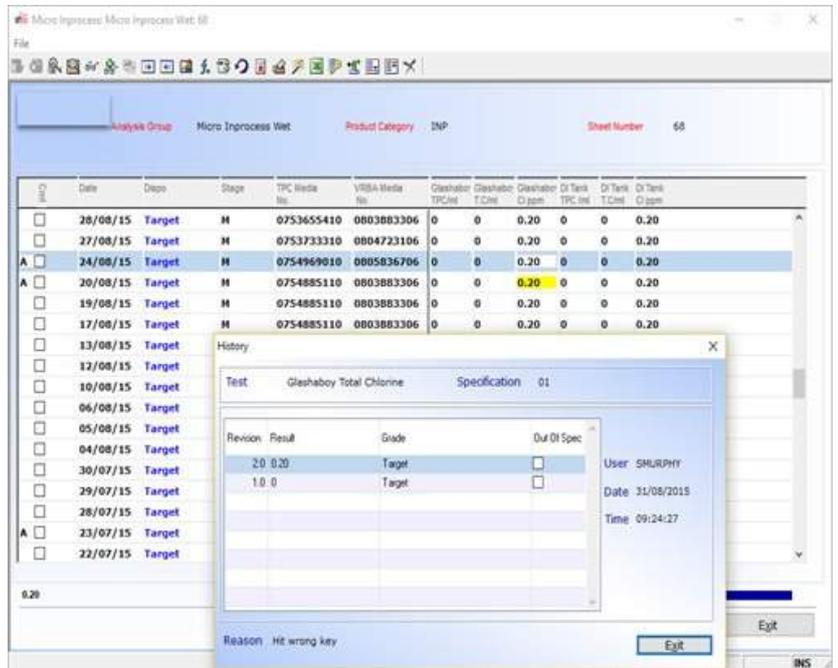
- Generate micro plate barcode labels (specific to each test and test stage).
- Prohibit result entry outside the prescribed incubation period.
- Scan and record media batches.
- Validate media for use and verify the media expiry date.
- Generate a media usage record.
- Automatically transfer final stage results to the designated worksheet cell.



Integrated Barcode Functionality

SoftTrace QM provides full support for the generation and use of barcode labels throughout the system – for sample identification, tracking, validation and chain of custody support. The design, content and point of print for each label are fully customisable. This streamlines data entry, reduces errors and facilitates the removal of paper records from laboratory processes:

- **Sample Registration:** the SoftTrace QM Sample Scheduler can be configured to automatically generate routine samples and print barcode labels.
- **Sample Reception:** scanning the barcode label automatically generates the sample test details (including sample ID, test ID and test stage), then validates and opens the sample for result input.
- **Ingredient Intake:** sample labels can be generated at the scales or in the laboratory as required.
- **Sample Identification:** creating a sample on SoftTrace QM can be configured to generate a corresponding sample barcode label containing human readable test and barcode details.
- **Multiple Labels:** can be generated for all tests and/or test stages pertaining to a single sample.





Traceability

SoftTrace QM has been designed to automate Dairy laboratory records, and integrate with laboratory instruments and business systems to provide a platform for full analysis quality management and traceability. It combines a comprehensive audit trail and high degree of overall application and data security with flexible, administrator-friendly facilities.

Each result recorded in SoftTrace QM is associated with the User ID, Date and Time of entry. Analysis results are dynamically compared to the assigned specification, with automatic non-conformance alerts. Result amendments are colour-coded and a full result history is maintained.

All inputs and result amendments are available for reporting to meet regulatory requirements (including traceability reporting). Where results are integrated to 3rd party software, amendments are flagged for transfer as they occur.

Reporting

SoftTrace Quality Module (QM) provides a comprehensive suite of standard and user-defined reports, enquiries and SPC graphs to meet internal and external reporting requirements. Customised reports can be provided to meet all requirements. Report data can be generated in multiple formats for email, print, and export to other applications - including in Excel and PDF format.

SoftTrace Quality Dashboard - configurable by site, individual site, and user group - provides comprehensive, actionable quality results at a glance (24 hours, 48 hours, 72 hours, or full week), with quick links to a suite of reports and enquiries:

- All quality analysis results for in-process and packing.
- A full overview of production for the specified period.
- Analysis results graphs.



Instrument & Systems Integration

SoftTrace QM can be rapidly and cost effectively deployed to integrate seamlessly with your existing laboratory infrastructure. It facilitates the automatic, real-time transfer of up to 20 results per sample to and from analytical instruments, average weights checkers, 3rd party ERP, process control, patron control, producer payroll, external laboratories, and commercial systems. This flexible, customisable dynamic interface and data transfer functionality delivers significant productivity gains, maximises resource utilisation and maintains data integrity.

Instrument Calibration

- Record instrument usage and performance details.
- Assign calibration and maintenance duties to laboratory personnel or external contractors.
- Set automatic alerts on calibrations due.
- Determine calibration events and details.
- Report on completed / due calibrations and full service history overview.





Security & Compliance

SoftTrace Quality Module (QM) supports Dairy industry users in meeting regulatory and accreditation needs. It conforms with GAMP, ISO 17025, GLP, HOKLAS, EN requirements for audit trails, security via multiple levels of permissions, data integrity, sample ID and tracking, corrective actions, control methodologies, access to SOPs, and data archiving. This includes compliance with CFR 21 Part 11 requirements for integrated security features, electronic records, and signatures.

Expert Support Services

- Technical and business consultancy
- Risk analysis and needs assessment
- Project management and implementation
- Software customisation
- Hardware implementation
- Customised training and on-going technical support

SoftTrace Systems Technology

To meet the technological challenges of today's business environment, the SoftTrace modules have been developed using the latest object oriented, rapid application development (RAD) technology. This facilitates efficient and rapid new product development. This means that we have the ability to easily customise and configure aspects of the SoftTrace modules for new customers, and efficiently provide updates to existing customers. The Client/Server, open systems architecture guarantees:

- High performance
- Superior data management capabilities
- Data access security
- Easy integration with 3rd party systems - ERP, process automation, laboratory instruments etc.
- The adaptability to meet evolving business needs

Designed and tested to meet rigorous Windows standards, SoftTrace provides users with a consistent, intuitive working environment incorporating:

- Windows compliance
- Client / server distributed networking
- Availability on a number of platforms
- Open databases - Oracle, MS-SQL, MySQL etc.

