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LIMS: Track, Trace and Eat Safe

Benefits of an Integrated Informatics Solution

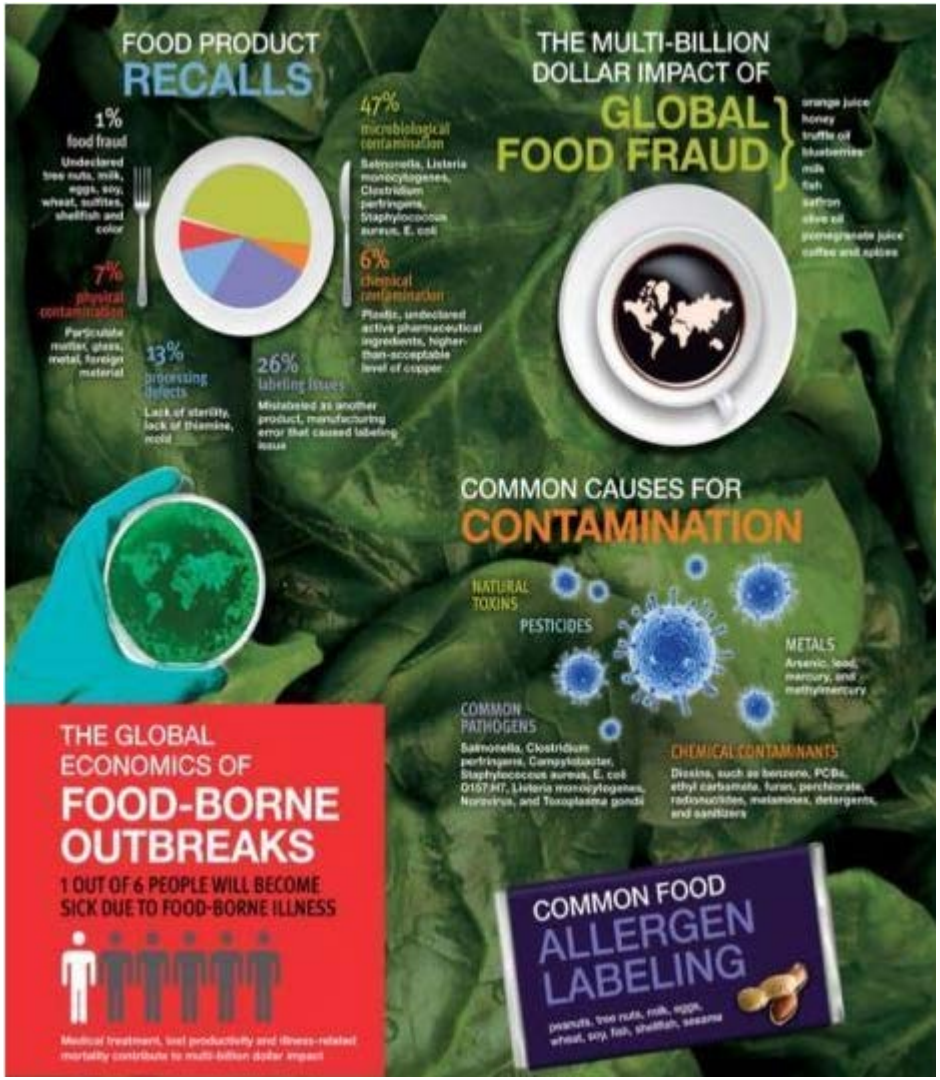
Speaker name
title

Agenda

- Define the problem
- Brand Protection
- Regulatory Compliance
- The concept of Integrated Informatics
- Defensible data
- Traceability
- Conclusions

Some background

- The food chain has become significantly longer over recent years.
- Food used to be locally produced and stores would stock seasonal produce
  - Now consumers expect a range of global options and year round availability
- The Food and beverage is the world's largest industry
  - Revenue of over $4.2 trillion in 2012
- The safety of consumers is no longer just about the activities within a single country



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Foodborne illness in the U.S.

- Each year, 1 out of 6 Americans gets sick from foodborne disease and 3,000 die as a result
- Reducing foodborne illness by just 10% would keep 5 million people a year from getting sick
- Preventing a single fatal case of E. coli O157 infection would save an estimated $7 million

“That's an unacceptable price to pay for that are mostly preventable.”
contaminations
– Kathleen Sebelius, Secretary of Health and Human Services

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Brand Protection

- Economic adulteration is a major problem in the food chain
  - The Grocery Manufacturers Association (GMA) estimates a cost to industry of $10-15 billion per year
  - Up to 10% of all commercially sold food products could be affected
- Most fraud does not constitute a risk to consumers
  - Substitution of lower value items to sell as a higher value product
- However adulteration of products has had serious consequences
  - Melamine contamination in pet food and baby formula
  - Salmonella contamination in peanuts
- Let's look at a real-life example:

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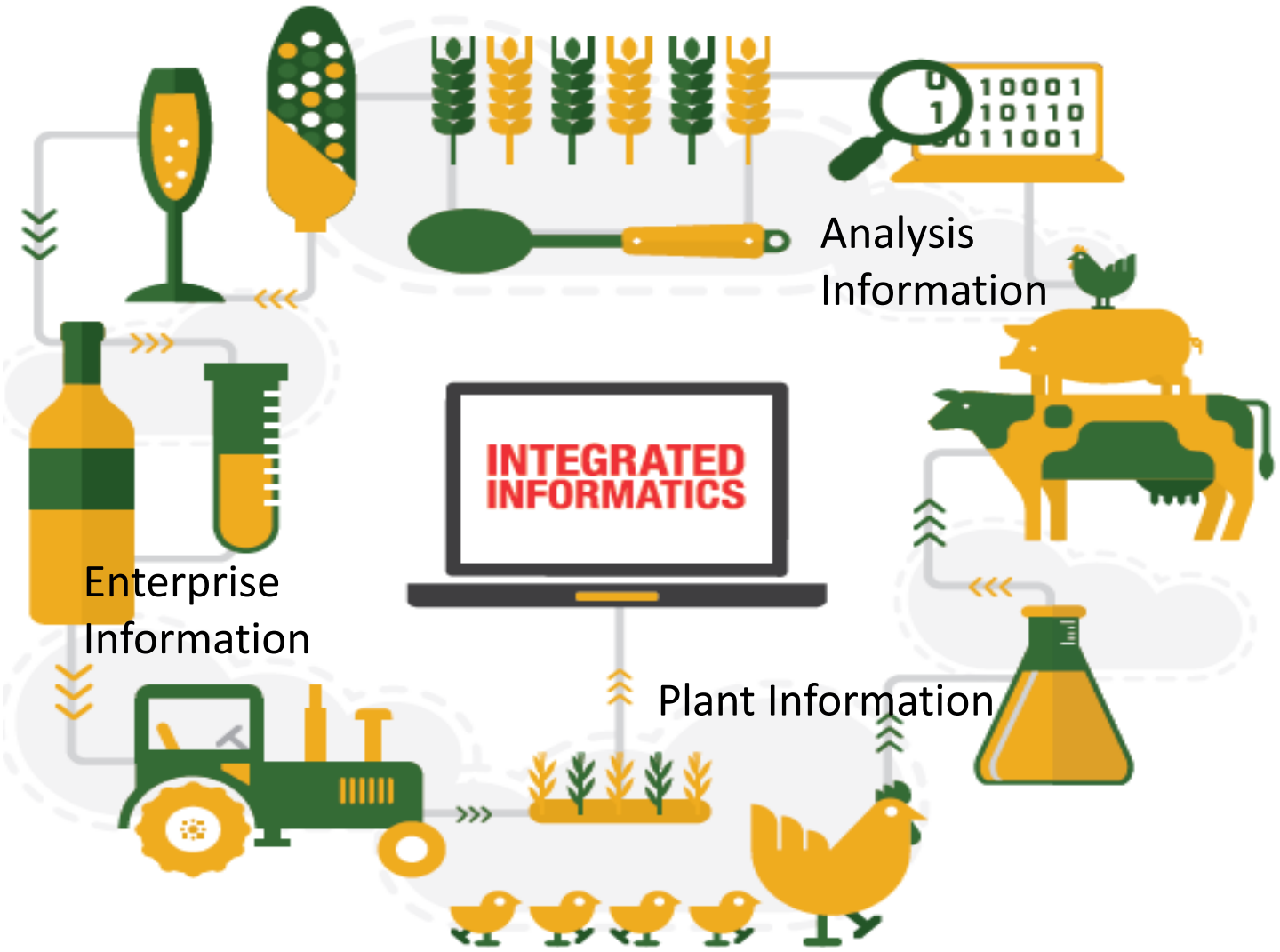
Protecting the Brand

- Clearly this situation was untenable for the genuine Manuka honey producers
- Around 80% of all Manuka honey sold globally was fake or adulterated
  - Potential to hugely devalue the brand when consumers became aware of the levels of fraud in the marketplace
- Honey producers established a trade association and developed accredited laboratory methods to positively identify manuka honey
  - Several unique chemical markers can be used to determine the provenance of the honey

The Integrated Informatics Approach



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Regulatory Compliance

- Food regulation development has lagged behind the rapid changes in society and industry
- It has sometimes taken a significant health issue to push forward regulations
- The challenge for governments today is how to monitor food that originates outside of your borders?

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Standardisation of Approach – FSMA Case Study

- We can use the US as a case study of how regulation has been developing globally
  - There are similar patterns of development, to a greater or lesser extent, across many authorities
- In 2011 the Food Safety Modernization Act was signed into law in the US
  - Significant change to the food regulatory framework
- Invests new authority into the FDA with the purpose of preventing food safety problems rather than reacting to them
  - Gave powers over the regulation of food imports and foreign producers
- The CDC (Center for Disease Control and Prevention) have highlighted the scale of the problem

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Regulatory Focus

- Traceability
  - '…a cornerstone of the EU's food safety policy'
  - '…requires importers…to ensure imported food is safe'
- Authenticity and Adulteration
  - '…plans to introduce more effective labelling rules'
  - '…establish measures that a food facility would be required to implement to protect against the intentional adulteration of food.'
- Risk Based Approach
  - '…requiring food facilities to evaluate the hazards in their operations…'

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Using Informatics to Manage Regulatory Compliance

- In a complex business such as a global food producer or drinks company, product quality data often originates in the laboratory
  - Raw material constituent analysis
  - Nutritional data
  - Microbiological data…
- Laboratory informatics systems hold key records for compliance
  - And also allow flexibility in reporting to different regulatory authorities
- Laboratory Informatics can also manage HACCP programs
  - Scheduling of Control Point sampling, reporting,
  - Dashboards, SOP management

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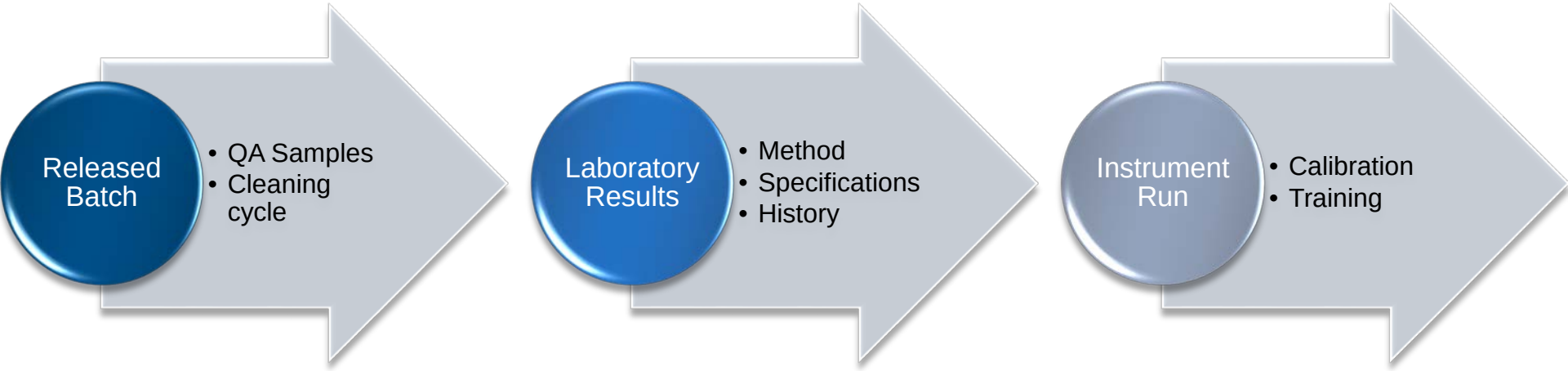
Defensible Data

- Being able to defend your data in an audit can be a daunting and time consuming task
  - Especially if you have paper records

- Auditors will start at a point and then follow the trail to see where it leads them e.g.



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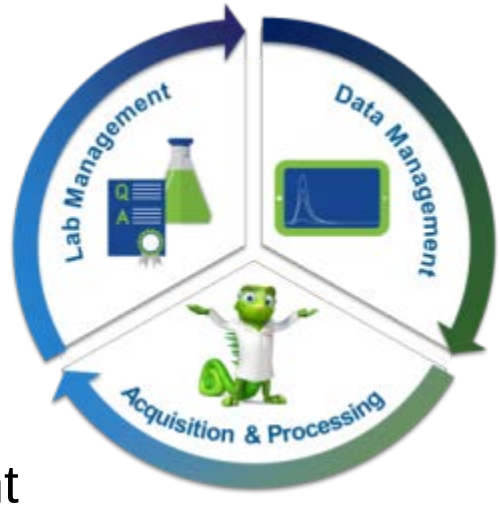
Integrated Informatics

- An integrated Informatics solution gives you this capability
  - Lot & batch relationships
  - Methods, specifications and results
  - Instrument Calibration history
  - User training Records
  - Method Execution
  - Statistical Trending



- As well as fully compliant records management
  - Date and time stamps against all data entry
  - Who entered data, where from
  - Audits of data changes
  - Electronic signatures

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Mapping the Real World – An example

- Small brewhouse
  - 3 Fermentation Vessels
  - One Yeast Press/Filter
- 5 day cycles
  - 4 days production
  - One day cleaning
- HACCP Schedule Post Cleaning Cycle:
  - Monitor FV inputs and outputs
  - Monitor YP inputs and outputs
  - Monitor Sample Taps
  - Use Micro testing

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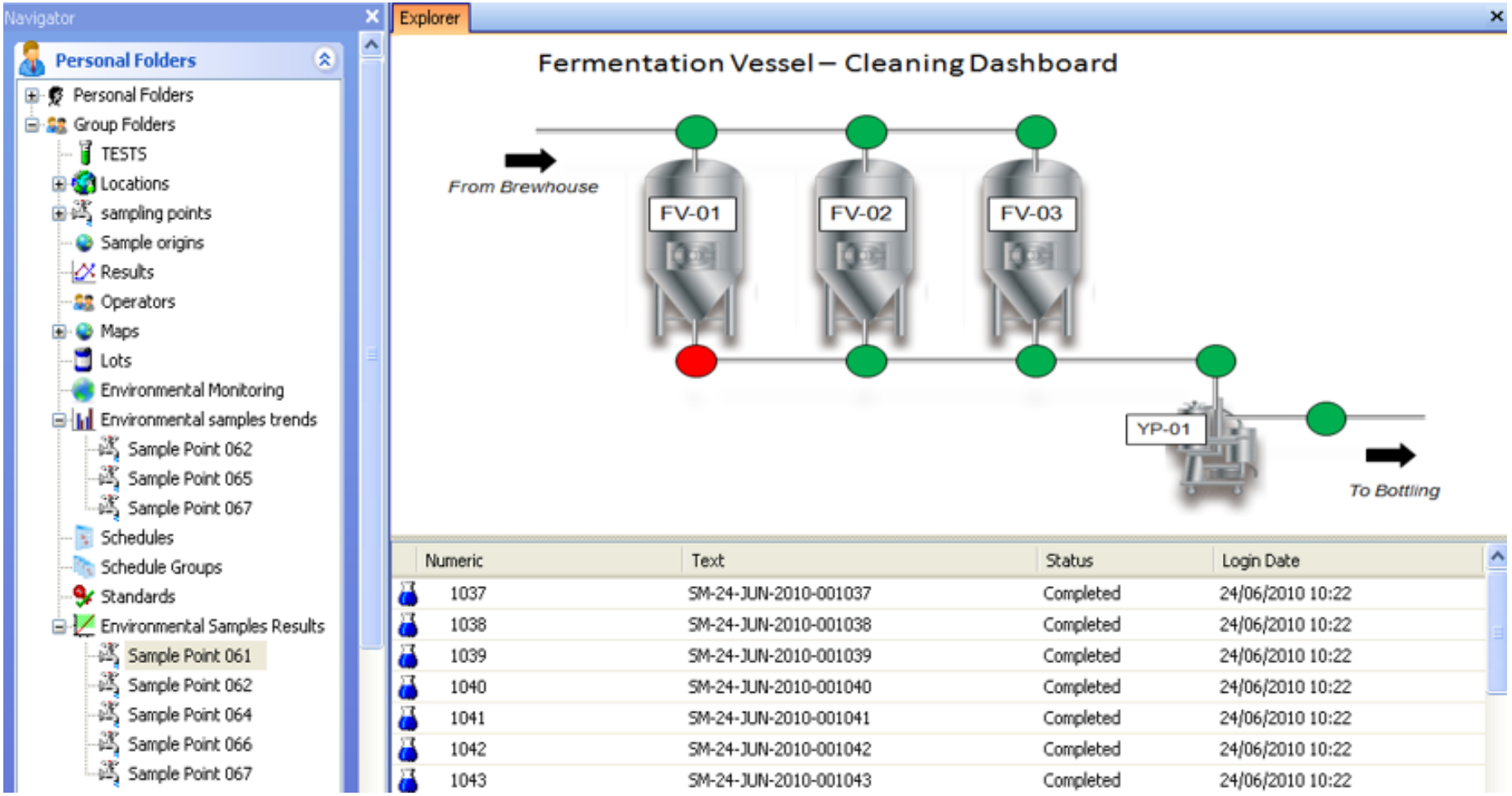
HACCP Dashboard



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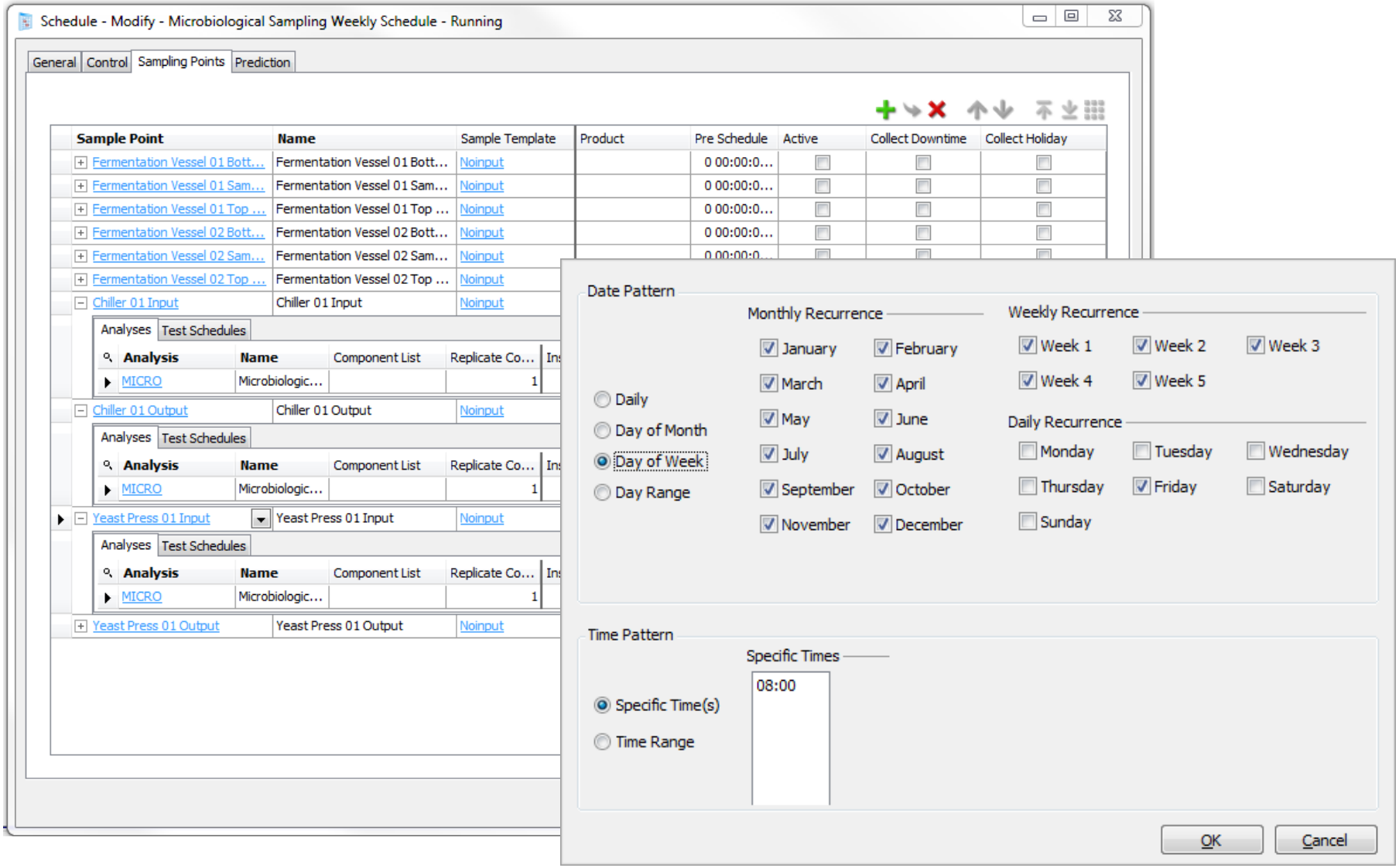
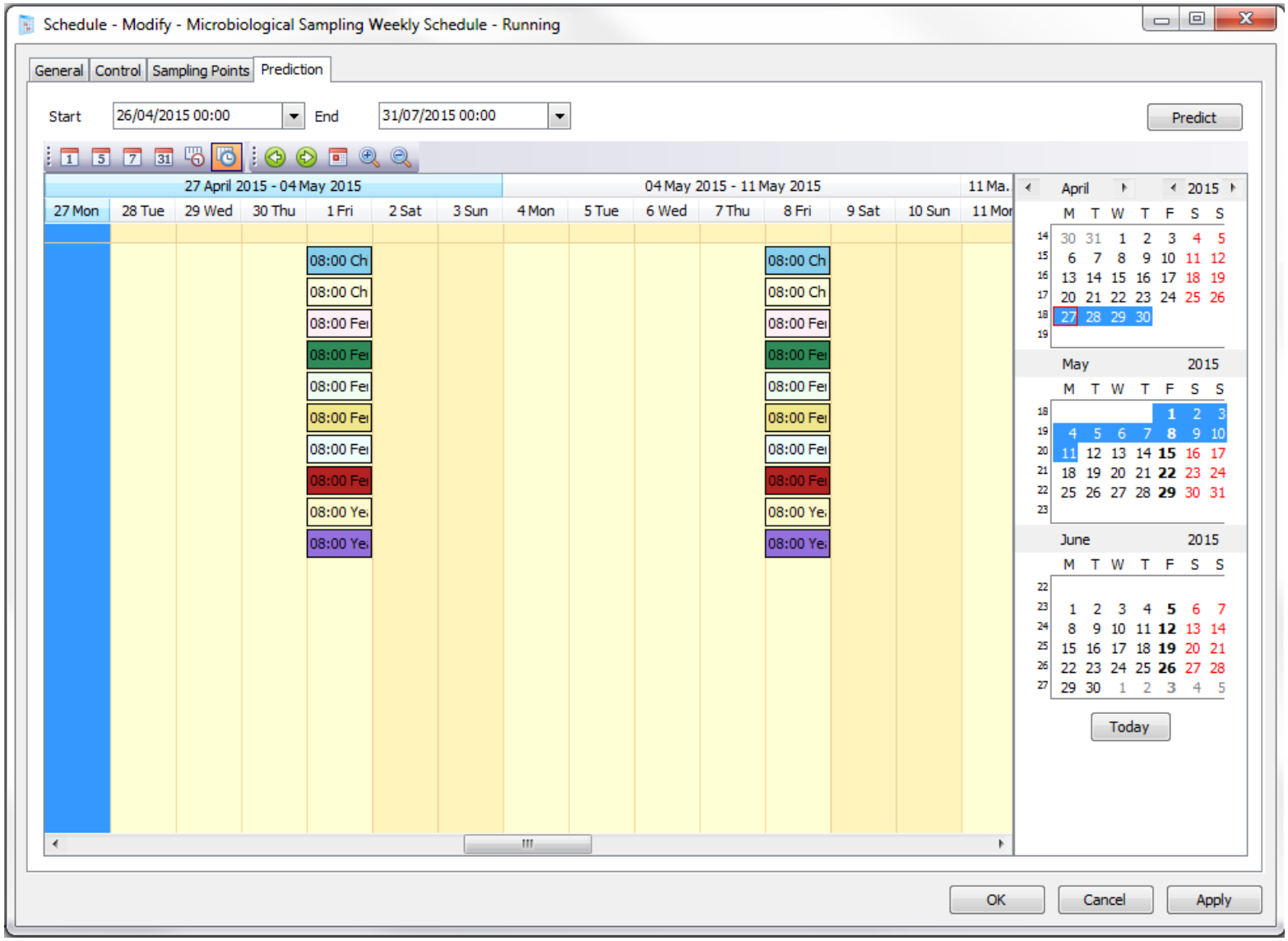
HACCP Sampling Schedule - Setup



HACCP Sampling Schedule - Calendar



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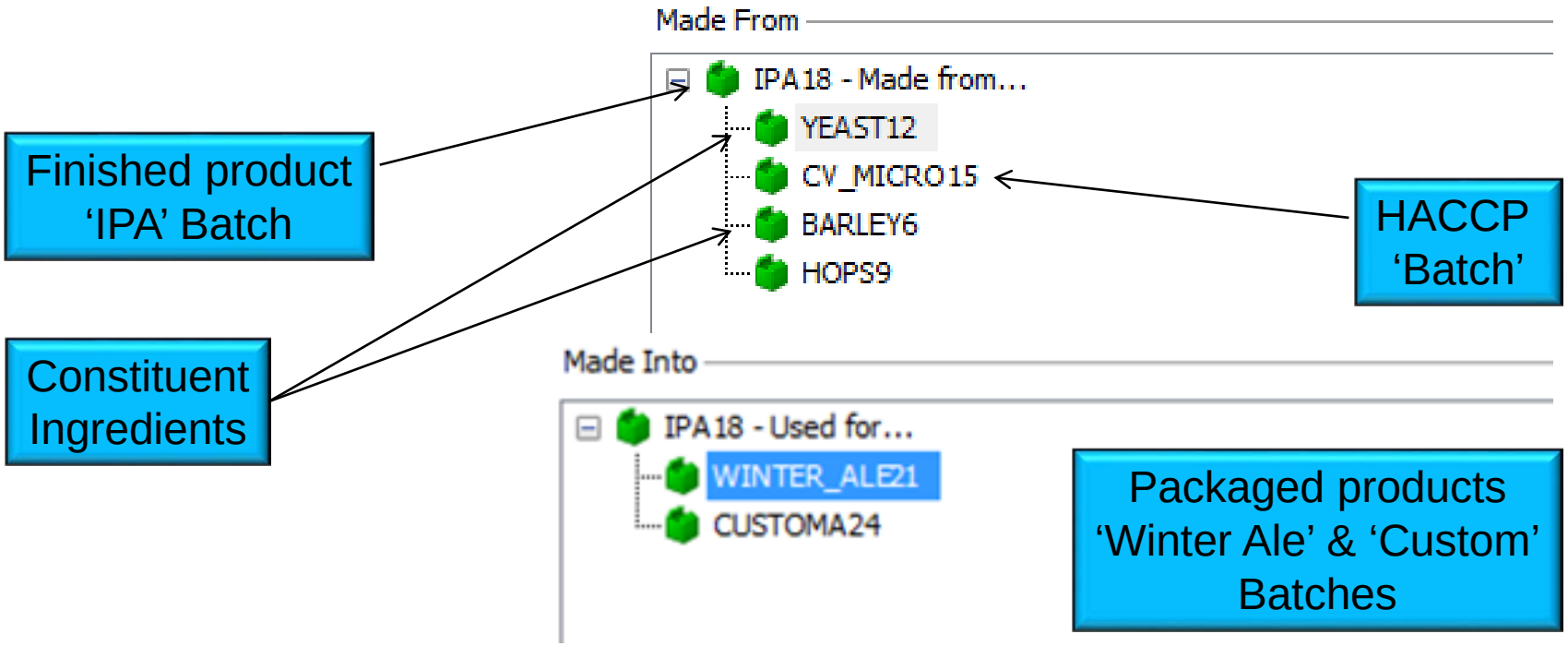
Traceability

- **Traceability** is the ability to verify the history, location, or application of an item by means of documented recorded
  - From Raw Materials through to Packaged Products
  - From each batch to its associated HACCP data
  - And to Compliance Data
    - Sample results, analytical methods, calibration, training…



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Multi-Stage QA Food Testing

This example uses a workflow to guide the operator through a multi-stage QA process where procedures must be performed in a specific order.

The initial sample received in the laboratory is a food product consisting of a sealed plastic pot containing salad and a sachet of salad dressing. The required quality testing has two phases:

1. The complete pot must first be checked to verify that it was fully sealed during the manufacturing process.
2. When the seal has been checked, the salad and dressing are logged as subsamples and each subsample requires a further set of quality tests.

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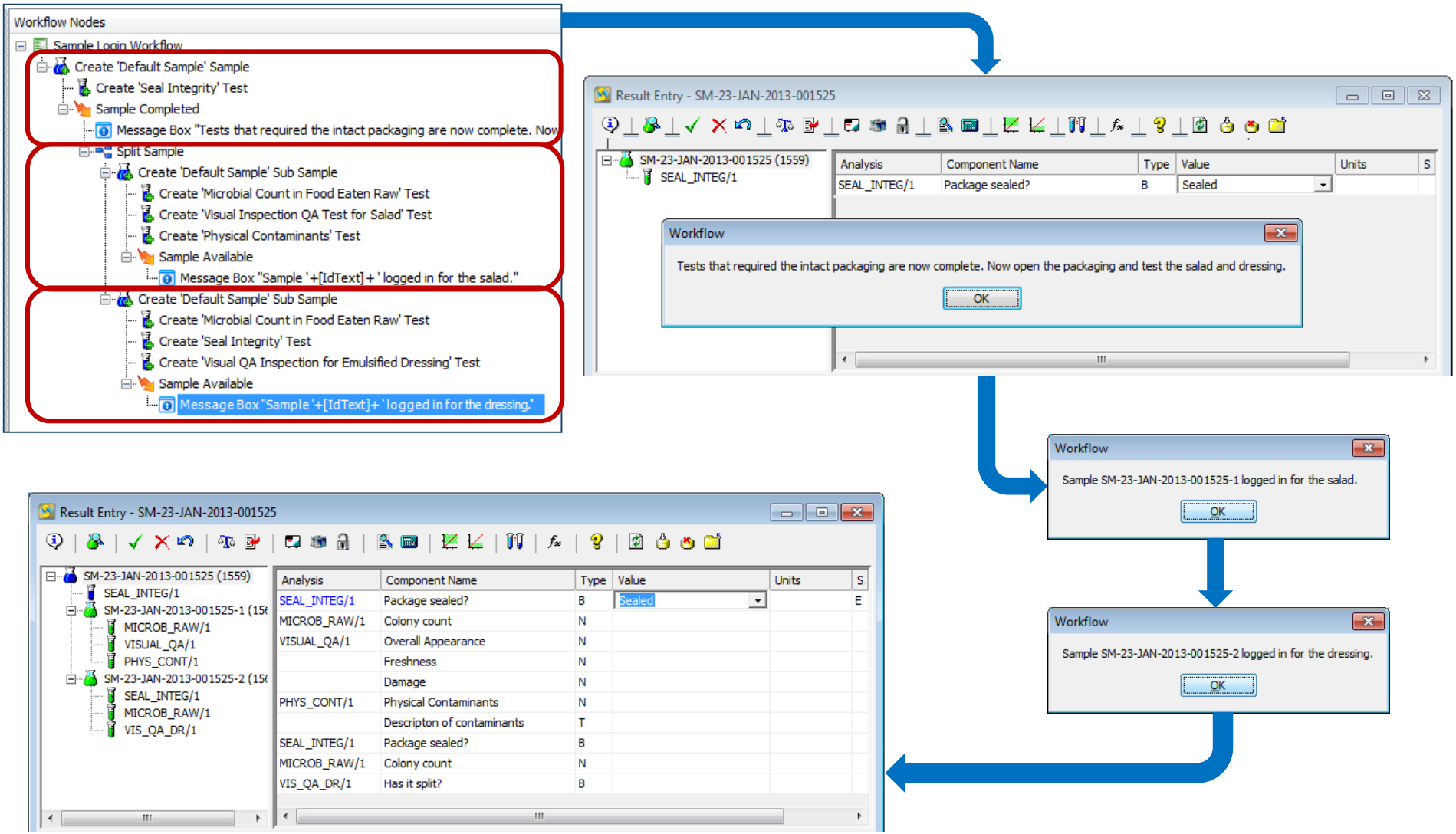
Multi-Stage QA Food Testing



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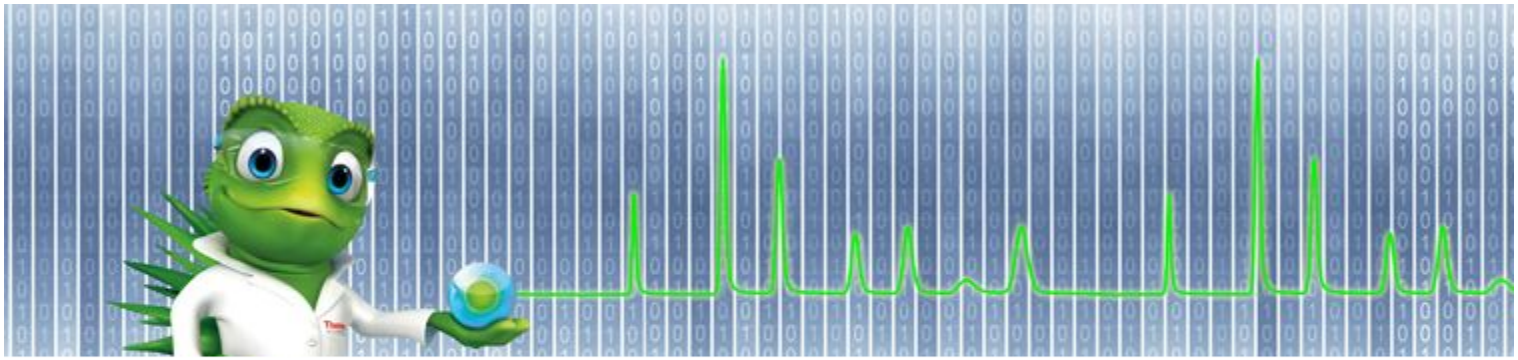
Sample to Instrument Data



Chromeleon Link Overview

Configuration

- Chromeleon Servers
- Method Mapping

Sequence Creation

- Create Sequence from Batch
- Create Sequence from Samples
- Create Sequence from Tests

Management

- Instrument Status
- Created Sequences

- Refresh Sequence
- Retrieve Results
- Result Display
- Result Entry
- Result Authorization
- Authorize Sequence
- Cancel Sequence

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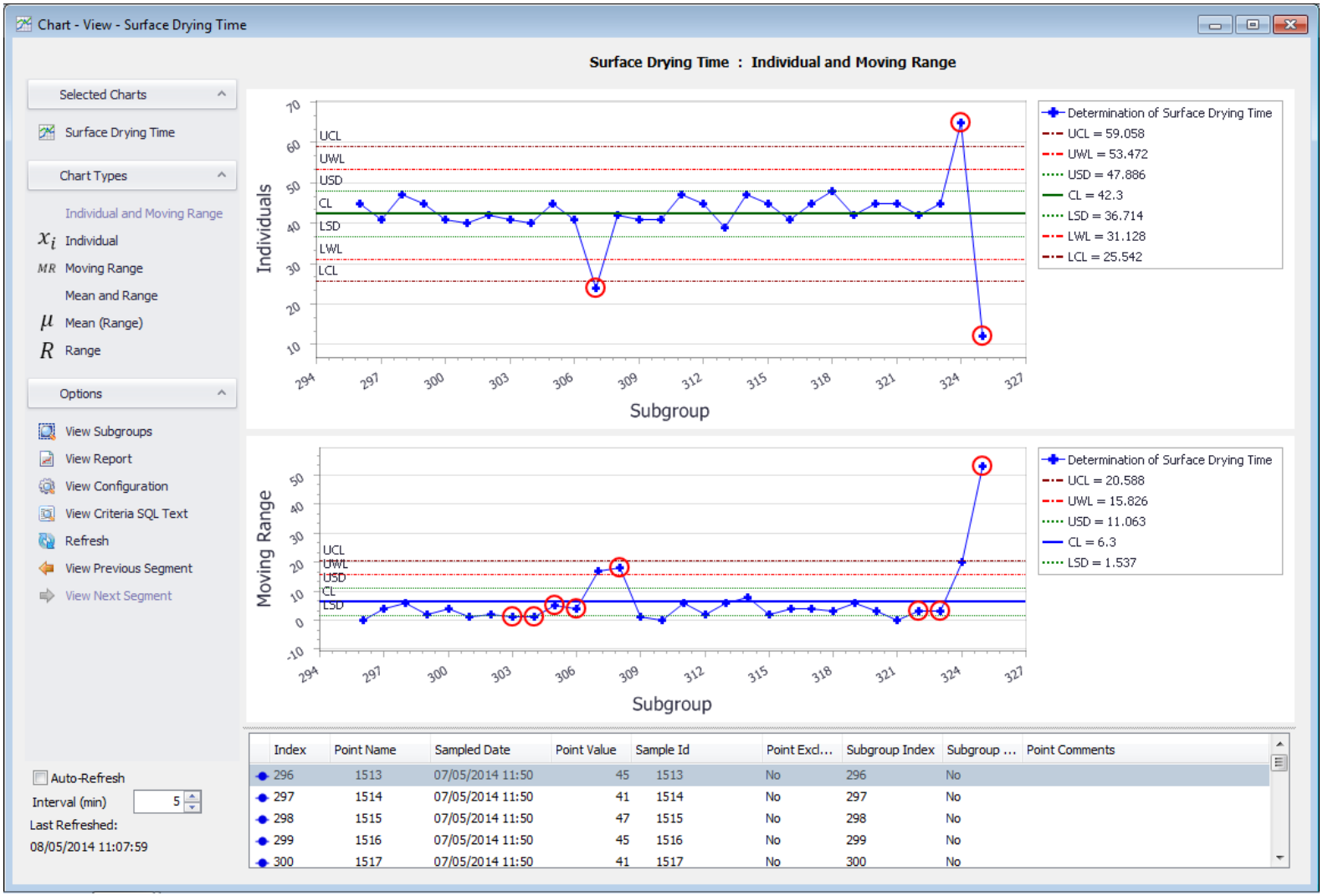
Sample to Statistical Trending Data



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Integrated Informatics gives Defensible Data & Traceability

- Integrated Informatics solutions gives you data that is robust, reliable and above all defensible
- Entity relationships allow you to view, report and drill down into your data
- You can follow the data trail from start to finish
- Allows you to take action quickly should you need
- Compliance rules ensure instruments are calibrated
- Reduced errors and improved repeatability
- LES ensures methods are followed
- SDMS ensures the raw data is recorded and available for review

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Conclusions

- Integrated informatics solutions can address business needs for the food and beverage industries offering support in the areas of in the areas of:
  - Compliance
  - Defensible data
  - Traceability
  - Brand protection

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SampleManager LIMS

Thermo Scientific™ SampleManager™ LIMS is more than just a laboratory management solution—it drives compliance, connectivity and efficiency to deliver increased productivity across your business. SampleManager includes:

- Comprehensive analytical data management (SDMS)
- Procedural execution (LES)
- Industry-leading instrument and system integration
- Unparalleled laboratory management capabilities

SampleManager LIMS Software

technical support

Various resources are provided to ensure dedicated and responsive support and training, enable collaboration with other users and drive continuous product improvement.

professional services

Our team has proven expertise in project management, implementation, validation and system optimization for laboratory software across all industries.

compliance, data integrity & security

Audit history
Ensure data integrity with audit history detailing the who, what, when and why for any events.

Access and security
Fully secured with passwords and eSignatures to meet FDA 21 CFR Part 11—customize user access to meet any regulatory requirements.

Training records
Ensure only qualified analysts run approved methods using in-service instruments, facilitating ISO 17025 compliance.

sample handling & procedural execution

Sample receipt
Streamlined reception of scheduled and ad-hoc samples using barcodes.

Test assignment
Fast automatic or ad-hoc test assignment.

Sample tracking
Simplified, highly granular location and chain of custody management using barcodes and RFID.

Procedural execution
Provides proof of SOP repeatability and drives quality by reducing analyst error.

resource management

Instrument management
Minimize downtime by scheduling instrument calibration and servicing.

Stocks and suppliers
Keep track of your inventory and auto-decrement reagents when used in methods. Manage suppliers to drive quality and improve invoicing.

data handling

Result review
Automatically highlight out of spec results and automate any next steps or corrective action.

Data management
Securely archive all forms of raw analytical data according to regulatory requirements. Access without the original software, future-proofing your lab.

Result retrieval
Secure instrument integration eliminates manual transcription errors and reduces time spent on manual entry and review.

reporting & data visualization

Report delivery
Data is processed and results reported in the format required to enable rapid decision making.

Dashboard views
Dashboards provide an instant snapshot of lab/production/process health for any data stored in the LIMS.

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Resource and Contact

Download the Food and Beverage ebook or find out more at:

www.thermofisher.com/integratedinformatics

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