

LIMS Helps Nutra Handle 50% Higher QC Workload with 25% Lower Headcount



Nutra Manufacturing Inc. is a leading manufacturer of tablets, softgels and two-piece hard-shells in the nutraceuticals and personal health enhancement market. Like other players in this industry, Nutra faced the challenge of meeting tougher quality standards while reducing costs to meet the challenge of global competitors. An important element in the company's success is its adoption of the latest laboratory information management system (LIMS) technology. This move has eliminated much of the paperwork that analysts previously had to perform, making it possible to perform 50% more tests at the same time that the number of analysts has

been reduced by 25% through attrition and movement to other positions in the organization. Another important advantage is that the automatic entry and movement of data has greatly reduced the potential for data entry and transcription errors.

Nutra produces 1300 different product codes and uses a roughly equal number of raw materials. A typical product run lasts for between three and five days. The company has two facilities, a manufacturing plant in Greenville, South Carolina, and a packaging and raw materials storage facility 30 miles away in Anderson, South Carolina.

Key Benefits

- ▶ Improved efficiency and accuracy
- ▶ Flexibility to handle different products and methods
- ▶ Interface to SLIM® Stability software
- ▶ Reduced paperwork and turnaround times
- ▶ Custom barcodes and reports

Analysts perform a battery of tests to ensure the identity and potency of raw materials, in-process materials, and finished products using instruments such as high performance liquid chromatography (HPLC), gas chromatography (GC), ultraviolet visible spectrophotometry (UV/Vis), inductively coupled plasma mass spectrometry (ICP-MS), Fourier transform infrared (FTIR) and others. Nutra has demonstrated capacity of 150 million bottles per year when operating 5 days per week and 24 hours per day.

Previous paper-based processes

In the past, the laboratory used paper forms to track the flow of work through the quality control laboratory and also to manage analysis results. Operators collected samples, filled in the labels by hand, and dropped them off at the lab. Analysts were responsible for locating the samples in their area of responsibility and performing the analysis. Then they would write out the results on paper forms. These forms were routed manually through the lab to obtain the required three levels of approval. The results were then typed into a spreadsheet that was used to prepare necessary reports for customers, regulatory agencies and management.

“The problem with managing laboratory data on paper was that a considerable portion of analysts' time was tied up doing data entry and transcription work that detracted from their productivity,” said Carolyn Vaughn, Quality Control Manager for Nutra Manufacturing. “Beyond that, our analysts spent far too much time looking for samples,

figuring out what they needed to do, making entries in paper logbooks, and manually preparing reports.”

“In the past, the manual movement of samples and forms and the manual entry of data created the potential for errors,” Vaughn added. “Many levels of checks were required to avoid the possibility of a sample being overlooked and not tested or a number being typed incorrectly into a report. One of the major goals in moving to LIMS was to improve our efficiency while at the same time exceeding our previous high level of quality assurance.”

Selection and implementation of LIMS

“The key requirement in our search for a LIMS was for a system with

the flexibility to handle our broad range of products and methods,” Vaughn continued. “The most consistent thing about our company is its inconsistency. By that I mean that we make so many different products with so many different requirements that we require a huge number of methods to meet the needs of our customers and ensure the safety of the users of our products. We looked at a number of different LIMS but selected LABWORKS® from PerkinElmer because its flexibility matches our own. The software can handle a wide range of tasks with considerably less customization than the other packages that we considered. We also liked the fact that PerkinElmer has developed an interface from LABWORKS to Stability Laboratory Information Manager (SLIM®) from

Violation	Time	Prd Code	Sample ID	Arit Code	Analyte	Result	Viol Type	Spec Value	User
03/03/2005	07:54	276099	AA00366	MSM_5405	MSM	271.1	Lower Warn	300	ANITAK
03/03/2005	07:55	276099	AA00367	MSM_5405	MSM	277.8	Lower Warn	300	ANITAK
03/03/2005	14:56	276099	AA00401	MSM_5405	MSM	276.7	Lower Warn	300	ANITAK
03/03/2005	14:56	276099	AA00409	MSM_5405	MSM	291.5	Lower Warn	300	ANITAK
03/24/2005	14:53	276099	AA00730	MSM_5405	MSM	276.0	Lower Warn	300	BOBBIEY
03/24/2005	14:54	276099	AA00731	GLUCOSAMINE_HCL_5278	Glucosamine HCl	494.1	Lower Warn	500	BOBBIEY
03/24/2005	14:54	276099	AA00731	MSM_5405	MSM	281.2	Lower Warn	300	BOBBIEY
04/06/2005	12:56	276099	AA01208	ORGANOLEPTIC_AVGWT_TAB	Average Weight	1391.4	Lower Warn	1410	MARYR
04/06/2005	12:58	276099	AA01205	CHOND_SULFATE_NA_5372	Chondroitin Sulfate Sodium	399.9	Lower Warn	400	MARYR
04/06/2005	12:59	276099	AA01207	ORGANOLEPTIC_AVGWT_TAB	Average Weight	1388.2	Lower Warn	1410	MARYR
04/06/2005	12:59	276099	AA01207	CHOND_SULFATE_NA_5372	Chondroitin Sulfate Sodium	395.2	Lower Warn	400	MARYR
04/06/2005	13:05	276099	AA01203	CHOND_SULFATE_NA_5372	Chondroitin Sulfate Sodium	397.4	Lower Warn	400	MARYR
04/06/2005	22:42	276099	AA01207	GLUCOSAMINE_HCL_5278	Glucosamine HCl	497.5	Lower Warn	500	CAROLL
04/06/2005	22:43	276099	AA01208	GLUCOSAMINE_HCL_5278	Glucosamine HCl	492.0	Lower Warn	500	CAROLL
04/29/2005	04:29	276099	AA02524	COLIFORMS_BAC_7046	Total Coliforms	INPUT	Target	<10	JENNIFERL
04/29/2005	04:29	276099	AA02524	E_COLI_BACT_7046	E. Coli	INPUT	Target	Negative	JENNIFERL

Figure 1. Quickly and easily find all the exceptions that have occurred over some time frame and see all the details of those exceptions.

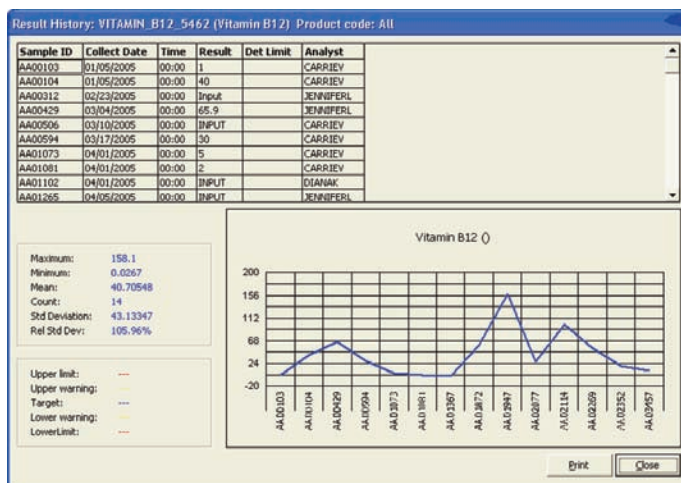


Figure 2. Review the historical results for any test on any product while in results entry.

H&A Software, the tool that we use for managing our stability study protocols.”

PerkinElmer consultants worked closely with Vaughn and other Nutra managers in customizing the user interface to handle the company's complete range of data management requirements. The implementation process included development of electronic fill-in-the-blanks templates for every method. Instead of writing out each step in the test in a paper notebook, analysts simply type in a few key pieces of information to indicate that they have followed the appropriate method. The software now automatically generates labels for each of the tests required for every batch of raw and intermediate material and finished product. The labels are affixed to each sample and also provide reminders to the operators of which samples need to

be collected. This helps eliminate the possibility of skipping a test and saves a large amount of time on the part of the analysts. Analysts now simply scan the label to enter all of the information required about the test except for the results.

The implementation process also included creating workflow that manages the movement of data involved in approvals at the sample, test, and product level. As soon as the test is completed, the test results move into the inbox of the person that is responsible for the first level of approval. As each level of approval is completed, the results move to the inbox of the person responsible for the next level. Finally, when all the approvals have been completed, the software makes the results available to other departments for final product release. Managers can easily generate reports on which samples are

ready to collect, ready for analysis, waiting for approval, etc. This makes it easy to evaluate the workload and backlog of the laboratory and identify and correct bottlenecks before they have a major impact.

Advantages of SLIM® interface

SLIM® tracks all the information needed to schedule and manage stability studies and calculate the results based on analytical testing. When the interface between LABWORKS and SLIM® is completed, it will save time and improve accuracy by automating the process of transferring analytical testing results from the various instruments to SLIM® as well as the movement of stability testing data back into LABWORKS where it will be available for inclusion in reports.

Vaughn said that the new LIMS has greatly improved the efficiency of the quality control lab. “Just the elimination of the need to fill out paper forms for every test has saved about 25% of our analysts' time,” she said. “Prior to implementing the LIMS, we had 16 analysts handling a workload of about 10,000 assays per month. Today, due to higher volume and increased quality standards, we are now performing 14,000 to 16,000 assays per month with only 12 analysts. The only major change in the lab over that period has been the implementation of the LIMS so it is clear that LABWORKS is responsible for the vast majority if not all of the improvement.”

Financial benefits from reducing turnaround time

Vaughn added that the elimination of most paperwork in the laboratory

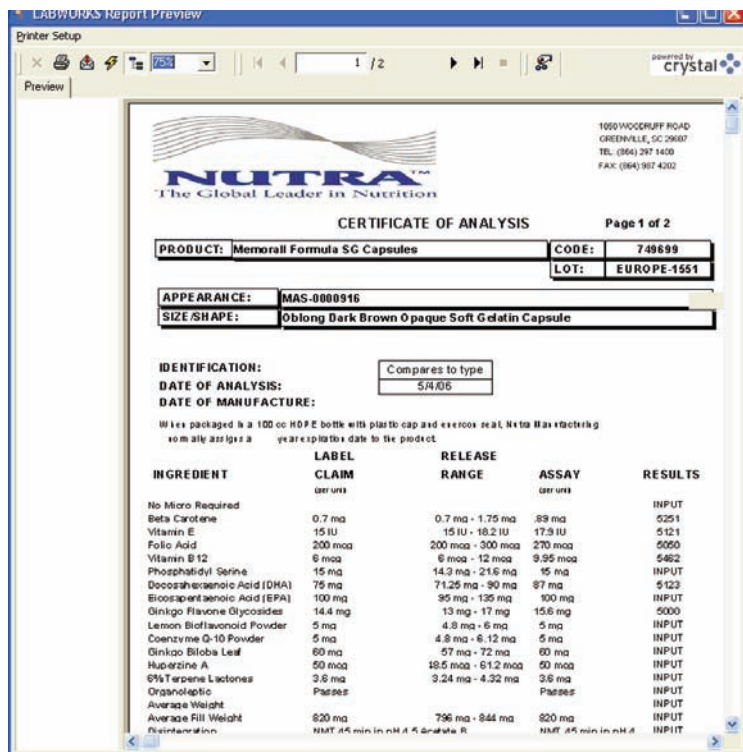


Figure 3. A custom report substitutes the label claim for results that were not actually run and indicates the results were just INPUT.

has had an additional measurable financial impact by reducing turnaround time. In the past, it used to take an average of 10 days from the time production was completed until the last tests had been performed and the product was ready to ship to the customer," she said. "Today, we can complete all testing on a product in an average of 7 days."

"LIMS has not only made our lives much easier," Vaughn concluded, "it's hard to see how we could have functioned in this increasingly

demanding environment without it. We have been able to manage a larger workload with a smaller staff while reducing turnaround time. The analysts are happy because they are spending less time on paperwork and more time utilizing their core skills. It's also important to note that these benefits have been achieved before we have even completed the implementation process. We still have a number of important items to finish up including the SLIM® interface, interface to our chromatography software, and automatic sample login from our

raw materials management software. It will be very interesting to see our progress a year from now." For more information, please visit www.labworks.com, www.perkinelmer.com, or call 1.800.762.4060.

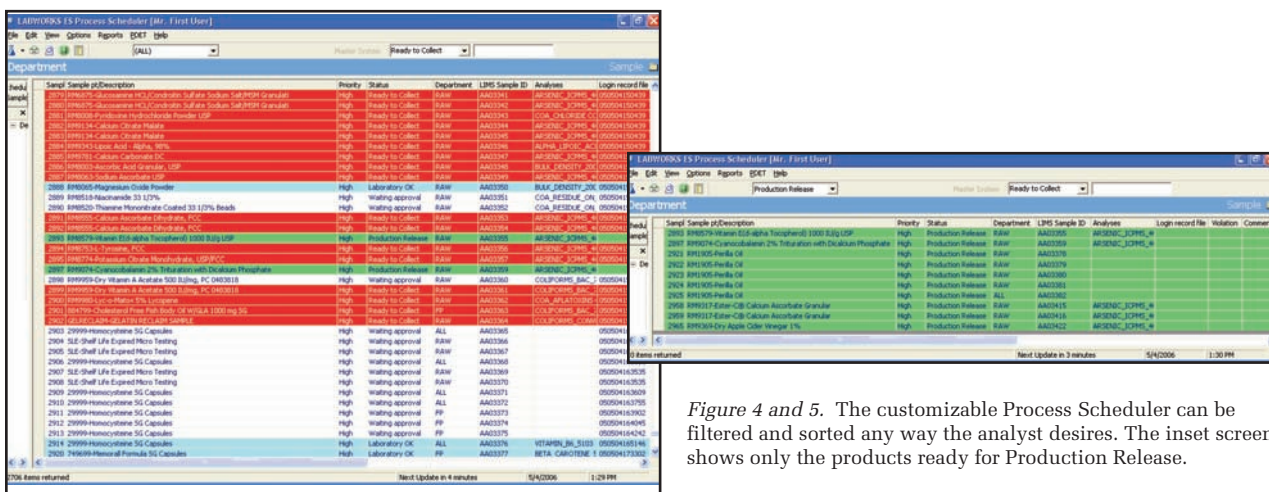


Figure 4 and 5. The customizable Process Scheduler can be filtered and sorted any way the analyst desires. The inset screen shows only the products ready for Production Release.

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