Water LIMS transforms information management at Nova Biologicals

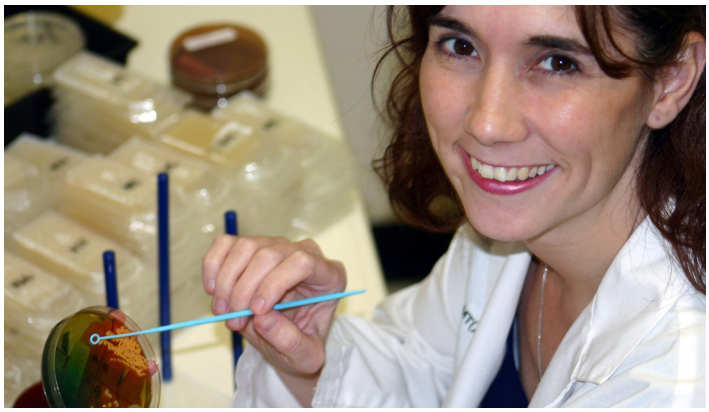
Nova Biologicals, Inc. is one of the leading full-service, NELAC accredited laboratories in Texas, providing laboratory testing and consulting services to the water, medical device, pharmaceutical, neutraceutical and food industries globally. As a full-service testing laboratory, Nova is dedicated to serving the many needs of its customers through superior service, a committed staff, and its investment in research and development.

Prompted by increasing government requirements and compliancy demands Nova needed to change its way of working in order to comply with its State of Texas license. Nova's history of proactively seeking solutions to customer and regulatory requirements prompted its search for better ways to provide excellent customer service. As such, it identified information management in its laboratory as a solution to future-proof the business. Nova also recognized the need to move from its time-consuming, manual, paper-based processes to a fully automated, versatile and efficient solution set. The company selected Thermo Scientific™ SampleManager™ LIMS software, integrated with NextDocs DMS – implemented as one, cohesive solution in its Texas facility.

Company background

Nova is one of the nation's largest providers of water testing for drinking and wastewater and has provided nationwide testing services to the industry, specializing in microbiological, chemical and toxicological testing.

Nova provides comprehensive diagnostic testing of specimens for the presence of infectious disease organisms and water testing under the Federal Safe Drinking Water Act.



The company works closely with Thermo Scientific SampleManager LIMS software, municipal utility districts, water control and improvement districts, drinking water vending companies and federal and state regulatory authorities to ensure safe water that has the trust of its consumers.

Water testing makes up 53% of Nova's total revenue. Coliform testing makes up the largest percentage of tests with approximately 10,000 water samples being processed on a monthly basis, all of which is undertaken in a single laboratory. Over the last ten years, Nova has expanded the microbiology portion of the business (environmental, medical and food related) testing for or against organisms.

Nova has been servicing its many customers, primarily in North America, but also in Africa, Asia, Canada, the UK and Italy, for more than 15 years. The company attributes its very low client turnover to its dedication to service and responsiveness.

Lab accreditation and compliance: growing requirements for water and environmental labs

Standards for environmental testing in laboratories have become more rigorous and far reaching over the last few years as new requirements have been introduced via NELAP and EPA regulations. The regulations provide a set of protocols outlining what is acceptable regarding the daily processes within a multi-disciplinary water laboratory in accordance with internationally accepted standards. Meeting these stringent requirements for Water and Environmental samples has introduced labor intensive procedures to ensure compliance, such as sample tracking, Chain of Custody (COC), record keeping, Demonstration of Capability (DOC), document control, reagent and standard traceability, proof of training and reporting.

Assessed against the provisions of the NELAC standard and the Texas Department of State Health Services (TDSHS), Nova is a NELAP accredited laboratory. It is also FDA registered and designated by the FDA as a private laboratory and complies with the FDA's GLP and GMP requirements.

NELAP stands for the National Environmental Laboratory Accreditation Program and is the program that implements the National Environmental Accreditation Conference (NELAC) standards. State and federal agencies serve as accrediting authorities with coordination facilitated by the EPA to assure uniformity. Accreditation by one NELAP accrediting authority is mutually recognized by the other state and federal accrediting authorities approved under NELAP. State programs are in place to certify the labs, making sure that quality protocols are in place and ensuring a standardized set of processes are implemented and followed.

Business challenges and system requirements

Organizations involved in water and environmental processing have additional needs to automate manual and paper processes, increase sample throughput and improve efficiencies, all while enhancing customer satisfaction and ensuring compliancy with the ever-growing demands of industry regulations. Meeting these needs can be hugely time consuming and expensive, especially for private labs who also need to package and report quality control information which is vital for sending to clients.

One such solution to these growing challenges is a Laboratory Information Management System (LIMS). LIMS have become much more prevalent and necessary in testing facilities as demand and regulations have grown and paper based systems are no longer effective. A LIMS works by scheduling and holding sampling plans, which are then used to generate a collection run for each sampler. The collection run defines where samples must be taken from, what sample bottles must be collected and what onsite tests have to be performed. Samples are then analyzed in the laboratory and water quality data, as well as details of what has been carried out in the field, is entered into LIMS. This is important as water companies must collect and analyze their water samples in a closely regulated environment, maintaining complete quality control records in case of inspection or audits.

Prior to implementing the Thermo Fisher Scientific and NextDocs solution, Nova managed its work using paper that was supported by an out-dated laboratory information system. The laboratory system had significant deficiencies in that it only allowed entry of Coliform data and had limited reporting capabilities. Continued use would not sustain Nova's growing business in microbiology, medical device and pharmaceutical testing. In addition, since the old system was located on one computer, only one employee could use the system at a time, which created bottlenecks in the laboratory and significantly limited the volume of samples that could be processed in a given day.

After the State of Texas adopted NELAC standards, Nova recognized that it needed to make changes to its current process or find a more advanced system that would support its growing and future needs. Nova chose the latter and commissioned a consultant to help draw up requirements for the vendor selection process. The system needed to be user-friendly, easily maintained and configurable, web-based, support flexible functionality, capable of complex reporting requirements and meet all of its regulatory requirements (GLP, GMP, NELAC, HIPAA, etc.).

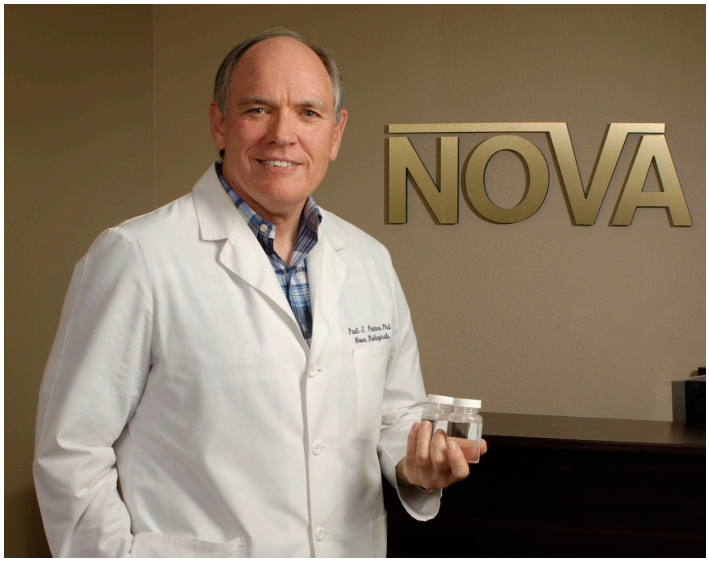
The new system had to be able to:

- Centralize all data in a single database that would support multiple departments across the site
- Configure and extend with ease
- Track the status and workflow throughout the lab lifecycle from submission to final analysis
- Automate processes to eliminate timely error-prone redundant data entry processes and paper trails
- Be accessible by multiple users both internally to Nova and with external customers
- Manage documents such as SOPs and training records for audit purposes and traceability
- Easily and efficiently migrate data to and from customers

Vendor selection

Nova took a very inclusive approach to the vendor selection process, with the whole team listening to the vendor presentations and scoring them against a predetermined list of criteria. Based on employee votes, the Thermo Scientific and NextDocs solution set stood well above the competition. Dr. Pearce, CEO and Founder of Nova says, "The Thermo Fisher presentation and demo was based on our actual needs. They took the time to find out about our company and what we were looking for – they went beyond what we asked for in the RFP. For example, during the discovery phase they uncovered the fact that document management was one of our key challenges and tailored their solution accordingly. They brought NextDocs into the discussion and completely integrated their Document Management Systems (DMS) with their LIMS."

Another key factor in the selection process was finding a system that was versatile. "Microbiology is not like chemistry which is primarily based on numbers," explains Donna Reioux, Quality Manager, Nova. "An organism can be unpredictable so a system needs to be more able to cope with variables, many of which cannot be anticipated. We felt that the SampleManager LIMS software and NextDocs integrated solution gave us what we needed – a highly configurable system that could meet our current and future needs."



In addition, Nova was also aware of Thermo Fisher's reputation as a leading provider of LIMS solutions to the water and environmental industry. For more than 25 years, Thermo Fisher has effectively controlled the processes of large water and environmental companies worldwide with rigorous testing and real-time monitoring so they came with a proven track record.

Benefits

Nova is delighted with the benefits that the new solution has brought to fruition, many of them being tangible benefits that were anticipated and some of them that were not anticipated. It has been instrumental in helping Nova maintain its NELAC accreditation in the state of Texas, refine work processes and improve reporting to customers in terms of quality and speed. The implementation consisted of SampleManager LIMS software and NextDocs DMS. Implementation was carried out by both vendors as one seamless supplier to provide a complete solution to facilitate compliance.

There was a perceived challenge around employees adapting to a new way of working that was quickly realized to be a strength. Says Donna Reioux, "Many of our upper management and lab technicians have worked here for 7 or 8 years – we have a very low staff turnover – so understandably there was a sense of 'we've always done it this way, why do we have to change?' With anything new it takes a little time for people to gain confidence and speed." During and following the implementation, everyone was cross trained and understood the system and how to use it, so user adoption and acceptance was easy. What was a perceived challenge in fact turned out to be very beneficial to the company.

Ability to manage sample fluctuation

The nature of sample testing means that there are peaks and valleys and some months, such as quarterly state reporting deadlines, are much busier than others. Nova may have as many as 1,500 Coliform samples to process in one day and in the past it was a struggle to manage these volumes because of the limited accessibility to the legacy system. The old system was located on one computer so only one employee could use the system at a time. This created bottlenecks in the laboratory and significantly limited the volume of samples that could be processed in a given day. With SampleManager LIMS software, as many as five people can process samples at any one time – which means that Nova can now process very high sample volumes in a short period of time when necessary. Furthermore, WebAccess means that users can access the system from any computer as long as they have a web browser.

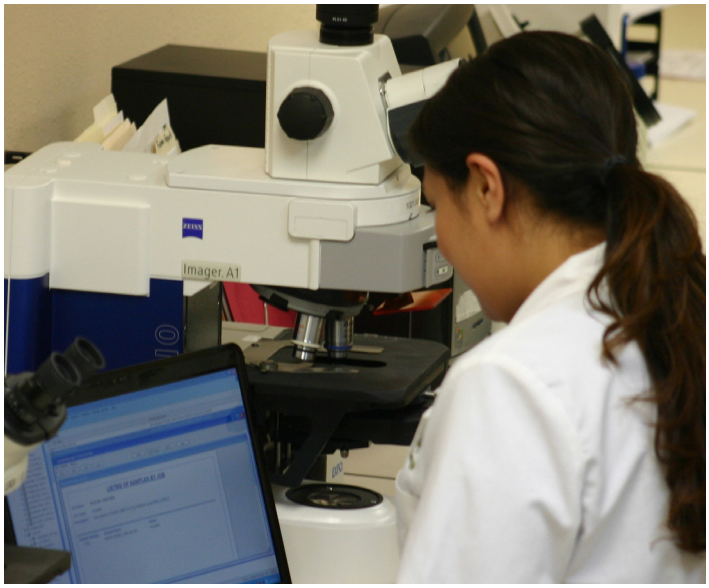
Efficiency, quality and personnel cost savings

With five members of the staff being able to log in samples at the same time, staff bottlenecks have been eliminated, saving many man hours across the company. In addition, significant improvements in efficiencies and data quality have been achieved with the system's automation, built-in document management capabilities and report generation and distribution functionality.

Improved knowledge continuity

Previously, the system was run by one or two people at Nova who knew everything and this meant that the business was potentially at risk if they left. With the new system, not only are more people now trained, but with SampleManager LIMS software in place, the support from the Thermo Fisher team means that the Nova will have no problems if one or two key members of the team were to leave. They are no longer relying on a home-grown system and now have the additional benefit and confidence that the continuity of Thermo Fisher Scientific support brings.

One of the unforeseen cost savings Nova benefited from is the fact that all laboratory analysts, regardless of the department they work in, are now able to receive deliveries on a Saturday and enter the samples in the LIMS. Previously, water department personnel were required to be scheduled on a Saturday along with an analyst to accept and enter samples into LIMS. Now Nova is able to save one or two days of resource from each month's payroll since staff have been cross trained and are comfortable with the system.



Reduced paper trail

The LIMS and DMS have helped Nova to significantly reduce the amount of paperwork used in its processes and methodologies. It has automated and accelerated processes within the company from sample collection to results and report generation, saving time and reducing costs through improved production efficiencies. The solution has helped to eliminate manual error-prone processes, improve data quality and save substantial amounts of time. Furthermore, secure access to sample data is available for laboratory staff, remote users and external customers, enabling all system users to view the same information and ensuring consistency and clarity.

Information about rejected samples had to be supplied to customers on a daily basis. Previously this was reported manually, whereas the LIMS allows rejected sample data to be entered and the customers can access this information daily as part of their report. By eliminating this daily manual process, scientists are able to concentrate on more value-added activities and process higher volumes of work.

Improved customer service and responsiveness

Superior customer service is a cornerstone of Nova's success and SampleManager LIMS software enables them to provide their clients with more meaningful information and data. For example, reporting on sample trends, patterns and volumes is something Nova has always been keen to do, but is now greatly facilitated by the ease of access to the information and capabilities of SampleManager LIMS software. This adds commercial opportunities to Nova's portfolio as the company can tailor reports to individual customer requirements, offering a bespoke reporting format to a wider customer base.

The Nova team is proud of its ability to handle a huge range of requirements from companies that operate all over the globe, requiring different information to be reported. “We have some very unique and specific customer requirements,” comments Dr. Pearce, “but now I feel that we can meet any requests since the system is so extensible.”

Ease of auditing and regulatory compliance

Auditing can take place sporadically, sometimes there can be only one in six months and then three in a month. The old paper-based system made audits time-consuming and onerous. Now, because everything is stored in chronological order with dedicated authorized folders sorted into months and years, the whole process of auditing is much easier and records are automatically updated. Managers can also now review records weekly instead of monthly making internal auditing more efficient.

Auditing of training documentation is particularly key and this is where NextDocs is invaluable to Nova, allowing automatic updating of customer training records into NextDocs. All Standard Operating Procedures (SOPs) are loaded and when staff members are trained this is recorded in the system. This information can be easily pulled out – there are links within SampleManager LIMS software to this information – and again this leads to higher confidence and speed where auditing is concerned and demonstrates compliance with regulations.

Nova was audited by the State of Texas for NELAC Accreditation. “We passed with flying colors!” said Donna Reioux.

Future

Nova is in the process of rolling the system out to cover the pharmaceutical, neutraceutical, medical device, cosmetic, food, and beverage microbiology testing side of the business. This covers approximately 47% of the samples processed. The clients submitting these samples are either undergoing approval processes through the FDA and/or EPA or are conducting lot release testing as required by the FDA, EPA, State authorities, and internal quality controls and processes. The types of microbiology testing required by Nova’s clients include: testing antibiotics, antimicrobials, or disinfectants against aerobic and anaerobic bacteria, yeast, molds, and viruses to determine their inhibitory or killing effects. Additionally, Nova tests client samples such as raw materials or finished goods in the medical device, cosmetic, food or beverage industries for sterility or the absence of aerobic and anaerobic bacteria, yeast, molds, and viruses. According to Donna Reioux, “The building of these tests is harder; because there are so many variables in microbiology, the tests are less predictable. However, at the same time, the implementation process will be quicker because I know more now and have total confidence in the system.”

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Conclusion

The solution deployed at Nova is an illustration of how Thermo Fisher can bring the full strength of its company resources and industry partnerships to addressing the challenges faced by customers around the world. With SampleManager LIMS software and NextDocs DMS, a personalized, seamless solution was developed for Nova.

By offering an end-to-end solution that facilitates the integration of various instruments and systems, Thermo Fisher helps customers expand the business of science from the laboratory throughout the enterprise.

Nova is FDA registered (Registration Number 1641521) and is designated by the FDA as a private laboratory and complies with the FDA's GLP and GMP requirements. Nova is certified by the U.S. EPA's National Environmental Laboratory Accreditation Program (NELAP) and TDSHS (TDH) and participates in proficiency testing programs established by MicroCheck.

Find out more at **thermofisher.com/digitalscience**

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