MasterControl™

Nutrawise Health & Beauty's Journey to Electronic Logbooks

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Nutrawise Health & Beauty, LLC designs and manufactures supplements that facilitate health and wellness as a way of life. Since 2010, it has evolved into one of the largest manufacturers of collagen and turmeric in the United States. Nutrawise produces two-piece capsules, tablets, and powder products, and is collaborating on liquid and gummy manufacturing.

To keep up with its expanding portfolio of products, Nutrawise has always adopted the latest technologies to support the business. For starters, the company implemented MasterControl's Quality Excellence solution for all of its quality management needs. Then it became an early adopter of MasterControl Logbooks to help sustain its Good Manufacturing Practice (GMP) compliance for logbooks management.

MasterControl spoke with Nutrawise Senior Manager for Electronic Quality Management System Anthony E. Contreras about the company's experience with MasterControl Logbooks.

1	**Could you provide a brief description of your responsibilities?**	As the senior manager for electronic quality management system (eQMS), when I was hired, my responsibilities were to implement MasterControl and keep it in a validated state. I collaborate with quality assurance (QA) and quality control (QC) in support of GMP compliance. In addition, we are currently transforming our manufacturing operations from a paper-based system to an electronic-based system.
2	**What MasterControl solutions does Nutrawise use?**	Currently, we use Quality Excellence, mainly for our documents and our training. We also have our quality events associated with it, which includes change management, deviation, nonconformance, issue review, CAPA (corrective action/preventive action), and out of specification (OOS). In the near future, we will be implementing MasterControl's Manufacturing Excellence solution.
3	**What drove you to select MasterControl?**	There are many features that compelled us to choose MasterControl. For example, we've had audit observations for certain things that would be almost impossible to do on a manual, paper-based system. The traceability and efficiency have been a game changer.
4	**Since you're still in transition with MasterControl Logbooks, how do you currently manage your logbooks? What parts of the business involve logbooks?**	Our logbooks have always been paper-based and very rudimentary. In fact, we have an old-school binding and coiling machine that is not much fun to use. The QA department manages and reviews our logbooks. The reviews are issued on another paper-based logbook — yes, we have logbooks for logbooks. They are primarily used in our GMP environments. Our logbooks range all the way from a visitor log that tracks when people come to the office to logbooks that track everything happening in our production rooms, such as daily calibration verification, cleaning, or line/room usage. Each production room has several logbooks associated with it to log line utilization all the way to which pieces of equipment are in there.
5	**What does a typical logbook review process look like?**	We review and verify logbooks in our production environment. Typically, our production associates document the line utilization or room utilization. Then our QA associates verify their entries — usually several times a day. When a logbook is full, it goes through an extensive review for GDP (good documentation practices), such as for correct entries and readability. Finally, when we're closing it out, we stamp, sign, seal, and mark where it will be stored. Prior to storage, we scan the logbooks to put onto our drive for ease of access. However, we know that this type of digital data is dated and not real time.

6   **What are some common issues you've experienced with your logbooks?**

Our paper logbooks do work, and they do pass audits. However, they are very labor-intensive and demand a lot of resources to maintain and archive. We have several logbooks per room, and they are cycled through on an annual (sometimes quarterly) basis, so you can imagine how they are starting to accumulate and take up physical space throughout our warehouse.

Logbook reviews are a manual process, so we review them line-by-line. The biggest challenge we have with paper-based logbooks is GDP errors. The process of documenting an incorrect entry by crossing it out, initialing it, and adding a justification and the appropriate timestamps is challenging with any paper-based model.

Other challenges are time entries. They are a proof of concept that we've been called out on a couple of times. The auditor will say "your records are beautiful, but in a perfect world, things are not documented every 15 minutes on the second." Entry time issues happen when people look at the clock and see that it's 7:31, so they just put 7:30. One of the features that is so attractive about MasterControl Logbooks is the timestamp. When the user marks a step complete, you know you're going to get the exact date and time the data was captured. It will always be captured accurately.

I don't know what it is with the logbooks, but they tend to grow legs and walk away from where they are supposed to be. That's always a challenge unless you have dedicated spots — and even then, they vanish, which requires us to create a deviation and document that a logbook is missing. We've established processes to limit who interacts with logbooks to make sure this doesn't happen, but with a paper record, it's always something that you will deal with.

Also, we've had to retire logbooks, especially in the turmeric rooms because everything is yellow. It's unprofessional to show an auditor pages from a logbook that are yellow. Even though we keep the logbooks in plastic, turmeric gets everywhere. Therefore, we try to cycle those logbooks so they don't inherit the yellow coloring.

7   **How many pages do most of your logbooks have, and how long does it take to review them?**

Some of our logbooks are 250+ pages. On a packaging line, we will go through several 250-page logbooks a year. Those that we don't use as much will get dated out until we revise the associated template. Some of our most frequently used logbooks are in our quality control lab where we do quarterly maintenance on our scales. We have our daily verification on them as well as a usage log associated with them. Those logs typically have a life of three months and then we stamp our review dates on them to ensure consistency.

8 If you had to guess, how many paper logbooks do you currently have?

We have a minimum of three logbooks per room. With 15 rooms plus the lab, I would say we have upwards of 100 logbooks throughout the facility. For example, for each room, we have our cleaning log that is handled by our production team. Then we have the line/room usage log, so any time a product is run in that room and the equipment is maintained, it's documented in that log.

Every room typically has two scales and balances. A floor scale, which will also have a verification log and then an analytical balance on the desktop, so that's four logbooks right there. Then the room has tablet counters and pieces of equipment where we do process checks. Each of those areas will have additional logbooks. Then we have our quality control lab, our verification, and visitor logs. As if we didn't have enough logs already, we decided that every major piece of equipment should have a dedicated usage log and a maintenance log. That last requirement came from management right before I learned about MasterControl Logbooks. It felt like fate that our quality management system (QMS) provider would release an electronic logbook product because managing those logs on paper was going to be challenging.

9 What makes you the most excited about using MasterControl Logbooks?

To review a logbook, we have to suit up to make sure we're compliant to enter a GMP environment. Then we either have to take the logbook out of the room to make copies or take photographs of the pages we're reviewing. Visibility and traceability are some of the advantages I've seen as a MasterControl Logbooks early adopter, which is one of the reasons we wanted to get it. I enjoy having the ability to sit at my desk and view any logbook. Our quality control lab has receiving logs for every piece of material and the type of samples that come in. I can be in a meeting and instantly find out if samples were received without having to flip through a book — and the data is in real time.

10 Where do you plan to start rolling out Logbooks in your production environment?

We will start in the quality control lab because they are self-sustaining and already have the necessary hardware. They will get a feel for the product, and it will be quality control and quality assurance that interacts with them. Then we'll follow through with the rest of our manufacturing environments.

When we first became early adopters, I coordinated the usage effort with our packaging production, quality control, and quality assurance personnel. I gave a production associate the fundamental training; he was amazed and wanted to know when they would get the Logbooks product. Then he pulled a random associate off the line with no prior training and had him complete a log. The associate was able to go into the system and intuitively capture all the information they typically gather in that department.

11 **MasterControl Logbooks includes settings for limits or rules. Is having those limits important to Nutrawise in terms of data integrity?**

When I saw our first iterations of Logbooks, I was like, this is perfect. We can work with this. But as we meet every month, the improvements get better and better. I can create a record or test a record and it doesn't let me verify my own stuff, which is a dream for quality. It's building quality into our product without us having to verify that the quality is there.

We like how when you're reviewing tasks, it buckets the information. The operators don't see all the information, they see only what has not been completed, what has not been reviewed, and so forth. But if I had to pick one, it would be the roles. Having certain roles associated with the field step is making our process more efficient.

12 **Quality Excellence, Manufacturing Excellence, and MasterControl Logbooks all function on the same robust platform, how do you see this changing Nutrawise?**

It has already changed Nutrawise. It has been a game changer, especially during the pandemic when remote audits were more prevalent — those types of audits will continue. Having a digital infrastructure for our quality management system has changed the way we review data, collect data, and present data to auditors, other regulatory agencies, and even internally. We don't have to search through SharePoint or file folders, we're able to categorize all the data that's been captured with MasterControl. Also, the reporting functionality has given us insight into all of the operations that we're performing — everything from our chemical control lists, our preventive maintenance, and our calibration in addition to our docs and training.

13 **How are you talking with leadership about these solutions, and how are you helping them to understand the value?**

We've always been at the forefront of technology. Nutrawise has been in existence for 13 years, and they've always been backers of technology. They want it to improve our processes. We were recently acquired by Jamieson Wellness. Initially, the company didn't have a quality management system. Instead, it used team folders and network drives to manage quality. When I met with leadership to request the technology, we were able to show them how the processes looked on paper and how they looked in the system. This gave them a good compare-and-contrast scenario.

14 **What would you tell someone who is looking at Logbooks but wondering if they really need a digital logbooks solution?**

First, I would show them my binding machine. Aside from that, traceability and accessibility are the key functions to a digital logbook. When we were using MasterControl Logbooks in our test environment with our production personnel, I was literally sitting in my office watching an associate create entries in real time. From where I was, I could either verify them or add information to them simultaneously.

You're not bound by the limitations of paper logs. We've even considered if we need a logbook for every single room because we have a logbook that's transparent to all rooms. This goes for each piece of equipment as well. Obviously, the equipment is unique, but the verifier just needs a laptop to retrieve information, such as which standards need to be met and which verification test points are needed.

15 **Creating templates and individual logbooks in MasterControl is fast and easy. Do you have any concerns about user adoption?**

First off, I want to keep our logbooks as is because people are familiar with certain operations. I want it to be an easy transition where at one point it was paper, now it's digital. A lot of associates use MasterControl to facilitate their training, reference documents of work instructions, and so forth. But they've never experienced documenting in the system, so we'll keep that information as equal as possible. Once we've rolled it out, are comfortable with the system, and identified the usability of it, we will have users create process improvements.

16 **Tell us how you feel about the transition away from paper in quality management and next with logbooks and manufacturing.**

Paper has always been the standard, but it creates a lot of inefficiencies. We have to go to file cabinets to retrieve documents. Before filing a document, we have to scan it to get a digital copy. What if we skipped the scanning and went straight to digital? You no longer have those inefficiencies or have to store paper documents. I've worked at companies that had warehouse-sized rooms for storing their paper, and finding what you need is not ideal.

In a digital system, everything is a mouse click away. You can immediately find what you need and provide it to management to make decisions. That's been the key with Logbooks. Paper is useful for a certain period of time until something goes wrong. Then you're looking through pages and pages versus being able to go into the system to search for a certain item number or function that's being performed. The quicker we can make decisions from the data, the better positioned we are for the future.

How MasterControl Logbooks Resolves Critical Issues for Nutrawise

On every manufacturing floor there's usually a multitude of logbooks for a variety of processes. Logbooks are a necessity, but if they're paper-based, they require a considerable amount of time and effort to complete and maintain. MasterControl Logbooks eliminates the burdens and headaches of managing paper logbooks.

Benefits of MasterControl Logbooks

- **Streamline logbook execution** – Bring logbook processes into your company's digitization initiatives, allowing for production record integration and data capture and analytics.
- **Eliminate errors, deviations, and lost logbooks** – Prevent handwriting errors, missing entries, and logbooks from getting lost or damaged.
- **Ensure data integrity** – You enter data in a real-time environment. You also prevent inaccurate entry times because data is timestamped when it is entered.
- **Configure logbooks** – Determine how frequently you want logbooks reviewed and how quickly you want them verified. If you have repeated tasks, such as cleaning, you can configure templates that you know will have repeatable steps requiring the same information each time.
- **Organize logs** – Categorize logs that are all associated, such as all the actions taking place on a single piece of equipment.

About MasterControl

With MasterControl quality management system (QMS) and manufacturing execution system (MES) software, you never have to sacrifice compliance to achieve efficiency. Our solutions are designed to ensure compliance with regulatory requirements while also increasing operational efficiency. By natively connecting quality and manufacturing data in one powerful digital tool, MasterControl enhances data connectivity and provides real-time visibility into processes across the entire life cycle of your regulated products.

Visit **www.mastercontrol.com** to learn how you can add efficiencies, embed quality into manufacturing operations, and bring your life-changing products to market faster.

Dx	Cx	Rx	Qx	Sx	Mx	Px
Development	Clinical	Regulatory	Quality	Supplier	Manufacturing	Postmarket

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