

USANA Health Sciences, Inc.



Implementing a Consistent, Global Standard for Best Practices of Records Management

CUSTOMER: USANA Health Sciences, Inc.

BUSINESS: Nutrition and Personal Care Products Manufacturer

CHALLENGE: Company needed to implement a corporate standard for records management and to systematically address routine FDA audits, including preparation for new legislation related to reporting adverse product-related events.

USANA Health Sciences has been manufacturing high quality personal care and weight management products since 1992 and is a leader in the field of health and nutrition. With 800 employees worldwide – 600 in the U.S. alone – the company markets its products through a vast network of independently contracted distributors in Australia, New Zealand, Canada, the United Kingdom, the Netherlands, Hong Kong, Japan, Taiwan, Korea, Mexico and the United States. A public company headquartered in Salt Lake City, Utah, USANA has seen rapid growth, leading to annual revenue of more than \$325 million. Its key constituencies are shareholders, distributors and consumers.

In the international nutrition industry, USANA must conform to standards set by U.S. and international regulatory bodies to ensure the safety, quality and reliability of its products. The status of USANA as a publicly traded company raises the level of exposure and governance.

USANA's Assistant General Counsel, Kevin McMurray drafts and negotiates corporate contracts and manages many of the company's legal and intellectual property issues. He is a key advisor to company management on laws and regulations regarding nutritional supplements, multi-level marketing and corporate governance. Anticipating the requirements of Sarbanes-Oxley coupled with new FDA reporting regulations, McMurray set a course to establish policies and operational procedures for the storage, management and auditing of the company's records.



"Iron Mountain helps to ensure that our company acts responsibly and consistently in managing our corporate records. By helping USANA to develop a sound records management program based on current legal requirements and industry best practices, we can give our shareholders greater peace of mind in knowing that we put a premium on corporate governance and compliance."

*- Kevin McMurray
Assistant General Counsel
USANA Health Sciences*

THE CHALLENGE:

Formalize a Process for Managing Corporate Records and Set Standard Practices for Addressing FDA Audits

Prior to working with Iron Mountain, USANA had not implemented a formal records management program. While USANA diligently saved and stored all of its records on warehouse racks, the company did not categorize or differentiate retention requirements for the various types of business documents the company creates and stores. The decentralized storage made documents difficult to locate and time consuming to sort through. USANA's in house storage burden put documents at risk and the lack of a company standard rendered the processes for maintaining records across departments inconsistent and inefficient.

Sarbanes-Oxley governance issues have become essential and USANA needed to develop reasonable, cost-effective and consistent records management compliance practices as part of its ongoing efforts to improve operations and build shareholder confidence. "In the wake of corporate scandals, both the government and our own shareholders have no tolerance for non-compliance," said Kevin McMurray, Assistant General Counsel, USANA Health Sciences.

Additionally, the company needed to be aware of changing health regulations mandated by the FDA and prepare for addressing new FDA audit requirements. USANA has undergone routine inspections by the FDA and other international food and drug regulatory bodies. McMurray adds, "USANA has always kept records of customers reporting adverse events related to the use of USANA's products – we have done that voluntarily as a good corporate citizen. Now, new federal legislation requires dietary supplement companies to report serious adverse events to the FDA. We want to be sure that our record keeping practices allow us to respond timely and accurately to auditing requests and reporting requirements with minimal disruption to our daily operations."

THE SOLUTION:

Iron Mountain Provides Offsite Storage of Product Samples and Implements a Records Retention Schedule for Compliant Records Management and Audit Preparation

USANA Health Sciences began its relationship with Iron Mountain almost two years ago with Iron Mountain's record management services. Iron Mountain approached USANA, offering to do an analysis of its current records management program while implementing a storage solution for USANA's product retention samples. Iron Mountain currently provides offsite storage of USANA's product retention samples in order to maintain evidence of proof of manufacturing for all of its nutrition supplements and personal care products. Iron Mountain keeps these products stored in a temperature-controlled environment, with humidity levels properly maintained and delivers the necessary samples to USANA as needs arise.

After a year, Iron Mountain proactively introduced its Compliant Records Management (CRM) Program and proposed a risk assessment to provide a health check on their compliance initiatives. The assessment evaluated 25 potential areas of vulnerability. Following the identification of risk areas, the next step was to bring in the Iron Mountain Consulting Services team to develop a Records Retention Program. The initial objective was to develop a customized Records Retention Schedule (RRS), specific to the needs of both health industry and public company auditing regulations.

Iron Mountain has subsequently developed the RRS for USANA's electronic and paper records, to streamline the process that USANA implements for retaining documents. The RRS accounts for content of inventory, the classification and category of records, and the provision of legal research. It serves as a guide for USANA to follow, ensuring that access to the more critical records is not hindered by the retention of old and unnecessary documents. Other aspects of the program include developing policies and procedures and training employees to ensure consistent implementation across the organization.

CASE STUDY

“Iron Mountain truly set itself apart from other vendors we could have potentially considered for compliant records management services,” added McMurray. “Iron Mountain approached the idea of assessing our records management risk as though they were an extension of our internal audit team. Until Iron Mountain presented its findings of the assessment, nobody at USANA really understood the nature and extent of our exposure. With that event, Iron Mountain transformed the relationship from a storage supplier to a true records management partner.”

With Iron Mountain’s services, USANA is creating a records classification system to limit the number of document categories. Unlike other vendors, who create several hundreds or thousands of categories that are cumbersome to manage and counterproductive, Iron Mountain is working to streamline the classifications to less than 200, establishing a manageable and usable system.

USANA will use Iron Mountain’s portal, Iron Mountain Connect™, to provide real-time, web-based access to information and services through which USANA can access and manage the retention schedule, record classification codes and input any necessary user restrictions.

“With Iron Mountain as one source for all of our existing and potential needs, it can scale with our growing and evolving business. Iron Mountain’s reputable and reliable services are complemented by a dedication to satisfaction. Our account team is always responsive and prompt and the pricing is very competitive. Overall there is a real synergy in the personalities of our companies so it is an obvious choice for USANA to make Iron Mountain the international supplier of record.”



THE BENEFITS:

Consistent, Global Standard for Best Practices of Records Management, Audit Readiness and Adherence to Regulations

USANA cites several advantages to outsourcing its storage and records management to Iron Mountain. For one, Iron Mountain helps alleviate the drain on internal resources, including staffing and the physical space required to maintain a proper storage solution. Keeping records stored and managed offsite with a recognized and reputable leader in the industry ensures best practices for complying with regulations and protecting the company's valuable information. The streamlined records classification system is significantly improving the efficiency of managing USANA's business records with a system that is clear and easy to administer.

With the Records Retention Schedule that Iron Mountain has designed, USANA gains the confidence that the company is taking major steps to comply with Sarbanes-Oxley regulations, FDA audits and other international regulations. With a process in place, USANA can address critical needs in a timely manner and respond promptly to changing regulations and specific health industry auditing requirements. Global consistency of a Compliant Records Management (CRM) Program implemented across the large international distribution network assures the accuracy and reliability of company processes and mitigates areas of risk or exposure.

"Iron Mountain helps to ensure that our company acts responsibly and consistently in managing our corporate records," said McMurray. "By helping USANA to develop a sound records management program based on current legal requirements and industry best practices, we can give our shareholders greater peace of mind in knowing that we put a premium on corporate governance and compliance. Iron Mountain has been a trusted partner to help us be proactive so that our shareholders won't have to question our records management practices."

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As Iron Mountain is able to serve as one single vendor for all of USANA's compliant records management needs, McMurray anticipates extending the relationship in the future to take advantage of Iron Mountain's end-to-end, fully integrated program to scale with the company. USANA is considering adding services such as Secure Shredding to implement policies and procedures around the destruction of records, in addition to the current retention system. USANA may also take advantage of Iron Mountain's offerings in training and in legislative research, to leverage Iron Mountain's ongoing insight into the changing laws, regulations and business requirements.

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