

CUSTOMER SUCCESS STORY

Environmental Monitoring, Risk Assessment & Food Safety Plan in Dietary Supplement Manufacturing

A premier private label and contract manufacturer of dietary supplements in the United States recently came to Novolyze when they added a new line of fruit gummies to their product portfolio. This trusted source for high-quality dietary supplements that focuses on supporting consumer health and wellness has 6 facilities based in the western U.S.

Solution

- Environmental Monitoring Module
- Risk Assessment
- Food Safety Plan

Benefits

- | Quickly and easily find and identify potential risks when starting a new product line
- | Assess, plan, and adjust processes for new types of ingredients
- | Find and prevent issues before they happen

Risk Assessment & Food Safety Plan

The company was introducing probiotic fruit gummies as a new product in their portfolio. This meant adding a new manufacturing line in their facilities, and the operation, food safety and quality team faced new challenges in terms of understanding the food safety components, the formulations and processes of the new product.

To help with the risk assessment and development of the Food Safety Plan of the new line, the company, which is strongly committed to Quality and Safety, wanted to have the best-in-class systems put in place and to engage with someone who could provide a strong expertise in Food Safety. Based on his assessment of several Food Safety Consulting companies, Rajesh felt that Novolyze was in the best position to serve their needs based on the type of values they were looking for and the unique expertise that Novolyze has.

One of the activities Novolyze helped with was the vendor risk assessment which is a very critical piece of the puzzle. For Rajesh and his team, Novolyze had a very good understanding of the product process, developed the Food Safety Plan which included the HACCP flow chart and food safety narrative, Critical control points and Preventive Control decision tree, the vendor risk assessment, Product descriptions, process flow charts, risk assessment matrix, risk analysis, Environmental Risk assessment, allergen prevention and control.

A second important activity that Novolyze helped with, was the risk assessment of the process development. As the gummy manufacturing process was set up, Novolyze helped identify potential risks along the process and offered solutions to mitigate these risks, while being adaptable as the process development was still ongoing.

From the collaboration with Novolyze, Rajesh and his team especially appreciated:

- The eye for detail
- The structure and speed (a clear timeline was presented and executed)
- The team always walked the extra mile and even conducted the first Food Safety Plan meeting and included all team members.



This great collaboration between the company and Novolyze teams made the project a phenomenal success, I would not hesitate to recommend Novolyze in a heartbeat, said Rajesh.

The environmental assessment was also a key piece of this project as high-risk ingredients were introduced in the facility. The company had been used to handling low water activity product (aw up to .25), the new product line introduced high water activity ingredients in the facility. Assessing how this new product could affect the environment was key to the project.

Digitization of Environmental Monitoring

Environmental Monitoring (EM) operations are currently manual, paper-based operations at the company.

Environmental Monitoring is a very important piece in today's world, with FDA, all the regulatory bodies and customers. As a company dedicated to keeping their environment the safest, the company has invested a lot to strengthen their environmental monitoring programs. For Rajesh, visualization, through the digitalization of EM programs and trending, is a great tool both in terms of keeping the risk at the lowest and most importantly providing actionable intelligence. Because having data is one thing but deriving an intelligence out of that is a different thing. While taking corrective actions is important, food safety today is less about reacting to issues and more about finding out how to prevent an event from happening. Visualization through digitalization of environmental monitoring programs is a powerful tool to help preventing potential events that can create food safety incident.

Having seen the power of digitalization in his past companies, he believed that Novolyze's digital EM module met his needs and further he liked the fact that Novolyze had integrated allergens as well in their EM program and it had the ability to catch undeclared allergens which is a unique feature.



Rajesh Krishnamachari is the former Vice President of Quality and Regulatory affairs and the Head of Quality for all the company's facilities. He was responsible for manufacturing Quality, Food safety and Regulatory Compliance of the products manufactured according to 21 CFR 111 & 117 and he oversaw all quality operations.

Rajesh Krishnamachari
Director of Quality Assurance