



# SOTERIAN SYSTEMS

Food Safety Management from Farm to Table

## 5-STEP PLAN FOR FSMA COMPLIANCE

- Does your company have the resources and technical expertise to create and implement the new required FSMA programs?
- Do you know the specific elements of 21 CFR part 117 that are required for your company?
- Are you required to develop a comprehensive Food Safety Plan and Preventive Controls?
- Do you know when your company compliance date for FSMA is?
- Does a culture and knowledge of Food Safety exist at your company?

### STEP 1 Proper Documentation

#### WHAT YOU NEED:

An effective solution for adequately documenting all records to fully comply with 21 CFR part 117

#### HOW WE CAN HELP:

Our FSMA Template Toolkit for Human Food contains over 170 templated documents that follow FSMA part 117, subsections B, C, and G. The toolkit includes comprehensive standard operating procedures and record-keeping tools for each subsection including cGMPs, merging HACCP with Food Safety Plans, and Supply Chain Program. To create these documents from scratch the average customer would spend around 350-400 man hours. That's roughly \$35,000 in salary loss and about three months of time.

### STEP 2 FSMA PCQI Training

#### WHAT YOU NEED:

A Preventive Controls Qualified Individual to prepare or oversee the preparation of all Food Safety Plans

#### HOW WE CAN HELP:

We offer a Preventive Controls Qualified Individual training course that has been developed by the Food Safety Preventive Controls Alliance (FSPCA) and is the standardized curriculum recognized by the FDA. Participants completing the course receive an official PCQI certificate.

### STEP 3 Gap Analysis

#### WHAT YOU NEED:

A Gap Analysis to locate deficiencies and non-compliance in your Programs, Records, Employee Qualified Individual Training, and Facility & Equipment Improvements

#### HOW WE CAN HELP:

With our Gap Analysis Tool, customers utilize a spreadsheet that follows each Subpart and allows the user to fill in each FSMA requirement including corrective actions, responsibilities, and completion dates. This tool organizes the project progression to compliance. We also offer on-site Gap Analysis.

### STEP 4 Implementation

#### WHAT YOU NEED:

Implement all required programs, procedures, and employee training

#### HOW WE CAN HELP:

By utilizing our Gap Analysis Tool plus our FSMA Template Toolkit, you will ensure all required documents and programs are fully implemented. The Soterian technical team can assist in the coaching and implementation.

### STEP 5 Employee Training

#### WHAT YOU NEED:

A Qualified Individual Employee Training Program as defined in 21 CFR § 117.3

#### HOW WE CAN HELP:

Our Qualified Individual training course is targeted to all employees in the facility that engage in the human food process. Rule 117.3 requires that employees have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. Each employee that completes the training will receive a certificate of completion.

[www.soteriansystems.com](http://www.soteriansystems.com)

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## FSMA Tools

SOPs and forms to build a solid FSMA framework

## HARPC & HACCP

Templates and assistance merging HACCP with new HARPC requirements

## Preventive Controls

On-site preparation, implementation, verification, and validation

## Food Safety Plans

Develop new or combine existing plans in accordance with HARPC

## Regulatory Compliance

Tools, training, and coaching to ensure FSMA compliance

## Online Training

HACCP, FSMA Qualified Individual, cGMP, Food Safety Culture, and more

## PCQI Training

Public and Private workshops that meet the FDA standardized curriculum

## Gap Analysis

Needs assessments for FSMA and GFSI compliance at all facilities

## Sanitary Design

On-site coaching establishing continuous operational improvements

## GFSI Audit Preparation

Registered consultants provide comprehensive preparedness

“I highly recommend both the PCQI course and the FSMA template package to anyone thinking of developing these on their own. The time savings was monumental.” – Brenda B., Denver, CO

“They were not only a fabulous resource but a pleasure to work with. The attention to detail, ability to manage many moving parts, and keen expertise regarding food safety, make Soterian Systems an invaluable resource in the world of food manufacturing.” – Morgan M., Louisville, CO

“The FSMA template package from Soterian Systems was much more inclusive than I had expected. They were easy to use and easy to format for our company.” – Nancy O., Baltimore, MD

“The support, assistance and guidance provided by Soterian Systems in our most recent NSF/SQF audit was outstanding. This was our first audit process and without question we would not have been able to successfully achieve our certification in the time period that we had if not for Soterian Systems.” – Harold M., Las Cruces, NM



## Nancy Scharlach

President, Chief Technical Director

Nancy Scharlach is the President and Chief Technical Director for Soterian Systems, LLC, an innovative food safety and quality management technical advising and training firm that provides clients with industry leading tools and training specifically designed to successfully build and maintain world class Food Safety Management Systems. She is a Lead Instructor for FSPCA FSMA Preventive Controls for Human food (certificate #7323330) and a Lead Instructor through the International HACCP Alliance. She has been a Registered SQF Consultant in High Risk Processing since 2010, and has worked in the food industry her entire career. With over 20 years of experience, Nancy has worked for nationally recognized companies such as The Schwan Food Company, The Hain Celestial Group, and Jamba Juice Company. Nancy earned a B.S. in Microbiology from the University of Montana in 1996.

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