Food Manufacturing Facilities
FDA Food Safety Modernization Act (FSMA)
Preventive Controls for Human Food

The FDA Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years. The law is now final and compliance dates for some manufacturers take effect in September, 2016. The seven foundational rules are now issued and they will help produce farmers, manufacturers, transportation companies, and food importers to take steps to prevent food safety problems before they occur. Much of the attention is focused on risk and risk management. The first rule is Preventive Controls for Human Food. It is probably the most significant part of FSMA. It will certainly require the most work, if you are required to follow it.

If your business is required to register with the Food and Drug Administration (FDA), you are required to meet the new FSMA requirements that apply to you, with only a few exceptions. To see a quick overview: [http://www.fda.gov/Food/GuidanceRegulation/FSMA/](http://www.fda.gov/Food/GuidanceRegulation/FSMA/).

The Preventive Controls for Human Food Rule will take training, time, effort, and expertise to implement. It is the law and if you are required to implement a Preventive Controls Food Safety Plan you must do so. Montana Manufacturing Extension Center recommends a two-step process to ensure you are compliant with the most significant part of the new FSMA requirements.

1. **HACCP – Hazard Analysis and Critical Control Points**
A HACCP Plan is a food safety management system built through the analysis and control of biological, chemical, and physical hazards throughout your process from receipt of raw materials to shipping of final product. It works hand-in-hand with your Good Manufacturing Practices (GMPs) and other Prerequisite Programs, but the focus is entirely FOOD SAFETY. A good HACCP plan will provide the best environment and a solid foundation for you to implement the FSMA requirements, including the most comprehensive requirement;

2. **PCQI - Preventive Controls Qualified Individual (PCQI)**
One of the most significant new rules is the Preventive Controls for Human Food rule. This rule states that every human food manufacturer must have somebody accessible who has completed a Preventive Controls for Human Food class. This is a 3 day class and successful completion of the class provides that person a certification that they are a Preventive Controls Qualified Individual. Only a PCQI can prepare the REQUIRED facility Food Safety Plan and provide ongoing verification of the Plan. PCQI training requires a background in and/or significant knowledge of food safety for the attendees.

Montana Manufacturing Extension Center (MMEC) is providing both HACCP and PCQI training. The instructor is Claude Smith, who is certified as a Preventive Controls Lead Trainer and is the MMEC’s and MT Department of Ag’s Food and Process Specialist.