Developing the Food Safety Management System for the University of Wisconsin-River Falls Dairy Pilot Plant

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ABSTRACT

The concern over food safety and the implications associated have increased over the last several years due to high profile and large scale recalls. The recalls have forced many companies to invest in a more comprehensive food safety management system where the focus has shifted from being reactive when food safety issues arise to becoming more proactive through ways of prevention.

Solid food safety management programs begin with a comprehensive and robust Good Manufacturing Practices (GMP) program. General GMP standards to be implemented by a food processing facility are described by Codex Alimentarius as: hygiene in the primary production, hygienic design of equipment and facilities, control of operations, maintenance and sanitation practices, personal hygiene, transportation, product information and consumer awareness training.

The University of Wisconsin-River Falls Dairy Pilot Plant (DPP) employs approximately 15 students each school semester. Products produced are available for retail sale and sold wholesale for food service and select local retail stores. The majority of the students employed have very limited experience or knowledge with dairy manufacturing when they begin employment. The students’ training in the past has consisted of mostly hands on training, working alongside more experienced employees without the use of a policy or reference manual. Employees of the DPP have lacked the written procedural information they need to learn the skills to execute GMPs and SSOPs properly.
This project involved creating a current and concise documented food safety management plan. Specifically, the project includes a new Good Manufacturing (GMP) Code of Compliance manual and a detailed Sanitation Standard Operating Procedure guide. In addition, a new GMP Code of Compliance for Visitors form, Visitor Log, and post sanitation checklists for cheese and ice cream production are included in the new food safety management system.
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CHAPTER ONE: INTRODUCTION

The food industry encompasses a diverse magnitude of food production facilities, including processed food and ready-to-eat (RTE) convenience foods. In 2006, there were 28,000 food-manufacturing establishments; approximately five percent of those were dairy production facilities. The Food and Drug Administration (FDA) is responsible for regulating over 80% of the food products produced by those 28,000 companies with food safety concerns on the rise (U.S. Department of Commerce Industry Report, 2008, p. 1,7).

The concern over food safety and the implications associated have increased over the last several years due to high profile and large scale recalls (U.S. Department of Commerce Industry Report, 2008, p. 7). Those recalls have drawn public awareness to the importance of producing high quality, safe foods for public consumption. The recalls have forced many companies to invest in a more comprehensive food safety management system. Focus has changed from being reactive when food safety issues arise to becoming more proactive through ways of prevention.

Thorough training programs involving well-documented Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs) mitigates cross contamination that could occur due to human error and interaction (Duizer & Koopmans, 2004, p. 23). There is a definitive interrelation between GMPs and SSOPs (Gravani & Marriott, 2006, p. 106). Without the minimum requirements of a
thorough GMP program, a wholesome, safe food would be challenging to produce (Gravani & Marriott, 2006, p. 10).

Properly written GMP’s should include the basic framework to produce hygienic foods for human consumption. The complete essential elements for current GMPs can be found in 21 CFR part 110. Following are topics included in the FDA’s GMP elements in 21 CFR:

- Personnel
- Building and facilities
- Sanitary operations
- Sanitary facilities
- Equipment
- Production and process controls
- Defect action levels

The GMP elements listed above are referenced in the new GMP Code of Compliance developed through this project.

Properly documented SSOPs are also a critical factor in building a solid foundation for a food safety management system (Lowry, 2010, p. 107). Although the GMPs and SSOPs are interrelated, they are two separate but equally important pieces that cannot be effective without the other. Deficiencies in sanitation programs have led to numerous food safety incidences, including a monumental case involving the outbreak of listeriosis in Mexican-style cheese in 1985 with 142 confirmed cases and 48 deaths (Lowry, 2010, p. 107).
Hazard Analysis Critical Control Point (HACCP) is considered to be a food safety centered scientific program focused on prevention and is a good introductory food safety management system (Cullor, 1997, p. 3449). HACCP was developed by a team of scientists from Pillsbury Co., NASA, and the Army Natick Laboratory to ensure a zero-defect program for food production (Chandan & Kilara, 2008, p. 489). According to Howard Bauman, lead scientist at Pillsbury Co. working on HACCP development in the early 1960’s, “HACCP is a preventative system of control based on rational and logical process of estimating the risk associated with production and marketing a given food product” (Chandan & Kilara, 2008, p. 488).

Introducing a Food Safety Management System (FSMS) such as HACCP allows companies to focus on prevention versus reacting to food safety issues that could arise post-production (Tamime, 2009, p.253). According to Tamime (2009) “the success of an HACCP system mandates educating and training management and production personnel in the importance of their role in manufacturing safe dairy foods” (p. 253).

Solid HACCP programs begin with a comprehensive and foundational GMP program. General GMP standards to be implemented by a food processing facility are described by Codex Alimentarius as: hygiene in the primary production, hygienic design of equipment and facilities, control of operations, maintenance and sanitation practices, personal hygiene, transportation, product information and
consumer awareness training (Dias, et al., 2012, p. 199). The processes and procedures to fulfill the GMP requirements are left up to each individual company and can often vary (Dias, et al., 2012, p. 200). Managing GMP’s and SSOPs takes continuous effort; there is always room for continuous improvement with regards to employee training and documentation on GMP’s and SSOPs (Mensah & Julien, 2011, p. 1216).

Working towards an optional third party quality certification program through an independent certifying agency, such as SQF, BRC, IFS or ISO 22000:2005, allows manufacturers to acquire global confidence in the marketplace (Julien & Mensah, 2011, p. 1217). The certification approval assures the food processor has an approved process-based food safety management system aimed at protecting consumer health (Julien & Mensah, 2011, p. 1216). The certification provides one food safety standard for the global economy.

This project examined the effectiveness of a current and concise documented food safety management plan.
DEFINITIONS and ACRONYMS

BRC – British Retail Consortium’s global food safety standard

Codex Alimentarius Commission – established by FAO and WHO in 1963 to develop harmonized international food standards

FSMS - Food safety management system

GMPs Good manufacturing practices

HACCP – Hazard Analysis Critical Control Point

IFS – International Food Standard

ISO 22000:2005

SQF – Safe Quality Food

SOPs – Standard Operating Procedures

PURPOSE

The University of Wisconsin-River Falls Dairy Pilot Plant (DPP) employs approximately 15 students each school semester. The purpose of the dairy pilot plant is to offer students an educational platform to learn dairy manufacturing processes and procedures, while also creating dairy products available for resale to the university community and beyond through web-based sales.

Students have the opportunity to learn quality concepts, manufacturing procedures, and sanitation basics. The majority of the students employed have very limited experience or knowledge with dairy manufacturing when they begin employment.
Typically the student employees have no prior working knowledge of GMP guidelines and policies of working in a food production facility.

Although the DPP serves as an educational laboratory platform, federal and state regulations apply, as the DPP is a licensed dairy plant in the State of Wisconsin. Due to our environment and the accessibility of the laboratory to students, visitors, and employees, GMP compliance is essential to producing safe food products.

The students’ training in the past has consisted of mostly hands on training, working along side more experienced employees without the use of a policy or reference manual. Employees of the DPP have lacked the written procedural information they need to learn the skills to execute GMPs and SSOPs properly.

The GMP Code of Compliance manual is specifically written for employees, students participating in coursework involved with the DPP, and personnel. The manual outlines good manufacturing practices and procedures specific to the University of Wisconsin-River Falls Dairy Pilot Plant, detailing the following:

*Personnel* – Manual specifically outlines policy regarding wearing jewelry, hair net compliance, clothing cleanliness, minor injuries to hands, good hygiene, illnesses, smoking, employee practices around products, and eating or drinking in the DPP.

*Clothing* – Manual specifically outlines policy regarding dress code, soiled clothing, pockets on clothing, shoes, and glove use.
Storage and Handling of Products – Manual specifically outlines policy regarding how to store ingredients when stored and the handling of raw material outer packages.

Process and Product Integrity – Manual specifically outlines policy regarding handling of raw materials and finished product, handling glass or brittle plastic in processing areas, maintenance of hoses and nozzles, and storing of bulk containers.

Shipping and Receiving – Manual specifically outlines GMP procedure for receiving and shipping of ingredients, including recording raw material receipt in ingredient log book.

Product Codes: Manual specifically outlines procedure for code dating products.

Sanitation: Manual specifically outlines policy regarding the SSOPs, color coded system for sanitation utensils, labeling chemical containers, post sanitation inspections, lubricant usage, gasket replacement, storage of clean equipment, and floor drain sanitation.

Recordkeeping – Manual specifically outlines recordkeeping policy including all pasteurization charts, production logs, product identification logs, and storage location, and responsibilities.
Quality Control – Manual specifically outlines policy regarding product quality and decision-making authority and responsibility.

Maintenance – Manual specifically outlines policy on facility and grounds surrounding DPP, including pest control barriers, refuse control, and construction projects.

Utilities – Manual specifically outlines policy regarding utility supplies for steam, water, lighting, and floor drains.

Visitor Rules - Manual specifically outlines policy for plant visitors, including further reference to the GMP Code of Compliance – Visitor Form.

Employee Acknowledgement Form – Employee completes as acknowledgement of receipt of GMP Code of Compliance manual.

The SSOP manual is specifically written for employees, students participating in coursework involved with the DPP, and UWRF personnel. The manual outlines policies and procedures specific to sanitation, detailing procedures in the following areas:

HTST CIP Circuit

COP
Hand Cleaning

Ice Cream Post Processing

Cheese Post Processing

Validation and Recordkeeping

This project examined the effectiveness of the addition of written procedures in the form of manuals and checklists. The employees will utilize the training manuals as a reference for assembling equipment, operating equipment, disassembling equipment, and cleaning equipment.
CHAPTER TWO: LITERATURE REVIEW

Well-executed GMPs are a direct correlation to the success of a food safety management system in a food production facility. Federal regulation has proved the importance of GMPs by mandating the procedures in 21 CFR for food processors. Most employees, however, are not trained properly on the entirety of the foundation principles, which causes food safety concerns and gaps in a well-documented food safety management system.

Concise and current procedure manuals for training are often over looked and are under utilized in companies. Keeping procedures updated is challenging, especially when employees performing tasks are hesitant to write complete and well-documented procedures on their job procedures (Rathie, 1990, p. 15). The most important keys in writing and maintaining a procedure manual are the details, keeping the manual up to date and relevant to the audience.

Technical manuals are essential to job performance during and post-employee training (Barrett & Kalt, 1973, p. 357). Manuals serve as a reference guide to individuals looking to enhance their performance and therefore should be developed in a way that encourages learning with continuous exposure (Barrett & Kalt, 1973, p. 357).

Along with well-developed manuals, critical thinking should be infused into the training process. Introducing and encouraging critical thinking is necessary for
problem solving when it comes to working on the production floor. According to Schlick (1992), “effective empowerment means providing the responsibilities and the skills for people to manage their work” (p. 16). Schlick also states that critical thinking will become essential to improve quality and productivity of employees, (p. 18).

Training employees should be paramount to food production in a food processing facility. Training should encompass all aspects of SOPs, GMPs, proper sanitation procedures, and operation of specific job-related equipment (Bhatt, 1998). Job training could include on-the-job training, one-on-one instruction, computer based training, or other means of immersing the employee in a comprehensive training program for an employee to be successful, as well as the food safety management system to be successful.

GMP procedures have become increasingly important in RTE foods, since they represent a large portion of the American diet (FDA). Since those foods require little to no preparation prior to consumption, it is imperative the foods produced are safe for immediate consumption. Proper employee applications of GMPs play an important role in minimizing pathogenic organisms of concern in food manufacturing facilities. With HACCP becoming an increasingly larger focus for all processing facilities including dairy, the importance of properly trained employees on GMPs is priority.
According to Marcason (2011), foodborne illness in the US affects 48 million people per year and causes approximately 3000 deaths per year (p. 966). Dias et al. (2012) state “the existence of a manual describing how GMPs are accomplished by each processing plant is of foremost importance to ensure their continuous evaluation and improvement by processing plants, governments and partners” (p. 200).
CHAPTER THREE: METHODOLOGY

MANUAL DEVELOPMENT

The compliance manual was developed to be a training guide and source of reference for the following audiences:

- Dairy pilot plant employees
- Students' participating in practical coursework
- University of Wisconsin-River Falls staff utilizing the space for educational purposes

The primary learning objective of the compliance manual is for employees to learn and execute good manufacturing practices and sanitation skills without hesitation. The secondary objective is for employees to become leaders amongst their peers with regards to good manufacturing practices. The employee’s ability to comprehend and apply their learning of the GMPs is crucial to the foundation of the food safety management system at the DPP.

To accomplish the primary and secondary learning objectives, the Absorb-Do-Connect model of learning, proposed by W. Horton, will be employed. According to Horton (2012), “people learn by considering, researching, analyzing, evaluating, organizing, synthesizing, discussing, testing, deciding and applying ideas” (p. 51).
The *absorb* activity for the GMP Code of Compliance is reading the manual. By reading the manual, learners absorb the material and gain knowledge on the subject material. Although the learner is physically idle, their mind is a sponge for the material presented.

Following reading of the manual, the learning audience participates in a group activity of answering questions and encouraging critical thinking by utilizing the drill and practice activities learning example. During this *do* activity, learners are presented with questions in a team environment, encouraging discussion amongst the group. The activity is designed to engage multiple persons in conversation about the GMP Code of Compliance and SSOP.

The final activity used for learning is the *connect* activity. During this activity, learners are paired with subject matter experts (SME’s) and their *absorb* and *do* learning is directly applied to their position at the DPP.

**RECORDS**

In a food safety management system, documentation is necessary to provide proof that activities were performed as claimed. Therefore, if an employee was trained on proper GMP compliance, the documentation needs to be on record. According to the global food safety standard, ISO 22000:2005, section 6.2.2 (g) training records are to be maintained to identify the necessary competencies of personnel who impact
food safety. This record fulfills the ISO 22000:2005 requirement for employee GMP training.

The GMP Code of Compliance for visitors’ form and Dairy Pilot Plant visitor log were developed to comply with records retention requirements for food safety management systems. These records require visitors to agree to follow the GMP guidelines addressed on the form and sign off on the agreement. This record fulfills the ISO 22000:2005 requirement for visitor GMP training.

The DPP Visitor Log was created to raise awareness of security issues related to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The DPP Visitor Log requires all visitors to sign in with proof of identity and purpose of visit. This record partially fulfills the ISO 22000:2005 requirement for food protection from outside sources.

The SSOP Checklists were created to record required sanitation activities from the SSOP for every production activity that occurs inside the DPP. The checklist provides information for which the activity was assigned to, who completed the activity, and any comments for the reviewer. The form also requires an approval signature after review. Typically the reviewer would be someone who reviews the checklist at the time of sanitation and signs off for approval. This record fulfills the ISO 22000:2005 requirement for post-sanitation checklists.
CHAPTER FOUR: DISCUSSION

GMP CODE OF COMPLIANCE USE

The GMP Code of Compliance was put into use for a short time at the University of Wisconsin-River Falls Dairy Pilot Plant. Three DPP employees were given the manual to read; together they performed the group activity and then were paired to work with trained employees. The result was positive with the employees being able to perform their duties in GMP compliance better than employees with minimal on-the-job training. The three employees who participated in the updated training program were able to perform their required duties without hesitation and felt more confident regarding their role in the DPP.

GMP CODE OF COMPLIANCE USE – VISITOR FORM

The GMP Code of Compliance-visitor form was used during the Cheesemaker's short course held at the DPP in April, 2014. The attendees of the short course were given the Code of Compliance form and were presented with the material. Each visitor was required to sign and date the form prior to entering the DPP for the day of hands-on instruction. The impact of the visitor form was very positive which resulted in a significant improvement of visitor GMP performance while participating in production activities from the previous year's short course that occurred without the form.
CHAPTER FIVE: CONCLUSION

The purpose for developing the GMP Code of Compliance and SSOP manual was to provide a point of reference for DPP employees, students, and personnel. The goal of the manual is to ensure food safety guidelines are met during any activity held in the DPP through instruction and performance.

The secondary goal of developing the manual along with the checklists was to provide a foundation for the future layers of the FSMS that is required to become third party quality certified. The DPP will be able to build off the foundational programs of the GMP and SSOP manuals.

The GMP Code of Compliance has initially improved working knowledge of personal performance with engaged in activities in the DPP. Current employees have completed their tasks with more confidence and management has had more confidence that food safety guidelines have been met.

The training program for the GMP Code of Compliance could be improved by designing a computer-based training (CBT) module for current and future employees. Due to the challenging aspect of the laboratory - educational facility doubling as a business with high employee turnover, training could be improved by allowing instruction in a more schedulable format.
Likewise, the SSOP could be improved by designing a CBT module for current and future employees. This training could be performed outside of the DPP, at a time more convenient to the student’s schedule.

Both the GMP Code of Compliance and SSOP manual would remain in print for reference, but the initial learning activity of instruction could be reading online and the drill-and-practice learning activities could be performed using computer quiz format questions. Within the learning management system software would be an evaluation piece built in for testing the learner's knowledge as well as tracking the completion of the training module.

Overall, the GMP Code of Compliance and SSOP manual has improved the operations of the DPP by improving employee and visitor knowledge of GMP guidelines and sanitation expectations. The knowledge the employees receive at the DPP should surpass any employee training they have received in the past. I believe with the enhanced GMP Code of Compliance and SSOP manual along with the training the employees will receive, will allow the expectations to be met.
REFERENCES


## APPENDIX

### GLOSSARY OF PROJECT DOCUMENTS

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Document Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMP Code of Compliance – Visitors</td>
<td>Document specifically designed for visitors, detailing minimum GMP expectations</td>
</tr>
<tr>
<td>GMP Visitor Log</td>
<td>Documents visitors entering the DPP including the purpose of the visit.</td>
</tr>
<tr>
<td>Cheese Production Post Sanitation Checklist</td>
<td>Checklist for employees and reviewer to use for post cheese production sanitation task completion and verification.</td>
</tr>
<tr>
<td>Cheese Production Equipment Post Sanitation Checklist</td>
<td>Checklist for employees and reviewer to use for post cheese production equipment sanitation task completion and verification.</td>
</tr>
<tr>
<td>Ice Cream Production Post Sanitation Checklist</td>
<td>Checklist for employees and reviewer to use for post ice cream production sanitation task completion and verification.</td>
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</tbody>
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