

PubH 7200 Section 108 Course #88043
FSMA: From Legalese to Implementation - A Preventive Controls Qualified Individual Training
May Term 2017

Credits:	1 credit
Meeting Days/Time:	May 30, 31 8:00am – 5:00pm June 1 8:00am – 12:00pm
Meeting Place:	Blegen Hall - Room 210
Instructor:	Heidi Kassenborg DVM, MPH
Office Address:	
Office Phone:	651-436-2281
E-mail:	heidikassenborg@gmail.com
Office Hours:	By Appointment

I. Course Description

This course will be useful for those with an interest in preventing foodborne illness and food safety who are already in or just entering the workforce.

The Food Safety Modernization Act (FSMA) is described by the U.S. Food and Drug Administration (FDA) as the most sweeping reform of our food safety laws in more than 70 years. This regulation is intended to ensure the safety of manufacturing/processing, packing and holding of food products for human consumption in the United States. One of the key parts of FSMA is the Current Good Manufacturing Practice, Hazard Analysis and Risk-based Preventive Controls for Human Food regulation (referred to as the Preventive Controls for Human Food regulation). For the first time food manufacturing facilities will be required to document that active managerial control of all food safety hazards that can reasonably occur in a food manufacturing plant has occurred. Additionally, it requires that certain activities must be completed by a “preventive controls qualified individual”.

This course, developed by Food Safety Preventive Controls Alliance, is the standardized curriculum recognized by FDA: successfully completing this course is one way to meet the requirements for a “preventive controls qualified individual” and receive a PCQI Certificate. Even those who do not currently need to have this designation will benefit from this course as it will cover one of the main components of FSMA and how it is being practically implemented.

Acknowledgments: This course was developed by the Food Safety Preventive Controls Alliance.

II. Course Prerequisites

None

III. Course Goals and Objectives

By the end of this course, the student should:

1. Gain a basic understanding of foundational programs such as Good Manufacturing Practices
2. Know where to find information about specific food hazards and underlying principles used in food safety preventive controls
3. Describe underlying principles used in food safety preventive controls and how to apply these practices and principles in a systematic approach.
4. Discuss how to put together each section of a Food Safety Plan and how these sections relate to a complete preventive controls program and safe food processing

IV. Methods of Instruction and Work Expectations

This course will be a combination of lecture and group activities. Students are expected to participate in class and as part of a small group that will be constructing a food safety plan for a fictional food item.

V. Course Text and Readings

Required Text: FSPCA Course manual

Access Course Moodle Site

- go to www.umn.edu click on the “myU” button
- login with your University ID and password
- scroll to your course and click on the Moodle site link

VI. Course Outline/Weekly Schedule

	Daily Schedule	Assignments
Day 1	Chapter 1 Introduction to Course and Preventive Controls Chapter 2 Food Safety Plan Overview Break Chapter 3 Good Manufacturing Practices and Other Prerequisite Programs Chapter 4 Biological Food Safety Hazards Lunch Chapter 5 Chemical, Physical and Economically Motivated Food Safety Hazards Break Chapter 6 Preliminary Steps in Developing a Food Safety Plan Chapter 7 Resources for Preparing Food Safety Plans	Group activities in defining chemical, biological hazards in food facilities; determining resources in developing and implementing a food safety plan
Day 2	Chapter 8 Hazard Analysis and Preventive Controls Determination Break Chapter 9 Process Preventive Controls Lunch Chapter 10 Food Allergen Preventive Controls Break Chapter 11 Sanitation Preventive Controls Chapter 12 Supply-chain Preventive Controls	Group activities in class -Conduct hazard analysis for production of a food item. -Determine process, sanitation, allergen and supply chain preventive controls for a fictional food item

Day 3	Review and Questions Chapter 13 Verification and Validation Procedures Chapter 14 Record-keeping Procedures Break Chapter 15 Recall Plan Chapter 16 Regulation Overview – cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Wrap Up	Group activities in class -Determine verification and validation procedures, record keeping requirements, and recall plan for the production of a fictional food item
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VII. Evaluation and Grading

To receive a Preventive Controls Qualified Individual Certificate the student must be present for the entire delivery and actively participate in the exercises.

25% (25 points) Active participation in the classroom discussion and exercises
75% (75 points) Written assignments

This course is offered A/F or S/N

- **A/F letter grade will be determined by total effort as follows:**
- **S Represents achievement that is satisfactory, which is equivalent to a C- or better.**

A	4.000 (94-100 points/percent) Represents achievement that is outstanding relative to the level necessary to meet course requirements
A-	3.667 (90-93 points/percent)
B+	3.333 (87-89 points/percent)
B	3.000 (83-86 points/percent) Represents achievement that is significantly above the level necessary to meet course requirement
B-	2.667 (80-82 points/percent)
C+	2.333 (77-79 points/percent)
C	2.000 (73-76 points/percent) Represents achievement that meets the course requirements in every respect
C-	1.667 (70-72 points/percent)
D+	65-69 (points/percent) 1.333
D	1.000 (60-64 points/percent) Represents achievement that is worthy of credit even though it fails to meet fully the course requirements
F	Represents failure (or no credit) and signifies that the work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement

	between the instructor and the student that the student would be awarded an I.
S	Represents achievement that is satisfactory, which is equivalent to a C- or better.

For additional information, please refer to:

<http://policy.umn.edu/Policies/Education/Education/GRADINGTRANSCRIPTS.html>.

Course Evaluation

The SPH will collect student course evaluations electronically using a software system called CoursEval: www.sph.umn.edu/courseval. The system will send email notifications to students when they can access and complete their course evaluations. Students who complete their course evaluations promptly will be able to access their final grades just as soon as the faculty member renders the grade in SPHGrades: www.sph.umn.edu/grades. All students will have access to their final grades through OneStop two weeks after the last day of the semester regardless of whether they completed their course evaluation or not. Student feedback on course content and faculty teaching skills are an important means for improving our work. Please take the time to complete a course evaluation for each of the courses for which you are registered.

Incomplete Contracts

A grade of incomplete "I" shall be assigned at the discretion of the instructor when, due to extraordinary circumstances (e.g., documented illness or hospitalization, death in family, etc.), the student was prevented from completing the work of the course on time. The assignment of an "I" requires that a contract be initiated and completed by the student before the last official day of class, and signed by both the student and instructor. If an incomplete is deemed appropriate by the instructor, the student in consultation with the instructor, will specify the time and manner in which the student will complete course requirements. Extension for completion of the work will not exceed one year (or earlier if designated by the student's college). For more information and to initiate an incomplete contract, students should go to SPHGrades at: www.sph.umn.edu/grades.

University of Minnesota Uniform Grading and Transcript Policy

A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable):

For full-semester courses, students may change their grade option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e. summer and half-semester courses) can be found at onestop.umn.edu.

Course Withdrawal:

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Office of Admissions and Student Resources at sph-ssc@umn.edu for further information.

Student Conduct Code:

The University seeks an environment that promotes academic achievement and integrity, that is protective of free inquiry, and that serves the educational mission of the University. Similarly, the University seeks a community that is free from violence, threats, and intimidation; that is respectful of the rights, opportunities, and welfare of students, faculty, staff, and guests of the University; and that does not threaten the physical or mental health or safety of members of the University community.

As a student at the University you are expected adhere to Board of Regents Policy: *Student Conduct Code*. To review the Student Conduct Code, please see: http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf.

Note that the conduct code specifically addresses disruptive classroom conduct, which means "engaging in behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning.

The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities."

Use of Personal Electronic Devices in the Classroom:

Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. To this end, the University establishes the right of each faculty member to determine if and how personal electronic devices are allowed to be used in the classroom. For complete information, please reference:

<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Scholastic Dishonesty:

You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis. (Student Conduct Code:

http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf) If it is determined that a student has cheated, he or she may be given an "F" or an "N" for the course, and may face additional sanctions from the University. For additional information, please see:

<http://policy.umn.edu/Policies/Education/Education/INSTRUCTORRESP.html>.

The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: <http://www1.umn.edu/oscai/integrity/student/index.html>. If you have additional questions, please clarify with your instructor for the course. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam.

Makeup Work for Legitimate Absences:

Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Such circumstances do not include voting in local, state, or national elections. For complete information, please see:

<http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html>.

Appropriate Student Use of Class Notes and Course Materials:

Taking notes is a means of recording information but more importantly of personally absorbing and integrating the educational experience. However, broadly disseminating class notes beyond the classroom community or accepting compensation for taking and distributing classroom notes undermines instructor interests in their intellectual work product while not substantially furthering instructor and student interests in effective learning. Such actions violate shared norms and standards of the academic community. For additional information, please see: <http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Sexual Harassment:

"Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment in any University activity or program. Such behavior is not acceptable in the University setting. For additional information, please consult Board of Regents Policy:

<http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf>

Equity, Diversity, Equal Opportunity, and Affirmative Action:

The University will provide equal access to and opportunity in its programs and facilities, without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression. For more information, please consult Board of Regents Policy:

http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EO_AA.pdf.

Disability Accommodations:

The University of Minnesota is committed to providing equitable access to learning opportunities for all students. The Disability Resource Center Student Services is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations.

If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DRC at 612-626-1333 or drc@umn.edu to arrange a confidential discussion regarding equitable access and reasonable accommodations.

If you are registered with DS and have a current letter requesting reasonable accommodations, please contact your instructor as early in the semester as possible to discuss how the accommodations will be applied in the course.

For more information, please see the DS website, <https://diversity.umn.edu/disability/>.

Mental Health and Stress Management:

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance and may reduce your ability to participate in daily activities. University of Minnesota services are available to assist you. You can learn more about the broad range of confidential mental health services available on campus via the Student Mental Health Website: <http://www.mentalhealth.umn.edu>.

The Office of Student Affairs at the University of Minnesota:

The Office for Student Affairs provides services, programs, and facilities that advance student success, inspire students to make life-long positive contributions to society, promote an inclusive environment, and enrich the University of Minnesota community.

Units within the Office for Student Affairs include, the Aurora Center for Advocacy & Education, Boynton Health Service, Central Career Initiatives (CCE, CDes, CFANS), Leadership Education and Development – Undergraduate Programs (LEAD-UP), the Office for Fraternity and Sorority Life, the Office for Student Conduct and Academic Integrity, the Office for Student Engagement, the Parent Program, Recreational Sports, Student and Community Relations, the Student Conflict Resolution Center, the Student Parent HELP Center, Student Unions & Activities, University Counseling & Consulting Services, and University Student Legal Service.

For more information, please see the Office of Student Affairs at <http://www.osa.umn.edu/index.html>.

Academic Freedom and Responsibility: *for courses that do not involve students in research:*

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

OR:**Academic Freedom and Responsibility, for courses that involve students in research**

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom and conduct relevant research. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.* When conducting research, pertinent institutional approvals must be obtained and the research must be consistent with University policies.

Reports of concerns about academic freedom are taken seriously, and there are individuals and offices available for help. Contact the instructor, the Department Chair, your adviser, the associate dean of the

college, (Dr Kristin Anderson, SPH Dean of Student Affairs), or the Vice Provost for Faculty and Academic Affairs in the Office of the Provost.

** Language adapted from the American Association of University Professors "Joint Statement on Rights and Freedoms of Students".*

Student Academic Success Services (SASS): <http://www.sass.umn.edu>:

Students who wish to improve their academic performance may find assistance from Student Academic Support Services. While tutoring and advising are not offered, SASS provides resources such as individual consultations, workshops, and self-help materials.

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