

ACU Dallas Approval Chart for Curriculum Changes

A = Approve I = Information Item R = Advise & Respond

Course Number: PCM 633 - Laboratory Regulatory and Operational Compliance

Highlight the item that corresponds to the requested change.

	Change to a Course	U	P	A	O	S
1.	Title (description unchanged)	A	A	I	I	I
2.	Description (not affecting content)	A	A	I	I	I
3.	Course term(s)	A	A	I	I	I
4.	Content (substantive change)	A	A	A	A	I
5.	Number of credit hours	A	A	A	A	I
6.	Course number within the hundred	A	A	I	I	I
7.	Course number beyond the hundred	A	A	A	A	I
8.	Prerequisites	A	A	A	A	I
9.	Course fee(s)	A	A	--	A	I
10.	From U to G or G to U	A	A	A	A	I
11.	Cross list with another program or department	A	A	A	A	I
12.	Program/department of record	A	A	A	A	I
13.	Open or close a course	A	A	A	A	I
14.	New course (application required)	A	A	A	A	I

	Change to a Degree Plan	U	P	A	O	S	F
1.	Major/Program — Revision	A	A	A	A	A	--
2.	Major/Program — Adopt or change admission requirements	A	A	A	A	A	--
3.	Major/Program — Add	A	A	A	A	A	--
4.	Major/Program — Offer existing university program on campus	--	A	A	A	A	--
5.	Major/Program — Discontinue (proposed by Program or College)	A	A	A	A	A	I
6.	Major/Program — Discontinue (proposed by Provost)	R	R	A	A	A	I

7.	GPA — Revise major/program or cumulative requirement	A	A	A	A	A	--
8.	Minor — Revise course selection	A	A	I	I	I	--
9.	Minor — Add	A	A	A	A	A	--
10.	Minor — Discontinue (proposed by Program or College)	A	A	A	A	A	--
11.	Minor — Discontinue (proposed by Provost)	R	R	A	A	A	--
12.	Degree — Add	A	A	A	A	A	I
13.	Degree — Discontinue (proposed by Program or College)	A	A	A	A	A	I
14.	Degree — Discontinue (proposed by Provost)	R	R	A	A	A	I

	Change to Undergraduate University Requirements	A	A	A	A	A	A	A	A
15.	University Requirements — Change in approved course content	A	A	A	A	A	A	--	A
16.	University Requirements — Add or drop a required course from the University Requirements chart	A	A	A	A	A	A	A	A
17.	University Requirements — Add or drop a course from a menu within the University Requirements chart	A	--	--	A	A	A	--	A
18.	University Requirements — Change hours within a menu on the University Requirements chart	A	A	A	A	A	A	A	A
	Change to Catalog Information For Campus								
1.	General requirements for graduation including course requirements that are common to all majors for all degrees	--	--	A	--	--	A	--	A
2.	Admission requirements	--	--	A	--	--	A	--	A
3.	Policies governing academic probation and suspension	--	--	A	--	--	A	--	A
4.	Requirements for graduating with honors	--	--	A	--	--	A	--	A

Program Director/Department Chair

Maghan Hope

Mar 17, 2022

Signature

Date

Signature

Date

Dean(s)

Nannette W Glenn, Ph.D.

Mar 17, 2022

Nannette W Glenn, Ph.D. (Mar 17, 2022 12:07 CDT)

Signature

Date

Signature

Date

College Academic Council

Chair's Signature

Date

Chair's signature

Date

University General Education Council

Chair's signature

Date

Undergraduate Academic Council

Chair's signature

Date

Provost

Signature

Date

Faculty

Faculty Representative signature

Date

President

Signature

Date

Application for a New Course v10.7

Discard instructional pages A-C before submitting application. Consult with the program director and dean before changing responses in red type.

Course ID (<i>Subject and Number</i>)	PCM 633
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I. Systems and Catalog Information Complete each item.

1	Course Developer	Rusty Kruzelock, PhD & Meghan Hope, JD, MHA
2	Course Instructor	TBD
3	Course Title	Laboratory Regulatory and Operational Compliance
4	Course Abbreviation for Banner if title is more than 30 characters	Lab Reg & Op Compliance
5	College	College of Graduate and Professional Studies
6	Department or School	School of Health and Human Services
7	Number of Credit Hours	3
8a.	Number of contact hours – lecture	3
8b.	Number of contact hours – lab/activity	0
9	Is the course for a fixed or variable number of credit hours?	Fixed
10	Explanation for variable credit	N/A
11	Is the course repeatable for additional credit?	No
12	Maximum total number of credit hours a student can earn for this course	3
13	What type of course is this? (Select one option. Please see Schedule Type definitions on Page C.)	☒ Traditional lecture ☐ Traditional lab ☐ Traditional lecture/lab ☐ Experiential Learning ☐ Seminar ☐ Studio ☐ Thesis ☐ Dissertation

14	Number of faculty workload hours	3
15	Grade Mode	☒ Standard ☐ Credit/No Credit (undergrad only)
16	Maximum Enrollment	27
17	Catalog Description (50 words or less)	Diagnostic laboratories are subject to unique regulatory and payment guidelines. This course explores key clinical laboratory practices needed to demonstrate knowledge, intent and processes that comply with important safety and legal regulations. Also discussed will be practices for remaining current with changes in relevant laws and regulations.
18	List any prerequisites (course/s, test scores, class standing, major, etc.)	PCM 601, PCM 605
19	List any corequisites (these <i>must</i> be taken at the same time; note that a single requirement cannot be both a prerequisite <i>and</i> a corequisite)	none
20	If the course is cross-listed, specify the Course ID(s)	N/A
21	Does this course require any additional student course fees?	☒ No ☐ Yes If yes, attach a completed "Request to Add or Change Course Fees" form. Describe in section IV-7.
22a	Will the course be offered in fall terms?	☐ No ☒ Yes If yes: all, even, or odd years?
22b	Will the course be offered in spring terms?	☐ No ☒ Yes If yes: all, even, or odd years?
22c	Will the course be offered in summer terms?	☐ No ☒ Yes If yes: all, even, or odd years?
23	First semester this course will be offered under new Course ID. <i>May not be earlier than two parts of the term in the future.</i>	Summer 2, 2022
24	Is this course required for a degree/s?	☐ No

		☒ Yes If yes, attach a revised degree plan(s) reflecting the placement of the new course.
25	Should the addition of this course be retroactively applied to the degree plan it supports? <i>This is rare, and rationale should explain compelling extenuating circumstances.</i>	☒ No ☐ Yes If yes, provide rationale:
26	Has this course been offered as a Special Topics course? <i>New courses are not required to be taught as Special Topics courses prior to approval.</i>	☒ No ☐ Yes If yes, provide course ID, term, and enrollment:
27	List any courses in which the content overlaps the proposed course. (Course ID and Name) <i>Attach a statement from the instructor/dept chair of the existing course justifying the new offering in Section IV-4.</i>	None

II. Curriculum

- A. Explain effect on degree plans. If the addition of the course alters degree requirements, submit a separate Approval Chart for Curriculum Change to update the degree plan.
 - a. This course is part of the required sequence for both the Masters of Science in Precision Medicine and is an elective option in the Certificate in Precision Medicine.
- B. Justify the addition of this course to the current curriculum, explaining the gap it meets.
 - a. This course introduces students to the unique regulatory environment of diagnostic laboratories. Students will learn practices to help remain current with ongoing changes in relevant laws and regulations and skills and techniques for maintaining laboratory compliance.

III. Course Design

- A. Audience and Course Goal
 1. Describe the intended audience, including prerequisite skills.
 1. Students in the Masters of Precision Medicine Program. This course will be an elective option for students in the Certificate of Precision Medicine Program.
 2. Students will need to have completed PCM 601 and PCM 605 in order to take this course.
 2. State the overarching course goal(s) in performance terms.

1. The overarching goal is to understand the regulatory framework and compliance environment necessary for safety and adherence to appropriate laboratory practices.
2. Activities in the course center upon analyzing federal regulations and stakeholders and creating a compliance plan addressing laboratory reimbursement, safety, privacy, and fraud and abuse.

B. Student Learning Outcomes and Measurements

	Student Learning Outcome	Measurement
1	SLO #1.5: Students will demonstrate knowledge of laboratory safety, professional conduct, and ethical principles.	Assignments and Discussion
2	SLO #4.1 Students will demonstrate an understanding of regulatory, external, and internal safeguards needed to keep specimen, environment, as well as patients and their data safe	Assignments and Discussion
3	SLO #4.2: Students will demonstrate an understanding of regulatory and quality assurance aspects to ensure safety of the patient and community.	Assignments and Discussion

3. Text and Resources

Give the full publication information of the textbook/s and other required resources and outside readings. For **combined undergraduate/graduate** courses, make two lists:

- A. Garcia, L. S., Baselski, V. S., Burke, M. D., Schwab, D. A., Sewell, D. L., Steele, J. C. H., Weissfeld, A. S., Wilkinson, D. S., & Winn, W. C. (2014). Clinical laboratory management. ASM Press.

IV. Supporting Documentation

Required of all applications	
1	Approval Chart for Curriculum Changes
2	Syllabus — Attach the syllabus for the course based upon the anticipated first-semester offering.
3	Library — Submit new course application and syllabus to the Library dean's office.

	Attach the Library's provisional memo of support.
Attach if applicable	
4	Content Overlap — Include one document for each course you listed in Section I-28. Attach statement from instructor/dept chair of existing course justifying the new offering.
5	Program Resources — List the resources that support the course and are available only through the program, if applicable. Attach the list of the holdings and the location/s.
6	Resources — List resources (other than library or program resources) that are needed to support this course (computers, lab equipment, other technology, etc.). Attach a complete list of all items and indicate possible sources or estimated cost of each. List the sources of any needed funds.
7	Expenses — List additional expenses needed to implement this course (full-time or part-time faculty, graduate or lab assistants, student employees, travel, special student costs, room renovation, storage facility, etc.). Attach a complete list of all items, the estimated cost of each and the source of the funds.
8	Justification — Attach any documents to which you refer in Section II-B.

PCM 633: Laboratory Regulatory and Operational Compliance

2022 Section PCM 633 3 Credits 10/14/2019 to 10/14/2020 Modified 03/17/2022

Mission Statements

University Mission Statement

The mission of Abilene Christian University (ACU) is to educate its students for Christian service and leadership throughout the world.

This mission is achieved through the following:

- Exemplary teaching, offered by a faculty of Christian scholars, that inspires a commitment to learning;
- Significant research, grounded in the university's disciplines of study, that informs issues of importance to the academy, church, and society; and
- Meaningful service to society, the academic disciplines, the university, and the church, expressed in various ways, by all segments of the Abilene Christian University community.

College Mission Statement

The mission of the College of Graduate and Professional Studies (CGPS) is to prepare students for Christian service and leadership by providing them with the knowledge and skills to advance their careers, thereby placing them in positions of influence for the expansion of God's purposes in the world.

Program Mission Statement

The mission of the Master of Science in Precision Medicine is to provide students with both theory and skills in applying the latest molecular diagnostic techniques and analytics procedures to assist in the planning and implementation of precise treatment protocols for patients confronting serious illness, as well as a foundation for effective laboratory management.

Integration of Christian Faith

Abilene Christian University was founded on the principles taught and modeled through the life of Jesus Christ. We believe that God loved this world so much that he sent his son to live among us and to teach us how to love God and others.

The programs in Precision Medicine are centered in this example of love and care. While teaching students the essentials and the emerging development of precision medicine and care to the seriously ill, this program is designed to build leadership in individuals who will champion the cause of those in need of care. The theory and practices provided will contribute to the quality delivery and development of innovative research and practice in healthcare within the context of Christian care and compassion. In addition, students will be provided opportunities to explore and develop their own vocational formation as they grow in their knowledge of precision medicine.

Course Description

Diagnostic laboratories are subject to unique regulatory and payment guidelines. This course explores key clinical laboratory practices needed to demonstrate knowledge, intent and processes that comply with important safety and legal regulations. Also discussed will be practices for remaining

current with changes in relevant laws and regulations.

Program and Student Learning Outcomes

	Student Learning Outcome	Measurement
1	SLO #1.5: Students will demonstrate knowledge of laboratory safety, professional conduct, and ethical principles.	Assignments and Discussion
2	SLO #4.1 Students will demonstrate an understanding of regulatory, external, and internal safeguards needed to keep specimen, environment, as well as patients and their data safe	Assignments and Discussion
3	SLO #4.2: Students will demonstrate an understanding of regulatory and quality assurance aspects to ensure safety of the patient and community.	Assignments and Discussion

Course Materials

Garcia, L. S., Baselski, V. S., Burke, M. D., Schwab, D. A., Sewell, D. L., Steele, J. C. H., Weissfeld, A. S., Wilkinson, D. S., & Winn, W. C. (2014). Clinical laboratory management. ASM Press.

Course Requirements

General descriptions of the course requirements are below. See the online modules for detailed assignment instructions.

Discussion Questions

Participation in online discussions is mandatory. In order to actively participate in these discussions you will need to log in at least 5 days each week. This will help you stay up-to-date on the discussions and allow you to make more thoughtful postings. Discussions begin on Tuesday each week and end on Monday at 11:59 PM Central. You are expected to answer all of the discussion questions assigned in a week in a substantive manner. Your initial post will be due on Thursday by 11:59pm CST. You are also expected to respond to at least 1 of your classmates' postings for each discussion question. No late posting will be accepted.

Course Policies

Note: Please see the Canvas course for information on the faculty as well as all due dates.

Engaged Learning in an Online Format

This online course invites students into a community of engaged scholarship. The course consists of seven weekly modules, with a new module beginning each Tuesday morning in the Canvas LMS (Learning Management System). We expect students to log in to the course frequently, master the course material, whether written or in other digital media formats, and to engage the professor and fellow students through the Canvas medium.

Note: If a student fails to log in the course for the first 7 days of the official course, the student will receive an email notifying them that they are at risk to be administratively withdrawn from the course. The student will have 72 hours to log into the course from that email notification. If the student does not log into the course in that period of time, they will be administratively withdrawn. The last day to withdraw from a course is the Wednesday before the last week of class. Please reference the handbook calendar for a full list of dates. If a student has not participated in the course at any point, before the last week of class the student will be administratively withdrawn. An assignment is defined as a paper, quiz, discussion post, or project in the

course. If a life situation occurs that will prevent the student from participating in the course for a brief period of time, the student is responsible for communicating this to their Student Service Advisor and/ or New Student Ambassador, and instructor to make appropriate arrangements.

Technology Requirements

Students should ensure they meet the technology requirements as outlined in the ACU Online Student Handbook.

Paper Specifics

All formatting and referencing should follow *The Publication Manual of the American Psychological Association, 7th Edition*. Papers should be written in Times New Roman, 12-point font and submitted as a .docx, .doc, or .pdf file. All papers should be neat, contain no misspellings, contain no typing errors, and employ proper grammar and syntax. If your paper contains pervasive APA and/or grammatical errors, the professor may return the paper without grading it. Your faculty will determine the date for submission for the revised paper and 10% will be automatically deducted in addition to any late penalty deductions if the assignment was submitted late.

Late Assignments

Assignments are due by 11:59 pm Central Standard time on the due date. Refer to the Canvas Syllabus link or the Canvas Modules link for a list of all due dates. Penalty for late assignments is 10% per calendar day late. Weekend days are counted as late days. No credit will be awarded for late discussion posts. Extra credit will not be available in this course.

Academic Integrity

Academic Integrity is defined as academic work completed as assigned for each class by the individual or group responsible for the work. Academic work includes but is not limited to reading assignments, assessments and examinations, attendance at required out-of-class activities, written or oral presentations, laboratory experiments and research. Assignments may or may not be submitted through the TurnItIn plagiarism checker.

The Academic Integrity and Honesty Policy is available on the ACU Provost's Office [webpage](https://cdn01.acu.edu/community/offices/administrative/office-of-the-provost/academic-integrity-policy/expanded-definitions-and-advice.html) (<https://cdn01.acu.edu/community/offices/administrative/office-of-the-provost/academic-integrity-policy/expanded-definitions-and-advice.html>), where you may find detailed information regarding what constitutes academic dishonesty and resultant disciplinary actions. The student should seek clarification from the instructor regarding the re-use of work, as this may or may not be appropriate and is dependent on the assignment. Academic dishonesty may have, but not be limited to, the following consequences:

- losing points on an assignment.
- failing an assignment.
- failing a course.
- having a record of improper conduct in the dean's office which oversees the course in which the infraction was made.
- being dismissed from the university.

The process and timeline for appeals can be found on the ACU Provost's Office webpage.

Academic Integrity Violation Process for Discussions Boards

In cases where a student posts an initial blank post and then proceeds to post a second time to the discussion with their answer to the discussion prompt, the following discipline processes will be followed:

1st Violation of Blank Post in a Course - "0" on discussion portion (not reply portion) and the instructor will issue a written warning that the second violation will be considered an Academic Integrity violation.

2nd Violation of Blank Post in Same Course - "0" on discussion portion and the student will be reported to the Dean's Office as having conducted an Academic Integrity Violation. See the syllabus for information about the Academic Integrity Violation process and possible consequences.

Anti-Harassment Policy

Harassment will not be tolerated at Abilene Christian University. As a Christian community, Abilene Christian University has committed itself, unequivocally, to ensuring a working and learning environment in which the dignity of every individual is respected. Harassment is defined as unwelcome behavior or conduct based on sex, religion, race, age, color, national origin, veteran's status, disability, or any other characteristic protected by law when (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment, education, or participation in University programs or activities, (2) submission to, or rejection of, such conduct by an individual is used as the basis for a decision affecting an individual's employment, education, or participation in University programs or activities, or (3) 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 environment for work, education, or participation in a University program or activity. Therefore, it is the purpose of the Anti-Harassment Policy to maintain a work and academic environment that is free of harassment, sexual or otherwise. This policy applies to all members of the ACU community, including trustees, faculty, staff, students, and volunteers at Abilene Christian University. For a more in-depth review of the university's anti-harassment policy, the full definition of harassment, and procedure for reporting, visit: <https://www.acu.edu/dean-of-students/required-legal-statements/anti-harassment-policy/> (<https://www.acu.edu/dean-of-students/required-legal-statements/anti-harassment-policy/>)

ACU Online Student Handbook

The current version can be found [here](#)

(https://acuonline.my.salesforce.com/sfc/p/#E0000000cKPT/a/440000006AA9/RWbLcDg6R9gR8DgTJwQdECczCHnjwM1_0WvJs6b4qeY).

ACU Dallas Student Code of Conduct

The ACU Online Student Handbook contains an online student Code of Conduct which describes appropriate and inappropriate forms of electronic communication and online behavior as well as information about student integrity in scholarly work. Students may be dismissed from the university for failing to adhere to the Code of Conduct.

ADA Compliance Statement

Abilene Christian University is dedicated to removing barriers and opening access for students with disabilities in compliance with ADA and Section 504 of the Rehabilitation Act. The Alpha Scholars Program facilitates disability accommodations in cooperation with instructors. In order to receive accommodations, you must be registered with Alpha Scholars Program, and you must complete a specific request for each class in which you need accommodations. If you have a documented disability and wish to discuss academic accommodations, please call our office directly at (325) 674-2667 or alpha@acu.edu.

Library

Abilene Christian University provides library services to online students through the Distance Learning Portal at <http://guides.acu.edu/distance>. Students will use their single sign-on credentials to gain access to the library content. The Distance Learning Portal contains information about citation help, requesting materials, research guides, and degree program specific resources. Video tutorials on how to search the library's resources, including electronic journal titles, are available for students to view at any time. ACU also has dedicated staff that serve our online students, for help with refining topics, including dissertation and final project topics, searching databases, or other library help. To contact the online librarian, please visit <http://guides.acu.edu/c.php?g=824708&p=5887421>. For research assistance, you can visit <http://asklibrary.acu.edu> and submit your question through the web form or get help via text or chat.

Title IX Statement

As a professor, one of my responsibilities is to help create a safe learning environment on our Abilene Christian University Dallas Online campus. I also have a mandatory reporting responsibility related to my role as a professor. It is my goal that you feel safe to share information related to your life experiences in classroom discussions, in your written work, and in our one-on-one meetings. I will seek to keep the information you share private to the greatest extent possible. I am required to share with the Title IX Coordinator information regarding sexual misconduct or harassment, dating or domestic violence, or stalking that occurred

while you are or were enrolled as a student at ACU. If you would prefer to share information in a confidential setting, I encourage you to access counseling services through TimelyMD. All of your options are available for review by clicking on the link to ACU's [policy](#).

✓ Grading

Grades are awarded based on point accumulation. Each assignment has a maximum number of points that can be earned by successfully completing the assignment. Partial points will be awarded for meeting some but not all of the standards identified for each project or assignment. There are limitations to the number of C's you may accumulate in a graduate program based on the number of credit hours in the program. A cumulative 3.0 GPA must be maintained to graduate. Letter grades correspond with points as outlined in the table below.

Points Earned	Grade
90-100 points	A
80-89.9 points	B
70-79.9 points	C
60-69.9 points	D
59 points and lower	F

📅 Course Outline and Schedule

(Schedule subject to change; See the Canvas course for updated information on due dates.)

ABILENE CHRISTIAN UNIVERSITY
LIBRARY

M E M O R A N D U M

DATE: March 9, 2022
TO: Meghan Hope
FROM: Mark McCallon, Library Associate Dean for Library Information Services
RE: New Course Application - PCM 633 - Laboratory Regulatory and Operational Compliance

Thank you for the opportunity to review the application and syllabus for the proposed course. Working with the subject matter expert and instructional designers, the Library will try to provide the resources requested from us for the course. Please let Dr. Melissa Atkinson (melissa.atkinson@acu.edu) know when the course development template is available for review and the specific sources that the library will need to provide for the course.