VME6620 Regulatory Toxicology

SEMESTER: FALL 2024
CREDIT HOURS: 3 CREDIT HOUR
GRADING SYSTEM: LETTER GRADE
PHASE: I/II/III

Course Coordinator

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Course Description

Regulatory toxicology includes the evaluation of substances in prescribed assays, the goal of which is to determine hazards to humans and environmental species. This course will review the basics in the practice of conducting studies using prescribed *in vivo* and *in vitro* systems and evaluating the results. Students will learn about how studies are conducted; what data are generated and in what forms; and how to interpret the data. The student will be expected to develop communications skills so that results can be presented in an unbiased way, and students will learn to translate significant results into Hazard Communications phrases and symbols. In addition, alternative, non-animal methods to generate information that previously relied on experimental animals will be presented. Students will learn about proper animal care, husbandry, and designs of animal facilities. Testing requirements and regulatory jurisdiction will be presented for industrial chemicals, pharmaceuticals, and nanomaterials. Students are expected to read sections in the textbook and regulatory documents freely available on the internet. These documents are the beginnings of reference materials for subsequent work in the regulatory arena.

Course Learning Outcomes

After successful completion of this course, students will be able to:

1. Use the elements necessary to conduct a Regulatory Toxicology study to write a protocol for a study.
2. Analyze and interpret data in a Regulatory context.
3. Write results in a neutral, unbiased way, and
4. Translate the results in the appropriate Hazard Communication phrase.
5. Apply the principles of Good Laboratory Practice regulations to non-regulatory studies.

Course Schedule

This weekly schedule contains topics, assignments, and exams. Please refer to Canvas for updates and announcements to any changes to this schedule.

Lectures and quizzes will be on-line for the student to review *ad libitum* during a designated week. Assignments and discussion topics for designated modules are available on-line and are required. Examinations are on-line during prescribed weeks; these are timed and required.

Date	*Topic/Module/Unit*	*Location*	SLO # Above	*Instructional Hours*
Week 1	Regulatory Agencies, laws, jurisdictions, and acronyms. Discussion/assignment	On-line	1, 4	3.0
Week 2	Good Laboratory Practice standards. Laboratory animals and their care. Assignment/ discussion/ practice quiz		1, 5	3.0
Week 3	Elements of a good study design. Testing of pharmaceuticals, biologics, and medical devices. Discussion/ practice quiz.		1	3.0
Week 4	Testing of chemicals (industrial and pesticidal) and nanomaterials in the US, Europe, Canada, and Japan. Testing of nanomaterials. Assignment		1	3.0
Week 5	Conducting single exposure studies and evaluating data. Conducting Irritation and Sensitization studies and evaluating data. Assignment/ discussion		2	3.0
Week 6	Genetic toxicity testing. Assignment/ discussion. Practice quiz		2	3.0
Week 7	Exam I			N/A
Week 8	Conducting Repeated-dose studies. Discussion/ assignment		2	3.0
Week 9	Conducting a lifetime study. discussion/ assignment Interpretation of in-life and post-life data. Discussion/ assignment		2	3.0
Week 10	Specialty endpoints: neurotoxicity, developmental and reproductive toxicity, endocrine disruption. Assignment		2, 4	3.0
Week 11	Reporting the results. Assignment. Hazard communication: Globally Harmonized System of Hazard Communication (GHS), Prop 65, TSCA 8(e) notification, FIFRA 6a2 notification, FDA adverse effects notification, consumer product labelling. Assignment/practice quiz		3	3.0
Week 12	Exam II			N/A
Week 13	Testing of environmental species: environmental fate estimations and		2	3.0

Date	*Topic/Module/Unit*	*Location*	SLO # Above	*Instructional Hours*
	impacts. Discussion/assignment Testing of aquatic species: freshwater, marine, bioconcentration. Discussion/assignment			
Week 14	Testing of terrestrial species: earthworms, plants, avian. TSCA 8 (e) notification; EPA pesticide and consumer product labelling, GHS classifications. Discussion/assignment		2, 3, 4	3.0
Week 15	Exam III			N/A
		Total		36.0

Required Textbooks and/or Course Materials

- *Handbook of Toxicology*, Michael J. Derelenko, Carol S Auletta, eds. CRC Press, 2014, 3rd edition. ISBN number: 978-1-4398-9013-4
- OECD document ENV/JM/TG(2005)5/REV1 (available www.oecd.org/chemicalsafety), EPA *Methods for Aquatic Toxicity Identification Evaluations* EPA/600/6-9 l/003 (available www3.epa.gov/npdes/pubs), EPA *Hazard Evaluation: Wildlife and Aquatic Organisms,* EPA-540/9-82-024

Recommended Textbooks and/or Course Materials

- 21 CFR 58;
- 40 CFR 160;
- Title 40- Protection of Environment

- Guide for the Care and Use of Laboratory Animals, or The Guide (NRC 2011)
- Accreditation (Frequently Asked Questions)
- Animal Welfare Act
- https://www.orf.od.nih.gov/PoliciesAndGuidelines/BiomedicalandAnimalResearchFacilitiesDesignPoliciesandGuidelines/DRMHTMLver/Chapter2/Pages/Section2-4AnimalResearchFacilities.aspx
- Guidance for Industry and Other Stakeholders Toxicological Principles for the Safety Assessment of Food Ingredients
- Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food
- Guidance, Compliance & Regulatory Information (Biologics)
- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065014.htm
- Recent Final Medical Device Guidance Documents
- https://www.fda.gov/RegulatoryInformation/Guidances/ucm122050.htm
- Safety Guidelines
- OPPTS Combined Testing guidelines 870 (Recent Final Medical Device Guidance Documents)
- OECD Guidelines for the Testing of Chemicals, Section 4;
- The guidelines related to the study reports for the registration application of pesticide ;
- Chapter 4 Initial Assessment of Data

- Hazard Evaluation Division, Standard Evaluation Procedure: Toxicity Potential (Guidance for Analysis and Evaluation of Subchronic and Chronic Exposure Studies), 1986
- Ramaiah L, Tomlinson L, Tripathi NK, Cregar LC, Vitsky A, Beust BV, Barlow VG, Reagan WJ, Ennulat D. Principles for Assessing Adversity in Toxicologic Clinical Pathology. *Toxicol Pathol*. 2017 Feb;45(2):260-266
- Hall RL. Practical Considerations in Clinical Pathology Data Interpretation and Description. *Toxicol Pathol*. 2017 Feb;45(2):362-365
- Kerlin R, Bolon B, Burkhardt J, Francke S, Greaves P, Meador V, Popp J. Scientific and Regulatory Policy Committee: Recommended (''Best'') Practices for Determining, Communicating, and Using Adverse Effect Data from Nonclinical Studies. *Toxicologic P*athology 2016, Vol. 44(2) 147-162
- Guidance Documents on Substantial Risk Notifications under TSCA
- OSHA Hazard Communication Standard 29 CFR 1910.1200, and Appendix A

Methods of Evaluation

Grades will be calculated based on the following:

Activity	Total Points	Percentage of Final Grade
Homework Sets (12)	60	15%
Discussion (10)	40	10%
Midterm Exam I	100	25%
Midterm Exam II	100	25%
Final Exam	100	25%
	400	100%

Grading Scheme

Course grades will be assigned based on the following grading scheme. This grading scale is **final**.

Percent	Grade	Grade Points
90.0 - 100.0	A	4.00
87.0 - 89.9	A-	3.67
84.0 - 86.9	B+	3.33
81.0 – 83.9	B	3.00
78.0 - 80.9	B-	2.67
75.0 - 77.9	C+	2.33
72.0 – 74.9	C	2.00
69.0 - 71.9	C-	1.67
66.0 - 68.9	D+	1.33
63.0 - 65.9	D	1.00
60.0 - 62.9	D-	0.67
0 - 59.9	E	0.00

Course Policies

Attendance will not be required because the course is offered on-line. Work assignments given roughly every other week and are graded P/F (S/U). Assignments that are judged unsatisfactory (F) will be returned with comment for revision. All work assignments shall be completed; incomplete assignments (or revisions not completed) will decrease the overall total points by 5 points per assignment. Exams that are missed due to an excusable absence can be completed upon request. Participation in discussion topics is required. Attendance will be judged by submitting a response to topic questions.

Curriculum Policies

DVM curriculum policies are consistently held and reinforced across all DVM courses. Please visit the DVM webpage and review the curriculum policies listed within the Online Student Handbook.

Community Respect

The University of Florida College of Veterinary Medicine strives to cultivate an atmosphere of respect, empathy, and open-mindedness within an exceptional community of students, faculty, and staff. It is our intent that students from varied backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of this course, and that the viewpoint of students brought to this course be considered a resource, strength, and benefit.

We intend to present materials and activities that are respectful to all. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our course meetings conflict with any of your religious events or practices, an excused absence will be provided when requested using the standard UF CVM Absence Request Form process as detailed in the https://education.vetmed.ufl.edu/dvm-curriculum/absence-request/

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF CVM Student Mistreatment Report.

Students with Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center by visiting www.disability.ufl.edu/students/get-started. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester. **Students in UF Health Sciences programs should be mindful that unique course accommodations may not be applicable in a clinical, fieldwork or practicum setting. Thus, planning a semester in advance with the DRC Health Sciences Learning Specialist is highly encouraged.** Our learning specialist can be contacted at the following email address: DRC@ufsa.ufl.edu**.**

The DRC is located on the main UF campus. ASA (Office for Academic and Student Affairs) works closely with the DRC to ensure student accommodations are met in the classroom and during exams. Sabrina

Barot in ASA assists in coordinating exams and meeting recommended disability-related requirements for students with accommodations (sbarot@ufl.edu).

Course and Instructor Evaluation

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Student Use of Artificial Intelligence (AI)

When authorized by the course director, students may use AI technologies in the completion of coursework as long as they cite all such use by naming the technology and how it was employed. Students assume full responsibility for all content, including errors and omissions. Assistive technology authorized as part of an accommodation for a disability is always permitted.

Course instructors may adjust limitations on AI technology use and must communicate any limitations to students sufficiently in advance of the assignment due date. Failure to cite the use of AI technology or disregarding specific course limitations is considered academic misconduct. **The use of AI on assignments, essays/reflection papers, exams, and quizzes when prohibited by course or college instructions is considered cheating** and students are violating the UF Regulations 4.040 Student Honor Code and Student Conduct Code.

It is important to note that many generative AI models (e.g., ChatGPT, ChatSonic, Google Bard, etc.) place any information that they are provided with into the public domain. When using such tools, students must therefore ensure that the tools are **never provided with confidential information**. For the avoidance of doubt, the use of such tools is prohibited for generating any confidential communications, including, but not limited to, communications relating to patient records, clients, students, and intellectual property. Students are also reminded that they should always review the terms and conditions of any third-party software being used (e.g., proof reading tools) to ensure that any data the tools are provided with are appropriately protected. Students should always verify information and sources generated by AI tools. AI has inherent bias and has been known to generate false information and to cite non-existent sources. Also, because AI-generated text mines people's intellectual property without appropriate credit, this raises ethical concerns.

It is not acceptable for students to use generative AI for reflective writing, as by its very nature, the process of reflective writing demands that the individual actively engages in the writing process. Delegating this to a natural language processing algorithm may produce convincing outputs, but does not demonstrate development in an individual's professional practice.

Students are responsible for understanding their dynamic data stewardship responsibilities to minimize personal, college, and university risk.

UF Integrated Risk Management – CHATGPT Privacy, Factual Accuracy and Usage Guidelines

Appendix A: Faculty Lecturers

Name: Raymond David
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Name: Leah Stuchal
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Appendix B: Other Information