Chair: Tracy Christofero

GC#9: Non-Curricular

Request for Graduate Non-Curricular Changes

PLEASE USE THIS FORM FOR ALL NON-CURRICULAR CHANGE REQUESTS (changes in admission requirements or requirements for graduation, changes in existing or new policies/procedures, changes in program descriptions in catalog, general language changes in catalog).

SIGNATURES may not be required, depending on the nature of the request and from where it originates. Consult Graduate Council Chair.

- 1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.
- 2. E-mail one identical PDF copy to the Graduate Council Chair.

Eric Blough

College: SOP

3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

Dept/Division: SOP

v7301

Contact Person: LITC DIOUGH	Phone: A7 394
Rationale for Request:	
The school of pharmacy has recently reviewed the pre-requirentiations currently employ. This study suggested that many semester or 4 credit hours of physics with a laboratory for prour peer institutions we wish to reduce our current requirem semester (or 4 credit hours) of physics with lab.	y of our competitors only require one ogram entry. To remain competitive with
Signatures: if disapproved at any level, do not sign. Return to previous si NOTE: all requests may not require all signatures.	gner with recommendation attached.
Department/Division Chair	Fall 2018
Registrar My S	5/2010 Date 1-25-18
College Curriculum Committee Chair	Date 1 23 2018
Graduate Council Chair	Date
NOTE: please complete information required on the following pages before	ore obtaining signatures above.
Form updated 1/2017	Page 1 of 5

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Request for Graduate Non-Curricular Changes – Page 2

- 1. Current Catalog Description (if applicable): Please insert the catalog description from the current catalog for entries you would like to change.
- 1. Completed all required pre-pharmacy courses (note: inquiries regarding prerequisite course equivalency should be forwarded to MUSOP Student Affairs at 304-696-7354). These courses include:

English Composition6 credit hours or 2 semesters
Calculus5 credit hours or 1 semester
Statistics3 credit hours or 1 semester
Biology with Lab8 credit hours or 2 semesters
Chemistry with Lab10 credit hours or 2 semesters
Human Anatomy4 credit hours or 1 semester
Human Physiology4 credit hours or 1 semester
Microbiology4 credit hours or 1 semester
Organic Chemistry with Lab9 credit hours or 2 semesters,
Physics with Lab 8 credit hours or 2 semesters
Social Science elective credit hours or 1 semester

Request for Graduate Non-Curricular Changes - Page 3

 Edits to current description: Attach or insert a PDF copy of the current catalog description prepared in MS WORD with strikethroughs to mark proposed deletions and use the highlight function to indicate proposed new text.

1. Completed all required pre-pharmacy courses (note: inquiries regarding prerequisite course equivalency should be forwarded to MUSOP Student Affairs at 304-696-7354). These courses include:

English Composition......6 credit hours or 2 semesters

Calculus......5 credit hours or 1 semester

Statistics.....3 credit hours or 1 semester

Biology with Lab......8 credit hours or 2 semesters

Chemistry with Lab......10 credit hours or 2 semesters

Human Anatomy4 credit hours or 1 semester

Human Physiology.....4 credit hours or 1 semester

Microbiology4 credit hours or 1 semester

Organic Chemistry with Lab9 credit hours or 2 semesters.

Physics with Lab8 4 credit hours or 2 1 semesters

Social Science elective credit hours or 1 semester

	N.	(Q)

Request for Graduate Non-Curricular Changes - Page 4

- 3. **New Catalog Description**: Provide a "clean" copy of your proposed description without strikethroughs or highlighting. This should be what you are proposing for the new description.
- 1. Completed all required pre-pharmacy courses (note: inquiries regarding prerequisite course equivalency should be forwarded to MUSOP Student Affairs at 304-696-7354). These courses include:

English Composition	6 credit hours or 2 semesters
Calculus	5 credit hours or 1 semester
Statistics	3 credit hours or 1 semester
Biology with Lab	8 credit hours or 2 semesters
Chemistry with Lab	10 credit hours or 2 semesters
Human Anatomy	4 credit hours or 1 semester
Human Physiology	4 credit hours or 1 semester
Microbiology	4 credit hours or 1 semester
Organic Chemistry with Lab	9 credit hours or 2 semesters,
Physics with Lab	4 credit hours or 1 semesters
Social Science elective credit hou	ırs or 1 semester

Request for Graduate Non-Curricular Changes - Page 5

Please insert below your proposed change information for the Graduate Council agenda.

Type of change request: Pre-requisite requirements for entry into program

Department:

SOP

Degree program:

PharmD

Effective date (fall/spring/summer, year): Fall 2018

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Chair: Tracy Christofero

GC#6: Course Addition

Request for Graduate Course Addition

- Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.
 E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
- 3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

College: Pharmacy	Dept/Division:Pharmaceutical Scie	Alpha Designator/Number: MSPS 631
Contact Person: Faruk Kl	nan	Phone: 63094
NEW COURSE DATA:		
New Course Title:		
Alpha Designator/Numb	per: M S P S 6 3 1 5 3	2
Title Abbreviation: P	harm Regullat	ory Affairs
	(Limit of 25 characters and space	ces)
Course Catalog Descript (Limit of 30 words)	and organizations around the work Conference on Harmonization (ICH	on drug. Topics covered include pharmaceutical regulatory agencies d and their International Regulatory Audits for Pharma, International I) guidelines, Pharmacopoeias and national formulary, US Food and ory of USFDA Law and Regulation, GLP, MMP, NDA, and ANDA.
Co-requisite(s): None	First Term to be C	Offered: Fall 2018
Prerequisite(s): MSPS En	rollment Credit Hours: 3	
Course(s) being deleted	in place of this addition (must submit cou	urse deletion form): none
Signatures: if disapprove	d at any level, do not sign. Return to prev	vious signer with recommendation attached.
	Win Win	12 /22 /17

Dept. Chair/Division Head Faruk Khan	/2/22/17 Date
Registrar 5 1 2010	Date 1- 25-18
College Curriculum Chair	Date 1 / 12 2018
Graduate Council Chair	Date

532 College: Pharmacy Department/Division: DPSR Alpha Designator/Number: MSPS 63-1 Provide complete information regarding the new course addition for each topic listed below. Before routing this form, a complete syllabus also must be attached addressing the items listed on the first page of this form. 1. FACULTY: Identify by name the faculty in your department/division who may teach this course. Faruk Khan 2. DUPLICATION: If a question of possible duplication occurs, attach a copy of the correspondence sent to the appropriate department(s) describing the proposal. Enter "Not Applicable" if not applicable. Not Applicable 3. REQUIRED COURSE: If this course will be required by another department(s), identify it/them by name. Enter "Not Applicable" if not applicable. Not applicable 4. AGREEMENTS: If there are any agreements required to provide clinical experiences, attach the details and the signed agreement. Enter "Not Applicable" if not applicable. Not applicable 5. ADDITIONAL RESOURCE REQUIREMENTS: If your department requires additional faculty, equipment, or specialized materials to teach this course, attach an estimate of the time and money required to secure these items. (Note: Approval of this form does not imply approval for additional resources.) Enter "Not Applicable" if not applicable. Not applicable COURSE OBJECTIVES: (May be submitted as a separate document) See Attached Course Syllabus

7. COURSE OUTLINE (May be submitted as a separate document)
See Attached Course Syllabus
8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)
Will be developed based on the referred Book
9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)
Lecture, Active learning

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)
Exams, IRATs, GRATs, Presentations, Projects

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE None

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)
See Attached Course Syllabus

Page 4 of 5

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department: Course Number and Title:

Catalog Description:

Prerequisites:

First Term Offered:

Credit Hours:

Department: DPSR

532

Course Number and Title: MSPS-631; Pharmaceutical Regulatory Affairs

Catalog Description: An overview of USFDA's regulation on drug. Topics covered include pharmaceutical regulatory agencies and organizations around the world and their International Regulatory Audits for Pharma, International Conference on Harmonization (ICH) guidelines, Pharmacopoeias and national formulary, US Food and Drug Administration (USFDA): History of USFDA Law and Regulation, GLP, MMP, NDA, and ANDA.

Prerequisites: None

First Term Offered: Fall 2018

Credit Hours: 3



SYLLABUS Pharmaceutical Regulatory Affairs MSPS 531 (Fall 2018)

School of Pharmacy

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.

Course meeting days and time	TBA
Location	TBA
Team Leader / Instructor	M. O. Faruk Khan, Ph. D.
Office	CEB 209
Phone	304-696-3094
Email	khanmo@marshall.edu
Office hours	TBA

Faculty	Email	Office Phone		Office Hours /
			Number	Appointments accepted?
M. O. Faruk Khan, Ph. D.	khanmo@marshall.edu		304-696-3094	TBA

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

Course Description:

This course gives an overview of pharmaceuticals regulatory affairs, particularly USFDA's regulation on drug. Topics covered include pharmaceutical regulatory agencies and organizations around the world and their International Regulatory Audits for Pharma, International Conference on Harmonization (ICH) guidelines, Pharmacopoeias and national formulary, US Food and Drug Administration (USFDA): History of Food and Drug Regulation, USFDA Law and Regulation, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), USFDA Organizations and Responsibilities, New Drug Approval Process; Investigator new drug (IND) application, the new drug (NDA) application, Abbreviated New Drug Application (ANDA) and Effective Dossier Management.

Prerequisites: Enrolled in MSPS Program

Text Books/Other resources:

Required:

1. FDA Regulatory Affairs:

3rd Edition, Editor: David Mantus, Douglas J. Pisano, Publisher: CRC Press ISBN-13: 978-1841849195

2. Burger's Medicinal Chemistry and Drug Discovery,

9th Edition. Author: Donald J. Abraham, Ph.D.; Publisher: John Wiley and Sons, Inc, 1999-2014. ISBN: 9780471266945

Resource:

3. https://www.fda.gov/Drugs/default.htm

Course Objectives: Instructor added (5 to 7 total)

At the conclusion of this course the student should be able to:

Number	Objectives	How Assessed
1		Class participation/Exams/ IRAT/GRAT/ALEs
2	Apply the regulatory requirements to get a new drug approved by the FDA	Class participation/Exams/ IRAT/GRAT/ALEs
3	Explain the drug/device/biologic evaluation process including all phases of product development in clinical research	Class participation/Exams/ IRAT/GRAT/ALEs
4	Practice regulations involved in the investigation, production, labeling and distribution of drugs.	Class participation/Exams/ IRAT/GRAT/ALEs
5	Demonstrate the mastery in the essential knowledge and skills required to help pharmaceuticals companies on regulatory related issues.	Class participation/Exams/ IRAT/GRAT/ALEs

Example Schedule of Activities: (Each session is a two-hrs session.)

Instru ctor	Date & Session #	Торіс	Course Student Learning Outcomes
Khan	TBA	Introduction to Phar 531	Describe an overview on Pharmaceutical Regulatory Affairs
Khan	ТВА	FDA and Drug Development	 Explain different functions and roles of US FDA in drug approval processes Review the FDA drug development laws and policies Describe drug development process
Khan	TBA	Investigational New Drug (IND) Application - FDA	 Describe the content and format of IND application Explain IND Amendments Distinguish between different types of IND applications
Khan	TBA	The New Drug Application	 Review the content and format of NDA application (Module 1 -5 of CTD formats) Describe the processes related to submission and review of the NDA
Khan	TBA	EXAM 1	On above 4 class materials
Khan	TBA	Meeting with the FDA	 Explain different types of FDA meetings and meeting objectives Illustrate FDA expectations and preparations for FDA meetings
Khan	TBA	FDA Medical Device Regulation	 Classify medical devices Describe the medical device clinical research and their approval processes

Khan	TBA	A premier of	Describe Federal and States Laws
		Drug/Device Law	Debate the difference between regulation and law
			Devise different FDA guidelines
Khan	TBA	EXAM 2	On class 5-7 contents
Khan	TBA	ALE	Examine different examples of Regulatory Affairs
			on topics learned in the first 7 classes available
			online from the FDA site:
			https://www.fda.gov/Drugs/default.htmm
Khan	TBA	The Development of	Explain the Orphan Drug development process
		Orphan Drugs	Describe and analyze the Orphan Drug Act
			Illustrate the Orphan Drug Designation
Khan	TBA	Chemistry,	Differentiate between pharmaceutical API and
		Manufacturing, and	excipients
		Control	Explain stability study, quality assurance, quality
			control, product specification etc.
Khan	TBA	Good	• Explain and Differentiate between GLP, GMP, and
		Manufacturing/Laborator	GCP
		y Practices (GxPs)	Interpret and apply GxPs US Regulations
Khan	TBA	FDA Regulation of the	Revise FDA Regulation and general policies of the
		Advertisement and	Advertisement and Promotion of the prescription
		Promotion	drugs
			Develop plan of the Advertisement and Promotion
			of the prescription drugs
Khan	TBA	EXAM 3	On Classes 8-11
Khan	TBA	FDA Advisory	Investigate structure and composition of FDA
		Committees	Advisory Committees and their operation
Khan	TBA	Biologics	Evaluate FDA oversight and biologics development
			Investigate biologics approval process
Khan	TBA	Regulation of	Review the Regulation of Combination products
		Combination products in	Classify and assign combination products
		the US	and monghi combination products
Khan	TBA	EXAM 4	Classes 12-14
Khan	TBA	ALE	Examine different examples of Regulatory Affairs
			on topics learned in the last 7 classes available
7			online from the FDA site:
			https://www.fda.gov/Drugs/default.htmm
Khan	TBA	Project Report: The	Demonstrate the mastery in the essential
		students will work on	knowledge and skills required to help
		group project on their	pharmaceuticals companies on regulatory related
		assigned drug products to	issues.
		prepare a submission to	
		FDA for approval	

Course Evaluation (grading)

Point or Percentage Distribution:

IRATS/GRATS combined = 10%

^{*}Four block exams = 65% (Points based on # of sessions covered, 8 questions (16 points) per session)

^{*}Project report = 15% (will need 70% to pass course)

Active Learning Events/Assignments/Participation = 10%

*Signifies a major assessment

IRAT – Individual readiness assurance test

GRAT = Group readiness assurance test

Letter grades distribution:

A = 89.50 to 100%

B = 79.50 to less than 89.50%C = 69.50 to less than 79.50%

F = Less than 69.50%

Course Evaluation (assessment):

Student Evaluation:

Survey: each student will have the opportunity to evaluate each instructor as well as course content via the school's universal evaluation survey

Faculty Evaluation: Faculty members participating in the course will attend class as often as possible to evaluate overall performance

Assignment and examination grades will be posted in Blackboard within 7 days unless otherwise stated.

Attendance policy:

Each student is expected to attend class. Attendance at graded events is mandatory. Only University or school of pharmacy approved excuses will be accepted. The instructor must be contacted prior to the exam, unless circumstances are prohibitory. Please note that the student is solely responsible for any materials missed.

UNIVERSITY POLICIES:

University policies regarding Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.

SCHOOL OF PHARMACY POLICIES:

Social Justice Policy Statement

Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course; I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

Academic, Ethical, and Professional Conduct

Student expectations for academic, ethical, and professional conduct are defined within the school's <u>Ethical and Professional Conduct Policy</u> and the university's <u>Academic Dishonesty Policy</u>.

Test Security Policy

In order to ensure the security of all examinations, please refer to the MUSOP Secure Testing Policy. The policy can be found on the Marshall University School of Pharmacy website in section 400.003 <u>Secure Testing Environment Standards</u>.

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Chair: Tracy Christofero

Phone: 304-696-5003

Alpha Designator/Number: MSPS 512

GC#6: Course Addition

Request for Graduate Course Addition

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.

Dept/Division: Pharm Sci (DPSR)

- 2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
- 3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

NEW COURSE DATA:				
New Course Title: Medicinal Chemistry and Drug Discovery Principles				
Alpha Designator/Number: MSPS512				
Title Abbreviation: MedChem&DrugDisc				
Course Catalog Description: (Limit of 30 words) This course gives an overview of drug discovery principles and technic chemist.	ques for the practicing medicinal			
Co-requisite(s): First Term to be Offered: Fall 2018				
Prerequisite(s): Admission to MSPS program Credit Hours: 1				
Course(s) being deleted in place of this addition (must submit course deletion form):				
Signatures: if disapproved at any level, do not sign. Return to previous signer with recommendation	attached.			
Dept. Chair/Division HeadFaruk Khan	Date			
Registrar Strya & 512 010	Date 1/25/18			
College Curriculum Chair Date Date				
Graduate Council Chair	Date			

College: Pharmacy

Contact Person: V. Blair Journigan/Kim Broedel-Zaugg

College: Pharmacy	Department/Division: Pharm Sci (DPSR)	Alpha Designator/Number: MSPS 531
	g the new course addition for each topic listed below tems listed on the first page of this form.	. Before routing this form, a complete syllabus
1. FACULTY: Identify by name the facu	lty in your department/division who may teach this	course.
Blair Journigan, Ph.D.		
DUPLICATION: If a question of possil describing the proposal. Enter "Not A.	ble duplication occurs, attach a copy of the correspo A pplicable " if not applicable.	ondence sent to the appropriate department(s)
Not Applicable		
REQUIRED COURSE: If this course will applicable.	ll be required by another deparment(s), identify it/th	nem by name. Enter " Not Applicable " if not
Not Applicable		
4. AGREEMENTS: If there are any agree	ments required to provide clinical experiences, attac	ch the details and the signed agreement.
Enter " Not Applicable " if not applicated Not Applicable		J J
Постринали		
	ENTS: If your department requires additional faculty,	
approval for additional resources.) Ent	ime and money required to secure these items. (Not er " Not Applicable " if not applicable.	e: Approval of this form does not imply
Not applicable		
6. COURSE OBJECTIVES: (May be subr	nitted as a separate document)	
See attached syllabus		

Burger's Medicinal Chemistry and Drug Discovery, 9th Edition. Author: Donald J. Abraham; Publisher: John Wiley and Sons, Inc, 1999-2014. Online ISBN: 9780471266945 Comprehensive Organic Transformations: A Guide to Functional Group Preparations, 3rd Edition. Editor: Richard C. Larock; Publisher: John Wiley and Sons, Inc. March 2018. ISBN: 978-0-470-92795-3. Strategic Applications of Named Reactions in Organic Synthesis, 1st Edition. Authors: Laszlo Kurti, Barbara Czako. Publisher: Elsevier. March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164	7. COURSE OUTLINE (May be submitted as a separate document)
Burger's Medicinal Chemistry and Drug Discovery, 9th Edition. Author: Donald J. Abraham; Publisher: John Wiley and Sons, Inc, 1999-2014. Online ISBN: 9780471266945 Comprehensive Organic Transformations: A Guide to Functional Group Preparations, 3rd Edition. Editor: Richard C. Larock; Publisher: John Wiley and Sons, Inc. March 2018. ISBN: 978-0-470-92795-3. Strategic Applications of Named Reactions in Organic Synthesis, 1st Edition. Authors: Laszlo Kurti, Barbara Czako. Publisher: Elsevier. March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164 9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)	See attached syllabus
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Comprehensive Organic Transformations: A Guide to Functional Group Preparations, 3rd Edition. Editor: Richard C. Larock; Publisher: John Wiley and Sons, Inc. March 2018. ISBN: 978-0-470-92795-3. Strategic Applications of Named Reactions in Organic Synthesis, 1st Edition. Authors: Laszlo Kurti, Barbara Czako. Publisher: Elsevier. March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164 9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)	Burger's Medicinal Chemistry and Drug Discovery, 9th Edition. Author: Donald J. Abraham; Publisher: John Wiley and Sons, Inc,
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March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164 9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)	
Lecture, Computational Chemistry Laboratory, Pharmacology Laboratory	9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)
	Lecture, Computational Chemistry Laboratory, Pharmacology Laboratory

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)

Midterm and Final Exams

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE

N/A

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)

Handouts, Primary and Secondary Scientific Literature

Burger's Medicinal Chemistry and Drug Discovery, 9th Edition. Author: Donald J. Abraham, Ph.D.; Publisher: John Wiley and Sons, Inc, 1999-2014. Online ISBN: 9780471266945

Comprehensive Organic Transformations: A Guide to Functional Group Preparations, 3rd Edition. Editor: Richard C. Larock; Publisher: John Wiley and Sons, Inc. March 2018. ISBN: 978-0-470-92795-3.

Strategic Applications of Named Reactions in Organic Synthesis, 1st Edition. Authors: Laszlo Kurti, Barbara Czako. Publisher: Elsevier. March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:
Course Number and Title:
Catalog Description:
Prerequisites:
First Term Offered:
Credit Hours:

Department: Pharmaceutical Sciences and Research/School of Pharmacy

Course Number and Title: MSPS 512 Medicinal Chemistry and Drug Discovery Principles

Catalog Description: This course gives an overview of drug discovery principles and techniques for the practicing medicinal

chemist.

Prerequisites: Admission to MSPS Program

First Term Offered: Fall 2018

Credit Hours: 1

Form updated 10/2011 Page 5 of 5



SYLLABUS Medicinal Chemistry and Drug Discovery Principles MSPS 512 (Fall 2018)

School of Pharmacy

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. The School should notify the students through the course notification system or by an email preferably through the Blackboard system.

Course meeting days and time	
Location	L05
Team Leader / Instructor	Blair Journigan, Ph.D.
Office	Coon Education Building 232
Phone	(304) 696-5003
Email	journigan@marshall.edu
Office hours/Appointments accepted	By appointment

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to e-mails and phone messages within 72 hours.

Course Description: This course gives an overview of drug discovery principles and techniques for the practicing medicinal chemist. Concepts include an overview of therapeutic structures pursued in the field, and drug discovery strategies for hit identification, hit to lead generation and preclinical lead optimization. Synthetic approaches and commonly used organic methodologies will be covered, along with structural characterization techniques. Further topics include hands-on learning exercises in computational drug discovery and pharmacology. Topics will be illuminated with small molecule and biologic preclinical and clinical candidates, well-represented in the scientific and patent literature, where applicable.

Prerequisites: Admission to MSPS program

Required Textbooks:

Burger's Medicinal Chemistry and Drug Discovery, 9th Edition. Author: Donald J. Abraham; Publisher: John Wiley and Sons, Inc, 1999-2014. Online ISBN: 9780471266945. *Note: Link to all volumes provided on Blackboard (register for access online)*.

Strategic Applications of Named Reactions in Organic Synthesis, 1st Edition. Authors: Laszlo Kurti, Barbara Czako. Publisher: Elsevier. March 2005. Paperback ISBN: 9780124297852. eBook ISBN: 9780080919164

Recommended Textbooks:

Comprehensive Organic Transformations: A Guide to Functional Group Preparations, 3rd Edition. Editor: Richard C. Larock; Publisher: John Wiley and Sons, Inc. March 2018. ISBN: 978-0-470-92795-3.

Software Required:

Scifinder Scholar: http://libguides.marshall.edu/c.php?g=343334&p=2312555

AutoDock 4 and AutoDock Vina: http://autodock.scripps.edu/

PyMOL: https://www.pymol.org/

Graphpad Prism:

Course Objectives:

Apply medicinal chemistry strategies used in various stages of the early drug discovery process, including hit identification techniques, hit to lead generation, and preclinical lead optimization.

Apply synthetic medicinal chemistry/organic chemistry approaches to the accession and characterization of biologically active small molecules and biologics, including peptides.

Tentative Schedule of Activities*:

	Tentative Schedule of Activities*:			
Date	#	Meeting Topic	Learning Outcomes	
Week 5	1	Therapeutic molecules	 Overview of various therapeutic molecules pursued as drug structures and their origins: small molecules, natural products, oligomers, peptidomimetics, biologics Interpreting biological activity: <i>In vitro</i> binding and functional assays: target engagement and selectivity, <i>In vivo</i> assays 	
Week 6	2	Early drug discovery strategies for hit identification	•Structure-based drug design: x-ray crystal structures and homology models, mutagenesis studies, docking, virtual screening, and computational chemistry principles and theories	
Week 7	3	Early drug discovery strategies for hit identification	 Ligand- and fragment- based drug design, the concept of privileged structures Screening approaches: High throughput screening, combinatorial library design, NMR-based screening 	
Week 8	4	Synthetic approaches and reactions: organic chemistry	 Approaches for synthesis of various chemotypes: retrosynthesis, total synthesis, analog synthesis from common synthons Reactions most utilized in medicinal chemistry, including mechanisms: reductions, oxidations, protections/deprotections, functional group interconversion, functional group addition 	
Week 9	5	Synthetic reactions and database searching: organic chemistry	•Reactions most utilized in medicinal chemistry, including mechanisms (cont): heteroatom alkylation and arylation, acylation and related processes, C-C bond formation, heterocycle formation •Introduction to Scifinder Scholar: Structure and reaction searching in publications and patents, text-based searches	
Midterm (Lectures 1-5)				
Week 10	6	Structural characterization: organic chemistry	•Structural characterization methods: Principles of Chromatography, Mass Spectrometry, and Nuclear Magnetic Resonance Spectroscopy and data interpretation	

^{*}All software is free to academics and educational-based activities

Week 11	7	Hit to lead generation: understanding the early drug discovery process	•Structure-activity relationship (SAR) studies •Mining the SAR results: 2D and 3D pharmacophores, docked and crystallized structures within the active site, the concept of ligand efficiency
Week 12	8	ADMET Profiling and Lead Optimization	 ADMET (Absorption, Distribution, Metabolism, Excretion, Toxicity) in vitro profiling: microsomal stability, plasma protein binding, hERG liabilities, P-gp efflux Physicochemical properties for oral bioavailability: molecular weight, pKa, log D, Hydrogen bond acceptors/donors, Modifications to Lipinski's Rule of 5 Additional physicochemical considerations for CNS penetration: topological polar surface area (TPSA) Lead optimization strategies: Bioisosteric replacement, chiral centers, designing out P-gp and hERG liabilities
Week 13	9	Computational drug design laboratory	Docking small molecules into the active site of a receptor with AutoDock 4 and AutoDock Vina, Visualization with PyMOL
Week 14	10	Drug discovery laboratory Guest Lecturer: Dr. Jinsong Hao	•Calculation of K _i and EC ₅₀ with Graphpad Prism
Final Exam (Comprehensive)			

Course Evaluation (grading):

Mid-term exam (paper-based): 50% Final Exam (paper-based): 50%

Final Exam (paper-based): Total:

100%

Letter grades distribution:

A = 89.50 to 100%

B = 79.50 to less than 89.50%

C = 69.50 to less than 79.50%

F = Less than 69.50%

Course Evaluation (grading): Grading for this course consists of both the mid-term and final exam, each worth 50%. Conceptual understanding of the material will be assessed at a higher level than that assessed at the Pharm D. level, in line with the expectations of the Master's program and Marshall University Graduate College.

Course Evaluation (assessment): At or near the end of the course, students are expected to complete an evaluation of the course content, learning approaches, student assessment and instructors according to School of Pharmacy procedures.

Assignment and examination grades will be posted in Blackboard within <u>7 business days</u> unless otherwise stated.

Attendance policy: Each student is expected to attend class. Attendance at graded events is mandatory. Only excused absences accepted – see university and school policies. The instructor must be contacted prior to the exam, unless circumstances are prohibitory. Please note – the student is solely responsible for any materials missed.

UNIVERSITY POLICIES

University policies regarding Grades, Probation and Dismissal, Responsible Conduct of Research and other topics can be found at http://www.marshall.edu/graduate/graduate-student-handbook/

University policies regarding Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.

School of Pharmacy Policies

SOCIAL JUSTICE POLICY STATEMENT

Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course, I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

ACADEMIC, ETHICAL, AND PROFESSIONAL CONDUCT

Student expectorations for academic, ethical, and professional conduct are defined within the school's Ethical and Professional Conduct Policy and the university's Academic Dishonesty Policy.

Test Security Policy

Refer to the following link for MUSOP's secure testing policies.

http://www.marshall.edu/pharmacy/faculty_staff/faculty-and-staff-policies/400-003-secure-testing-environment-standards/

Chair: Tracy Christofero

Phone: 304.696.7363

Alpha Designator/Number: MSPS 513

GC#6: Course Addition

Request for Graduate Course Addition

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.

Dept/Division:Pharm Sci & Res

- 2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
- 3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

New Course Title: Biopharmaceutics 2				
Alpha Designator/Number: M S P S 5 1 3				
Title Abbreviation: B I O P H A R M 2 (Limit of 25 characters and spaces)				
Course Catalog Description: (Limit of 30 words) Topics include mechanisms immediate and sustained drug release in formulations; novel drug delivery systems; drug pre-formulation; the drug approval process; drug preparation, liberation, absorption and stability of dosage forms.				
Co-requisite(s): N/A First Term to be Offered: SPRING 2019	_			
Prerequisite(s): BIOPHARMACEUTICS 1 Credit Hours: 1				
Course(s) being deleted in place of this addition (must submit course deletion form): NOT APPLICABLE				
Signatures: if disapproved at any level, do not sign. Return to previous signer with recommendation attached.				
Dept. Chair/Division Head Date				
Registrar Songe All Date 1: 25-16 College Curriculum Chair New 1 and Date 1/12/2011				
College Curriculum Chair Date Date				
Graduate Council Chair	Date			

College: Pharmacy

NEW COURSE DATA:

Contact Person: Cynthia B. Jones

College: School of Pharmacy	Department/Division: Pharm Sci & Research	Alpha Designator/Number: MSPS 542
	g the new course addition for each topic listed below tems listed on the first page of this form.	v. Before routing this form, a complete syllabus
1. FACULTY: Identify by name the facu	lty in your department/division who may teach this	course.
Cynthia B. Jones, Ph.D. Jinsong Hao, Ph.D. Brian Train, Ph.D.		
DUPLICATION: If a question of possi describing the proposal. Enter "Not a Not Applicable	ble duplication occurs, attach a copy of the correspo A pplicable " if not applicable.	ondence sent to the appropriate department(s)
3. REQUIRED COURSE: If this course wi applicable. Not Applicable	ll be required by another deparment(s), identify it/tl	hem by name. Enter " Not Applicable " if not
4. AGREEMENTS: If there are any agree Enter " Not Applicable " if not applica Not Applicable	ements required to provide clinical experiences, atta able.	ch the details and the signed agreement.
	ENTS: If your department requires additional faculty ime and money required to secure these items. (No er " Not Applicable " if not applicable.	
6. COURSE OBJECTIVES: (May be subr	nitted as a separate document)	
3. Describe, compare and contrast the	ations and the drug approval process nnological advances in pre-formulation and drug de e mechanisms of modified release in solid and semis preparation, liberation, absorption and stability of va	solid formulations

7. COURSE OUTLINE (May be submitted as a separate document)
See Syllabus
8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)
Martin's Physical Pharmacy & Pharmaceutical Sciences
Editors: Patrick J. Sinko & Yashveer Singh ISBN 978-0-7817-9766-5
9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)
Lab Lectures and in-class activities will be used throughout the semester.

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)

Student mastery of the material will be evaluated by quizzes and exams administered throughout the semester.

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE Not Applicable

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)

Not Applicable

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:
Course Number and Title:
Catalog Description:
Prerequisites:
First Term Offered:
Credit Hours:

Department: Pharmaceutical Sciences and Research

Course Number and Title: MSPS 542 Biopharmaceutics 2

Catalog Description: Topics covered include mechanisms of both immediate and sustained drug release in formulations involving solid and semi-solid systems; introduction to novel drug delivery systems; drug pre-formulation; the drug approval process, and regulations governing the pharmaceutical industry; drug preparation, liberation, absorption and stability of dosage forms.

Prerequisites: Biopharmaceutics 1

First Term Offered: Spring 2019

Credit Hours: 1

	5.	



www.marshall.edu

School of Pharmacy

SYLLABUS Biopharmaceutics II MSPS 513 (Spring 2019)

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.

Course meeting days and time	TBD
Location	TBD
Team Leader / Instructor	Cynthia B. Jones, Ph.D.
Office	MEB 228A/230
Phone	(304) 696-7363
Email	Jonescy@marshall.edu
Office hours	Tuesday and Thursday 12:30 p.m 1:30 p.m. and by appointment

Faculty	Email	Office	Phone	Office Hours /
			Number	Appointments
Cynthia B. Jones, Ph.D.	Jonescy@marshall.edu	228A	(304)696-7363	Tue & Thurs. 12:30 to 1:30
				p.m. or by appointment

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

Course Description: Topics covered include mechanisms of both immediate and sustained drug release in formulations involving solid and semi-solid systems; introduction to novel drug delivery systems; drug preformulation; the drug approval process, and regulations governing the pharmaceutical industry; drug preparation, liberation, absorption and stability of dosage forms.

Prerequisites: None

Text Book(s)

Required:

Martin's Physical Pharmacy & Pharmaceutical Sciences

Editors: Patrick J. Sinko & Yashveer Singh

ISBN 978-0-7817-9766-5

Recommended:

None

Materials:

Required

Course Objectives

Number	Objective	How Assessed
1	Understand the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements	Quizzes and Exams
2	Examine and interpret technological advances in research approaches for pre-formulation and drug delivery systems	Quizzes and Exams
3	Identify and describe formulation methods for modified release in solid and semisolid formulations	Quizzes and Exams
4	Explain, devise and evaluate stability-testing protocols of various dosage forms	Quizzes and Exams

Schedule of A Week	Netivities: Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
Week 1	Lab Lecture	Biopharmaceutics (Molecular & Cellular)	 Describe drug transport Construct plasma concentration v/s time curve 	Dr. Jones
Week 2	Lab Lecture	Biopharmaceutics (Organ Level)	Calculate pharmacokinetic parameters related to organ level biopharmaceutics	Dr. Jones
Week 3	Lab Lecture	Solubility & Distribution	Describe the influence of solvents and surfactants on solubility	Dr. Jones
Week 4	Lab Lecture	Diffusion	Define and calculate concept of Fick's First and Second Law of Diffusion	Dr. Jones
Week 5	Lab Lecture	Drug Release and Dissolution	Design drug release delivery systems	Dr. Jones
Week 6	Lab Lecture	Chemical Kinetics & Stability	Model reaction rate, reaction order and molecularity	Dr. Jones
Week 7	Lab Lecture	Colloidal Dispersions	Develop a modern colloidal drug delivery system	Dr. Jones
Week 8	Lab Lecture	Coarse Dispersions	Develop a pharmaceutical suspension and discuss the desirable qualities of pharmaceutical suspensions	Dr. Jones

1		*Midterm Exa	m		
Week 9	Lab Lecture	Rheology	•	Model Newtonian and Non-Newtonian systems	Dr. Jones
Week 10	Lab Lecture	Micromeritics	•	Describe and identify derived properties of powders and develop a novel formulation using micromeritics	Dr. Jones
Week 11	Lab Lecture	Oral Solid Dosage Forms	•	Apply basic physicochemical properties to active pharmaceutical ingredients Design oral dosage form performance test to ensure product quality and performance	Dr. Jones
Week 12	Lab Lecture	Routes of Delivery		Design a formulation for specific sites of drug absorption for each route	Dr. Jones
Week 13	Lab Lecture	Drug Delivery Systems	•	Design a drug delivery system designed for specific routes of administration	Dr. Jones
Week 14	Lab Lecture	Polymers		Develop a formulation using three types of polymers used in pharmaceutical preparations	Dr. Jones
Week 15	Lab Lecture	Biotechnology		Develop strategy to produce stable formulations of peptides, proteins, nucleic acids and viruses	Dr. Jones
Week 16	Lab Lecture	Targeted Drug Delivery	•	Create a prodrug approach for a chronic disease and list its benefit in drug delivery	Dr. Jones
		*Final Exam			

* indicates major assessment

Course Evaluation (grading): Student mastery of the material will be evaluated by quizzes and exams administered throughout the semester. The majority of testable material will originate from instructor-provided handouts (≥80%). The remaining testable material will be presented during class sessions. In-class activities will assess student understanding of the material and will be graded based on completeness and accuracy.

Point or Percentage Distribution: Quizzes: 10%

Midterm Exam: 40%

Final Exam: 50%

Letter grades distribution: A = 89.50 to 100%

B = 79.50 to less than 89.50% C = 69.50 to less than 79.50% D = 59.50 to less than 69.50%

F = Less than 59.50%

Course Evaluation (assessment): At or near the end of the course, students are expected to complete an evaluation of the course content, learning approaches, student assessment and instructors according to School of Pharmacy procedures.

Assignment and examination grades will be posted in Blackboard within 7 days unless otherwise stated.

Attendance policy: Each student is required to attend class. Attendance is mandatory at graded events. Only excused absences accepted – see university and school policies.

UNIVERSITY POLICIES

University policies regarding Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.

School of Pharmacy Policies

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Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course, I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

ACADEMIC, ETHICAL, AND PROFESSIONAL CONDUCT

Student expectorations for academic, ethical, and professional conduct are defined within the school's <u>Ethical</u> and <u>Professional Conduct Policy</u> and the university's <u>Academic Dishonesty Policy</u>.

Chair: Tracy Christofero

Alpha Designator/Number: MSPS 514

GC#6: Course Addition

Request for Graduate Course Addition

1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.

Dept/Division:Pharmaceutical Scient

- 2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
- 3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

Contact Person: Brain Train, Ph	Phone: (304)696-5807		
NEW COURSE DATA:			
New Course Title: Responsible	e Conduct of Research		
Alpha Designator/Number:	M S P S 5 1 4	, t	
Title Abbreviation: R E S	B CONDUCT RE	SEARCH	
	(Limit of 25 characters and spaces)		
(Limit of 30 words)	ethical issues that will arise through the co students understand how to conduct ethic	pharmaceutical sciences become familiar with the general burse of basic science research. This course will help graduate cal research, identify and focus on unethical situations in al dilemmas that may arise in the workplace	
Co-requisite(s): None	First Term to be Offered:	Fall 2018	
Prerequisite(s): None	Credit Hours: 1		
Course(s) being deleted in pla	ce of this addition (must submit course dele	tion form): Not Applicable	
Signatures: if disapproved at a	ny level, do not sign. Return to previous sig	gner with recommendation attached.	
Dept. Chair/Division Head	Allian	Date 1/13/2018	
Registrar Songe	y_	512010 Date 1-25-18	
ollege Curriculum Chair Lewyrnson Date 1/12/2018			
Graduate Council Chair		Date	

College: Pharmacy

College: School of Pharmacy	Department/Division: Pharmaceutical Science	Alpha Designator/Number: MSPS 514
	rding the new course addition for each topic listed below he items listed on the first page of this form.	w. Before routing this form, a complete syllabus
1. FACULTY: Identify by name the	faculty in your department/division who may teach this	s course.
Brian Train, Ph.D.		
	ossible duplication occurs, attach a copy of the corresp Not Applicable " if not applicable.	ondence sent to the appropriate department(s)
3. REQUIRED COURSE: If this cours applicable.	e will be required by another deparment(s), identify it/t	them by name. Enter " Not Applicable " if not
Not Applicable		
4. AGREEMENTS: If there are any agenter " Not Applicable " if not ap	greements required to provide clinical experiences, atta blicable.	ach the details and the signed agreement.
Not Applicable		
this course, attach an estimate of t	REMENTS: If your department requires additional facult the time and money required to secure these items. (No Enter " Not Applicable " if not applicable.	
6. COURSE OBJECTIVES: (May be	submitted as a separate document)	
2- Understand the best practices	ar with the best practices in experimental research and and rules for intellectual property and who owns data if	-

Form updated 10/2011 Page 2 of 5

7. COURSE OUTLINE (May be submitted as a separate document)
See Syllabus
8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)
No text books are required.
9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)
Lectures, videos, Online modules from NIH

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)
quizzes, active learning exercises and exams
11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE
Not Applicable

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)

Form updated 10/2011 Page 4 of 5

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:
Course Number and Title:
Catalog Description:
Prerequisites:
First Term Offered:
Credit Hours:

Department: Department of Pharmaceutical Sciences and Research

Course Number and Title: MSPS 514, Responsible Conduct of Research

Catalog Description: This course will help graduate students in pharmaceutical sciences become familiar with the general ethical issues that will arise through the course of basic science research. This course will help graduate students understand how to conduct ethical research, identify and focus on unethical situations in research, and how to solve future unethical dilemmas that may arise in the workplace.

Prerequisites: None

First Term Offered: Fall 2018

Credit Hours: 1



SYLLABUS
Responsible Conduct of Research
MSPS 514
(Fall 2018)

School of Pharmacy

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.

Course meeting days and time	TBA
Location	TBA
Team Leader / Instructor	Brian C. Train
Office	CEB 235
Phone	(304) 696-5807
Email	trainb@marshall.edu
Office hours	TBA

Faculty	Email	Office	Phone Number	Office Hours / Appointments accepted?
TBD				

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

Course Description: This course will help graduate students in pharmaceutical sciences become familiar with the general ethical issues that will arise through the course of basic science research. This course will help graduate students understand how to conduct ethical research, identify and focus on unethical situations in research, and how to solve future unethical dilemmas that may arise in the workplace.

Prerequisites: None

Text Books:

Required: TBD

Course Objectives: Instructor added (5 to 7 total)

Number	Objective	How Assessed
1	Understand and become familiar with the best practices in experimental	Quizzes, ALEs
	research and design	Reflection
		Papers, Group
		Presentation
2	Understand the best practices and rules for intellectual property and who owns	Quizzes, ALEs
	data in an academic setting	Reflection
		Papers, Group
		Presentation
3	Understand the best practices for research using human and animal participants	Quizzes, ALEs
		Reflection
		Papers, Group
		Presentation

Example Schedule of Activities:

Date Week of	Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
Week 1	Overview Discussion & ALE	Course overview and expectations	 Become familiar with the course design and syllabus 	TBD
Week 2	Overview Discussion & ALE	Research and Experimental Design	Become familiar with best practices of conducting research and proper experimental design	TBD
Week 3	Overview Discussion & ALE	Authorship	 Become familiar with ethical dilemmas in assigning authorship in research publications 	TBD
Week 4	Overview Discussion & ALE	Intellectual Property	Become familiar with the ethical dilemmas with ownership of data and intellectual property	TBD
Week 5	Overview Discussion & ALE	Data Management	Become familiar with the best practices for management of research data	TBD

Week 6	Overview Discussion & ALE	Human Subjects Research	 Become familiar with the best practices for conducting research involving human subjects Appreciate the ethical dilemmas that may arise during research involving human subjects 	TBD
Week 7	Overview Discussion & ALE	Research Misconduct	 Become familiar with best practices for handling research misconduct Learn from case examples of previous research misconduct to prevent and handle misconduct in the workplace 	TBD
Week 8	Overview Discussion & ALE	Mentorship and Conflicts of Interest		TBD
Week 9	Overview Discussion & ALE	Animal Subjects Research	 Understand the best practices for conducting research using animal subjects Understand the best practices for proper handling and care of animal subjects in research 	TBD
Week 10	Overview Discussion & ALE	Peer Review and Collaboration	• Understand the best practices for (?)	TBD

Week 11	Overview Discussion & ALE	Current Ethical Issues in Research	 Become familiar with current ethical issues in academic laboratories and in the pharmaceutical industry 	TBD
Week 12	Overview Discussion & ALE	TBD		TBD
Week 13	Overview Discussion & ALE	TBD		TBD

Course Evaluation (assessment):

At or near the end of the course, students are expected to complete an evaluation of the course content, learning approaches, student assessment and instructors according to School of Pharmacy procedures.

Course Evaluation (grading):

Point or Percentage Distribution:

Quizzes	25%
ALEs	10%
Reflection Papers	40%
Group Presentation	25%

Letter grades distribution: A = 89.50 to 100%

B = 79.50 to less than 89.50%C = 69.50 to less than 79.50%

F = Less than 69.50%

Assignment grades will be posted in Blackboard within 7 days unless otherwise stated.

Attendance policy: Each student is required to attend class. Attendance is mandatory at graded events. Only excused absences accepted – see university and school policies.

UNIVERSITY POLICIES

University policies regarding Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.

School of Pharmacy Policies

SOCIAL JUSTICE POLICY STATEMENT

Marshall University is committed to bringing about mutual understanding and respect among all individuals and groups at the University. As part of Marshall University, School of Pharmacy has made a commitment to social justice. Therefore, no one will be discriminated against on the basis of race, gender, ethnicity, age, sexual orientation, religion, social class, or differing viewpoints. Each student will be viewed as a valuable member of this class and as the faculty for the course, I will strive to facilitate an atmosphere/learning environment where mutual understanding and respect are actualized.

ACADEMIC, ETHICAL, AND PROFESSIONAL CONDUCT

Student expectorations for academic, ethical, and professional conduct are defined within the school's <u>Ethical and Professional Conduct Policy</u> and the university's <u>Academic Dishonesty Policy</u>.

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Chair: Tracy Christofero

GC#6: Course Addition

Request for Graduate Course Addition

- 1. Prepare one paper copy with all signatures and supporting material and forward to the Graduate Council Chair.

 2. E-mail one identical PDF copy to the Graduate Council Chair. If attachments included, please merge into a single file.
- 3. The Graduate Council cannot process this application until it has received both the PDF copy and the signed hard copy.

College: Pharmacy	Dept/Division:Pharmaceutical Scien	Alpha Designator/Number: MSPS54	Graded (** CR/NC
Contact Person: ARM Ruhul A	min	Phone: 3	304-696-7371
NEW COURSE DATA:			
New Course Title: Graduate F	Research Seminar		
Alpha Designator/Number:	M S P S 5 4 2		es.
Title Abbreviation: S c i	e n c e S e m i n (Limit of 25 characters and space	a r s es)	
Course Catalog Description: (Limit of 30 words)	This course will help graduate stude communication and how to critically of this course for credit. For the first "NC" (no credit). Upon completion o	y evaluate scientific literatures. Stu three course offerings, the studen	idents must complete four versions
Co-requisite(s): None	First Term to be Of	ffered: Fall 2018	_
Prerequisite(s): Enrolled in M	SPS program Credit Hours: 04		
Course(s) being deleted in pla	ace of this addition (must submit cour.	se deletion form): N/A	
Signatures: if disapproved at a	any level, do not sign. Return to previ	ous signer with recommendation	attached.
Dept. Chair/Division Head	Jelju-		Date 1/23/2018
Registrar My	DCe	512010	Date 1-25-18
College Curriculum Chair	Henzinson		Date 1 2 3 2018
Graduate Council Chair			Date

College: Pharmacy	Department/Division: Pharmaceutical Sciences and Alpha Designator/Number: PHAR542
Provide complete information also must be attached address	regarding the new course addition for each topic listed below. Before routing this form, a complete syllabus ing the items listed on the first page of this form.
1. FACULTY: Identify by name	the faculty in your department/division who may teach this course.
Dr. A.R.M. Ruhul Amin Dr. Omar Faruk Khan Dr. Eric Blough Dr. Cynthia Jones Dr. Tim Long	
	of possible duplication occurs, attach a copy of the correspondence sent to the appropriate department(s) ter " <i>Not Applicable</i> " if not applicable.
Not applicable	
3. REQUIRED COURSE: If this c applicable.	ourse will be required by another deparment(s), identify it/them by name. Enter " <i>Not Applicable</i> " if not
Not applicable	
4. AGREEMENTS: If there are a Enter " <i>Not Applicable</i> " if no	ny agreements required to provide clinical experiences, attach the details and the signed agreement. It applicable.
Not applicable	
this course, attach an estimate	QUIREMENTS: If your department requires additional faculty, equipment, or specialized materials to teach e of the time and money required to secure these items. (Note: Approval of this form does not imply rees.) Enter "Not Applicable" if not applicable.
6. COURSE OBJECTIVES: (May	be submitted as a separate document)
Please see the attached syllal	ous
	to the second se

7. COURSE OUTLINE (May be submitted as a separate document)
Please see the attached syllabus
8. SAMPLE TEXT(S) WITH AUTHOR(S) AND PUBLICATION DATES (May be submitted as a separate document)
Not Applicable
9. EXAMPLE OF INSTRUCTIONAL METHODS (Lecture, lab, internship)
Presentation and Discussion

10. EXAMPLE EVALUATION METHODS (CHAPTER, MIDTERM, FINAL, PROJECTS, ETC.)
In class evaluation based on developed rubric

11. ADDITIONAL GRADUATE REQUIREMENTS IF LISTED AS AN UNDERGRADUATE/GRADUATE COURSE Students must complete all four versions of the seminar as partial fulfillment of the degree requirement.

12. PROVIDE COMPLETE BIBLIOGRAPHY (May be submitted as a separate document)
Not Applicable

Please insert in the text box below your course summary information for the Graduate Council agenda. Please enter the information exactly in this way (including headings):

Department:

Course Number and Title:

Catalog Description:

Prerequisites:

First Term Offered:

Credit Hours:

Department: Pharmaceutical Science and Research

Course Number and Title: MSPS542, Graduate Sciences Seminar

Catalog Description: This course will help graduate students in the pharmaceutical sciences learn the basics of scientific communication and how to critically evaluate scientific literatures. Students must complete four versions of this course for credit. For the first three course offerings, the student will receive a "CR" (credit) or "NC" (no credit). Upon completion of the fourth version of the course the student will receive a letter grade. Completion of four course series is worth four credits and is required to successfully complete the MSPS program

Prerequisites: Enrollment in MSPS program

First Term Offered: Fall 2018

Credit Hours: 04

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SYLLABUS Graduate Research Seminar MSPS 542 Fall 2018

School of Pharmacy

This syllabus is not to be construed as a contract with the student and is subject to change.

The School of Pharmacy reserves the right to change the course syllabus. *The School should notify the students through the course notification system or by an email preferably through the Blackboard system.*

Materials used in this class may be copyrighted and should not be shared with individuals not enrolled in this course.

Course meeting days and time	TBA
Location	TBA
Team Leader / Instructor	A.R.M. Ruhul Amin, Ph. D.
Office	CEB 235A
Phone	(304)696-7371
Email	amina@marshall.edu
Office hours	TBA

Faculty	Email	Office	Phone	Office Hours /
			Number	Appointments accepted?
A.R.M. Ruhul Amin, Ph. D.	amina@marshall.edu	235A	(304)696-7371	TBA

Student: If the instructor accepts appointments, then please email the instructor for availability. The student can expect the instructor to respond to E-mails and phone messages within 72 hours.

Course Description: This course will help graduate students in the pharmaceutical sciences learn the basics of scientific communication and how to critically evaluate scientific literatures. Students must complete four versions of this course for credit. For the first three course offerings, the student will receive a "CR" (credit) or "NC" (no credit). Upon completion of the fourth version of the course the student will receive a letter grade. Completion of four course series is worth four credits and is required to successfully complete the MSPS program.

Prerequisites: None

Text Books:

Required: None

Course Objectives:

Number	Objective	How Assessed
1	Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research	Evaluations
2	Demonstrate the ability to critically evaluate research presented in a peer- reviewed article or in any other format	Class participation
3	Demonstrate the ability to prepare clear, concise written critiques	Class Participation

Course Activities:

In order to become proficient at delivering different types of common scientific presentations, students will be required to deliver presentations in each of the following formats:

- 1. Group Discussion/Journal club: An article will be selected based on one of the concepts taught in the class. Students will critically discuss the article. One student will lead the group discussion and this will rotate. MA students are required to complete two (2) presentations of this type while MS students are required to complete one (1) presentation of this type before finishing the course.
- 2. Student Presentation/progress report: Students will report their research progress or research proposal. Each student must present two of these talks. Each student is required to complete two (2) presentations of this type before finishing the course.
- 3. Thesis defense: MS students will defend their thesis. Each MS student is required to complete one (1) presentation of this type before finishing the course.

Example Schedule of Activities:

Date Week of	Meeting Format	Meeting Topic	Course Student Learning Outcomes	Instructor
Week 1	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Jones/Amin
Week 2	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. 	Dr. Amin

			3. Demonstrate the ability to prepare clear and concise written critiques.	
Week 3	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 4	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 5	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 6	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 7	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to 	Dr. Amin

			anitiaally avaluate mass	
			critically evaluate research	
			presented in a peer-reviewed	
			article or in any other format.	
			3. Demonstrate the ability to prepare	
XX 1 0		TDD.	clear and concise written critiques.	
Week 8	Seminar	TBD	1. Demonstrate the ability to present	Dr. Amin
			scientific material of a peer-	
			reviewed research article or	
			his/her own research.	
			2. Demonstrate the ability to	
			critically evaluate research	
			presented in a peer-reviewed	
			article or in any other format.	ra "
			3. Demonstrate the ability to prepare	
			clear and concise written critiques.	
Week 9	Seminar	TBD	1. Demonstrate the ability to present	Dr. Amin
			scientific material of a peer-	
			reviewed research article or	
			his/her own research.	
			2. Demonstrate the ability to	
16			critically evaluate research	
			presented in a peer-reviewed	
			article or in any other format.	
			3. Demonstrate the ability to prepare	
			clear and concise written	
			critiques.	
Week 10	Seminar	TBD	1. Demonstrate the ability to present	Dr. Amin
Week 10	Sommar	TDD	scientific material of a peer-	D1. 7 mmm
			reviewed research article or	
			his/her own research.	
			2. Demonstrate the ability to	
			critically evaluate research	
			presented in a peer-reviewed	
			article or in any other format.	
-			3. Demonstrate the ability to prepare	
			1	
			clear and concise written	
Week 11	Cominan	TBD	critiques.	Du Amin
Week II	Seminar	עפו	1. Demonstrate the ability to present	Dr. Allilli
			scientific material of a peer-	
			reviewed research article or	
			his/her own research.	
			2. Demonstrate the ability to	
			critically evaluate research	
			presented in a peer-reviewed	
		3.	article or in any other format.	
			3. Demonstrate the ability to prepare	
			clear and concise written	
			critiques.	

Week 12	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	•
Week 13	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 14	Seminar	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin
Week 15	Seminar -	TBD	 Demonstrate the ability to present scientific material of a peer-reviewed research article or his/her own research. Demonstrate the ability to critically evaluate research presented in a peer-reviewed article or in any other format. Demonstrate the ability to prepare clear and concise written critiques. 	Dr. Amin

Course Evaluation (assessment): Faculty evaluations, peer evaluations and written reports. Faculty will evaluate seminar presentations using an evaluation rubric with eight criteria that links to the course objectives. A minimum of two faculty will evaluate presentation and the average of all faculty evaluations will be taken for final presentation assessment.

Course Evaluation (grading):

Point or Percentage Distribution: Faculty evaluation: 60%

Written reports: 10% Peer evaluation: 10% Class Participation: 20%

Letter grades distribution: A = 89.50 to 100%

B = 79.50 to less than 89.50%C = 69.50 to less than 79.50%

F = Less than 69.50%

Attendance policy: Attendance is mandatory regardless of whether or not students are scheduled to give a presentation. Active participation in presentation analysis is an integral part of developing presentation skills. Students are encouraged to give one presentation per semester and may give more than one if scheduling allows. In order to monitor attendance, a sign-up sheet will be sent around at the beginning of class. It is the student's responsibility to sign this sheet, otherwise credit for attendance cannot be guaranteed. Arriving late to class or leaving early may result in an unexcused absence. The University's policy on class attendance is described within the Board of Governors Policy No. AA-13 Class Attendance document. For more information about excused absences and professional leave, please refer to the MUSOP Student Leave Policy (MUSOP Policy 200.010). Only one unexcused absence will be allowed each semester. Should a situation arise where a student will miss a second class, the course director must be notified in advance. Acceptance of the excuse is at the course director's discretion and only legitimate (see official University policy), documented excuses will be accepted.

Documentation must be received within 2 weeks of the absence. More than one unexcused absence will result in a no credit grade.

Test Security Policy

Please refer to the MUSOP Secure Testing Policy (MUSOP Policy 400.003).

School of Pharmacy Policies

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UNIVERSITY POLICIES

University policies regarding Academic Dishonesty, Students with Disabilities, University Computing Services' Acceptable Use, Affirmative Action, and Sexual Harassment can be found at http://www.marshall.edu/wpmu/academic-affairs/policies/.