I. Certificate Name and CIP Code

a. Graduate Certificate in Regulatory Science

b. CIP Code Legal Professions and Studies, Other for the proposed certificate: 22.9999

II. Requested by

College of Law

III. Program Affiliation

A stand-alone certificate in Regulatory Science offered by the College of Law and affiliated with the College of Pharmacy.

IV. Certificate Description and Purpose

This interprofessional graduate certificate program consists of a 13-credit (4 courses at 3 credit units each, plus a 1 credit unit colloquium) curriculum designed to equip students and working professionals across multiple disciplines with basic competencies in regulatory science. The program was developed with leaders in regulatory science from the health care industry and with UA academics across the colleges of law, pharmacy, public health, and medicine.

Regulatory science is “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products” (FDA). The competencies range from policies, ethics, and processes to pre-clinical trials and post-marketing responsibilities. The competencies are based on 11 Core Thematic Areas developed by the NIH's Clinical and Translational Science Awards (CTSA) Regulatory Science Workgroup and provide the framework for the curriculum's core and elective courses.

There is emerging growth domestically and internationally for professionals in regulatory science. Graduates of this certificate will be provided with the foundation to understand the roles of regulatory agencies that oversee drugs, biologics, devices and diagnostics. The specialized training will uniquely prepare graduates to facilitate and lead innovation in medical product development.
V. Certificate Requirements

a. The Regulatory Science certificate is a stand-alone program, available both to students seeking degrees in UA graduate/professional programs and to students seeking the certificate alone. The certificate requires 13 credit units, including a colloquium. Students can take courses in any order.

b.

Current Course

i) LAW 695D: Regulatory Science (1 unit)

This course explores the intersection of regulation and science, focusing on how regulators at federal and state levels can best accommodate science and how science can best be practiced to satisfy regulators. The course discusses the role of executive agencies such as the Food and Drug Administration (FDA) in ensuring safe and effective products to promote public health, different mechanisms executive agencies use to increase compliance, and current challenges for enforcement in a globalized world.

New Courses

i) Law 575A: Clinical Research Ethics (3 units)

This course explains the ethical principles underlying regulations and guidance governing clinical trials in regulatory science, especially as the principles pertain to informed consent, risk-benefit disclosure, and conflicts of interest. The course also outlines the elements and design of clinical trials, including federal regulations for research with human subject participants, with vulnerable populations, and international research ethics. The course concludes with research ethics in Big Data, Precision Medicine, and data sharing.

ii) Law 577A: Development and Innovation: Drugs, Biologics, Devices, and Diagnostics (3 units)

What are the fundamental incentives for development in the biomedical space? The topics covered in this course include introducing key concepts in oversight by the Food and Drug Administration, biologics and biosimilars, regulation of diagnostics, along with the medical device development and approval process. Proving safety and efficacy in clinical development and promoting innovation through the adoption of new technologies and novel adaptive trial designs will also be discussed. The
course concludes with a survey of intellectual property rights regime governing medical products and the regulatory challenges in international markets.

iii) **Law 576A: Drug Discovery, Development, and in the Market (3 units)**

This course navigates the path across the pre-clinical and post-marketing divide from the full range of drug regulation including drug discovery, development tools, and post-approval phase. Intellectual Property protection and evaluation will be covered, along with FDA-enforced market exclusivity and FDA-expedited review programs. The course concludes with international regulatory perspectives, including the European Medicines Agency, and the costs involved to bring drugs through the clinical trials to market in the US and abroad, and how this affects future investment and strategy.

iv) **Law 598A: Case Study Project (3 units)**

This course provides an opportunity for students to integrate knowledge and skills into a real-world regulatory science issue affecting leaders in the field. The course is built around an individual or team-based project that will be completed under faculty supervision, and entails the application of analytical approaches and communication strategies to a current or emerging topic in regulatory science.

c. Students are allowed to substitute 3 units of elective courses at the advisor’s discretion including face-to-face courses.

d. Indicate which courses will be offered on-campus and those offered off-campus, as well as the method of delivery.

   i. All courses will be delivered online to main campus and distance students.

e. If courses will be offered online, how will you protect academic integrity?

   i. University of Arizona students are expected and required to comply with the University's Student Code of Conduct. This Student Code of Conduct establishes the honesty in all class work, and ethical conduct in all labs and clinical assignments. This principle is furthered by the student Code of Conduct and disciplinary procedures established by ABOR Policies 5-308 through 5-404, all provisions of which apply to all University of Arizona students. Under the Student Code of Conduct, conduct consisting of academic dishonesty is prohibited.
ii. Protection of academic integrity in online courses is supported by five key practices:

1. Enrollment into online courses is protected through automatic syncing with UAccess to ensure the correct student is enrolled in each course.
2. Students log into their online courses through the University’s web authorization tool utilizing their University Net ID and password.
3. Desire2Learn provides online data analytics within each course. Student information such as IP addresses, login times, submission times and activity within each course site is available to instructors for review.
4. Online Instructors have access to the TurnItIn Originality Checker in each course for plagiarism prevention on paper assignments.
5. Online instructors have the option to use Examity. Examity is a campus-wide exam security option for the University of Arizona. Examity authenticates test-takers, prevents cheating and protects test from being copied.

a. If the certificate is to be offered fully online, have you met with Vincent Del Casino and the UA Online team to confirm pricing and other operations?

College of Law faculty and staff has been in regular contact with members of the UA Online team, including Joshua Steele, Stephanie Adamson, and Jana Hayhurst. Please find included in this implementation request a signed memo of support from Vincent Del Casino.

VI. Student Admittance/Advising/Completion – completion of a bachelor’s degree is required for admission to a graduate certificate. Completion of a Master’s degree or current enrollment in a graduate level program is required for admission to a Post-Master’s certificate.

b. List any prerequisites or standardized tests required for admission:

   i. There are no standardized tests for admission, aside from the TOEFL, if applicable, with a (minimum score of 79 iBT or 550 PBT).
   ii. A minimum 2.7 GPA
   iii. An earned accredited 4-year bachelor’s degree
   iv. In addition to the above, applicants will be required to submit:

1. Personal statement of 500 words summarizing qualifications for and interest in the certificate;
2. Official academic transcripts - which follow the UA Graduate College transcript requirements;
3. CV/resume; and
4. Two letters of recommendation
b. Indicate if concurrent enrollment in a degree program is allowed or required.

Concurrent enrollment allowed.

c. Can students be enrolled full-time in the certificate in their first semester? What is the standard length of time to finish the certificate if students are enrolled full-time the first semester?

Our initial course offerings will not allow for full-time enrollment status, but we hope to develop additional course offerings if the certificate attracts sufficient student numbers to allow for future full-time enrollment status. As of January 2019, we plan to offer at least two courses per semester, plus the colloquium, which is a total of 7 units. For the Certificate in Regulatory Science, this means a student could complete the certificate in two semesters for a total of 13 units.

d. Indicate the maximum number of transfer units (courses taken at institutions other than the UA) that may be applied to the certificate, keeping in mind that no more than 6 units of transfer credit may apply to a graduate certificate.

3

e. What provisions are included for student advising?

The Colleges of Law and Pharmacy have hired, Professor of Health and Director of Graduate Health Sciences Programs, Tara Sklar, a JD/MPH-level administrator, who will provide oversight for the program as well as student advising. In addition, student advising, recruitment and retention in the certificate program will be facilitated by Assistant Professor of Pharmacy and PharmD Forward Director, Elizabeth Hall Lispy. Designated faculty within the Colleges of Law, Pharmacy, and Public Health will also be available to advise certificate students, as needed.

f. If there are affiliated graduate programs (refer to section III above), may the units earned for the certificate be applied to the degree program? If so, how many?

All credits may be applied to a student’s program of study, pending approval by the student’s home department.

g. May a student use any units taken in Graduate non-degree status (GNDS)? If so, how many? (Per policy, 6 maximum may be used.)

Yes, per policy a maximum of 6 units may be taken in non-degree seeking status.
VII. **Certificate and Student Outcomes** – provide a plan and frequency for assessing the intended certificate outcomes both for students and the certificate.

a. **Student Learning Outcomes** – describe what students should know, understand, and/or be able to do after completing the coursework for this certificate.

Upon completing the required coursework, students should be able to:

1) Characterize the current U.S. and international regulatory systems and structures for drugs, biologics, devices, and diagnostics.

2) Summarize current and emerging regulatory science priorities, including FDA Priority Areas and others.

3) Explain the ethical principles and requirements related to the development of new regulations and guidance documents.

4) Recognize key elements of the federal regulations for research with human subject participants.

5) Describe the process of drug and device development.

6) Identify major aspects of, and regulatory issues associated with, preclinical, clinical and post-marketing requirements.

7) Describe principles and applications of various analytic tools and techniques (e.g., bioinformatics, patient-reported outcomes, clinical effectiveness research, translational research, etc.).

8) Articulate the need to provide guidance to sponsors and manufacturers about how to effectively and transparently communicate the risks, benefits, and uncertainties of regulated products to the public.

9) Describe emerging key technology areas and how they may impact regulatory science processes and policies (e.g., manufacturing, toxicology, etc.).

10) Apply and communicate regulatory principles to a real-world case study in an interdisciplinary team.

**Student assessment**

Students will have assessments at multiple points during the individual courses, including an initial assessment within the first three weeks, a second assessment at mid-point in the course, and a final assessment at the end of the course.
Students will also be assessed at the completion of each course with a final grade, and a grades will be marked A through E according to the University Policies and grading systems, http://catalog.arizona.edu/policy/grades-and-grading-system

Certificate assessment

We plan to assess the certificate outcomes by surveying students at entry into the program to test their baseline skills and knowledge of regulatory systems and approval processes in regulatory science. We will also conduct an exit survey, which aligns with the questions in the entry survey, to assess whether the certificate learning outcomes have been achieved. All faculty involved in the certificate will bi-annually review both the entry and exit points of the survey data, and, as needed, both certificate and course-level adjustments may be made.

b. Certificate Outcomes – identify factors that indicate that completion of the certificate leads to gainful employment and/or advancement opportunities.

Medical product development is an area of expected growth domestically and globally. The National Institutes of Health (NIH) has identified the need for a well-trained regulatory science workforce to advance the translation of research into clinical interventions. Potential employment could range from Research and Development, Quality Assurance, Quality Control and Clinical Research with regulatory agencies and in the health care and pharmaceutical sectors. This certificate curriculum covers the current topics that are in high demand for specialists in regulatory science. Graduates of the program will be able to advance their careers with this training, or move into the regulatory science field or related discipline.

VIII. Student Demand – is there sufficient student demand for the certificate?

a. What is the anticipated student enrollment for this certificate by the third year the certificate is offered? Anecdotal indicators of students’ interest in the certificate are not sufficient. Provide market analysis or other tangible evidence to support projected enrollment numbers.

The UA Health Sciences (UAHS) enrolls more than 6,000 health professions students, and UA’s James E. Rogers College of Law enrolls over 900 students. UAHS enrollment reflects in part Arizona’s development as a regional biotech hub.

The certificate will draw not only from the university’s expertise and resources in health sciences, but also from those of local partners. Important among these is the Critical Path Institute (C-PATH), a non-profit public-private partnership working to accelerate the drug development process by bringing together the
FDA, industry, and academia to develop new standards and methods. Several C-PATH staff already hold appointments at UAHS. Especially with the rapidly changing landscape of biotechnology in the health sciences, there is a need for safe and efficient regulatory pathways for moving drugs and devices to patients.

Our other industry partner is with the Roche Group, which has an office in Tucson, Arizona, among their many global offices. They specialize in innovating and manufacturing instruments, including the development of companion diagnostics, which has accelerated the future of personalized health care to identify patients more likely to respond to specific therapies. They are reputable international company that is supporting this certificate coursework in terms of providing guidance for the skills and knowledge needed to work on the most current issues in regulatory science. They also have experience providing real-world projects for students to work on as part of their coursework, and potential job-placement post the graduate certificate.

Given the enrollment in the currently offered Regulatory Science Colloquium, we expect an enrollment of 10 students per year from within University of Arizona programs. Furthermore, by offering the certificate as an online program, we expect enrollment of non-degree seeking, mid-career professionals seeking specialization for career advancement or change. After a period of scaling up, we expect non-degree seeking student average enrollment of 45 students per year.

We also conducted a market scan of comparable curricula at peer institutions that offer graduate certificates and advanced degrees in regulatory science, see attached Appendix. We identified three programs at leading competitors based on their course offerings, program focus, and target audience. The three universities offering competitive programs are George Washington University, University of Southern California, and the University of Rochester. We found our proposed graduate certificate distinguishes itself from the other program offerings in three important ways:

- We are the only graduate certificate offering where the host institution is a College of Law that collaborates with other schools in the health sciences;
- We offer a robust, but manageable 13-credit unit graduate certificate, and the price point is an attractive $11,271 for the entire certificate, which is thousands of dollars less than the least expensive competitor offering and half of the more expensive competitors.
- Lastly, our course offerings are unique due to their support from industry leaders in the regulatory science field:
  - As mentioned above, our courses will be taught with support from senior scientists at the internationally recognized C-PATH and Roche Group. In particular, they will provide students with real-world expertise as part of the Case Study Project course where students will have the option to work on C-PATH or Roche related research projects.
The colloquium has an established record of hosting internationally renowned experts since 2015, which provides a prominent advantage compared to competitor programs. See Appendix for a compilation of the nearly 50 prior speakers for LAW 695D: Regulatory Science is provided.

b) Will the certificate serve a community need, preparation for professional certification exams, degree program recruitment, employability enhancement, or other?

Yes, the certificate will draw from dynamic and expanding health sciences campuses in both Phoenix and Tucson, as well as a nationally ranked law school, to provide an opportunity for professionals across multiple disciplines to channel their training toward the timely translation of scientific knowledge to address health challenges. The certificate will equip students and professionals to enter a sector requiring specialized and in-demand skills, while supporting the state’s regional leadership in the biosciences.

In addition, our industry leaders in regulatory science with C-PATH and the Roche Group, as mentioned above, are very interested in potential employee recruitment through this graduate certificate, and are also willing to provide mentoring and career advice, as appropriate. C-Path and Roche have both provided letters of support to express their commitment to this new certificate.

c) Will there be any collaboration with other departments or universities to maximize resources?

The Regulatory Science Program currently offers a colloquium course cross-listed across the colleges of nursing, public health, pharmacy, and law, with students enrolled from multiple colleges any given semester. The colloquium hosts speakers from across the country and across campus. The program anticipates leveraging existing connections for student advising and teaching responsibilities for certificate coursework.

We also have provided memos of support from the Colleges of Public Health and Pharmacy that confirm the commitment of resources to this new graduate certificate. These two colleges have actively involved in the design and development of the courses in this certificate with the College of Law. In addition to instruction, designated faculty members from the College of Pharmacy will also be involved in student recruitment, retention, and advising.
IX. Expected Faculty and Resource Requirements

a. List the name, rank, highest degree, department and estimated level of involvement of all current faculty members who will participate in the program.

Tara Sklar, JD, MPH, Professor of Health Law and Director of Graduate Health Sciences Program, College of Law. High involvement as the program administrator, academic advisor, and co-instructor for LAW 598A Case Study Project.

Elizabeth Hall-Lipsy, JD, MPH, Assistant Professor and Director of PharmD Forward, College of Pharmacy. High involvement in administration support from the College of Pharmacy, academic advisor, and co-instructor for LAW 598A Case Study Project and LAW 695D Regulatory Science.

Christopher Robertson, JD, PhD, Professor of Law and Associate Dean for Research and Innovation, College of Law. High involvement in providing oversight as the Program Chair, including on curricular direction and industry partnerships. Also, as an academic advisor and provides instruction on particular topics.

Leila Barraza, JD, MPH, Assistant Professor, College of Public Health. High involvement in administration support from the College of Public Health, academic advisor, and co-instructor for LAW 695D Regulatory Science.

John-Michael Sauer, PhD, Research Professor, Department of Pharmacology, College of Medicine and Executive Director at the Critical Path Institute. Moderate involvement in providing instruction for Law 576A: Drug Discovery, Development, and in the Market, and as an academic advisor.

Mabel Crescioni, DrPH, JD, LLM, Adjunct Lecturer, College of Public Health and Director at the Critical Path Institute. Moderate involvement in providing instruction for Law 575A: Clinical Research Ethics, and as an academic advisor.

Ivo Abraham, PhD, Professor of Pharmacy and Medicine, College of Pharmacy. Low involvement by providing instruction on particular topics, as needed, and as an academic advisor.

Roy Spece, JD, Professor of Law, College of Law. Low involvement by providing instruction on particular topics, as needed, and as an academic advisor.

b. Describe additional faculty needed for the first three years of the certificate.

We plan to hire Marco Schito, PhD, as a Professor of Practice at the College of Law. Moderate involvement in the certificate by providing instruction for Law 577A
Development and Innovation: Biologics, Devices, and Diagnostics, and as an academic advisor.

We plan to hire Mabel Crescioni, DrPH, JD, LLM, as a Professor of Practice at the College of Law. Moderate involvement in the certificate by providing instruction for Law 575A: Clinical Research Ethics, and as an academic advisor.

We plan to hire John-Michael Sauer, PhD, as a Professor of Practice at the College of Law. Moderate involvement in providing instruction for Law 576A: Drug Discovery, Development, and in the Market, and as an academic advisor.

c. Give the present numbers of FTE students (graduate and undergraduate) and FTE faculty in the department or unit in which the certificate is offered.

College of Law Students:
JD: 360
LLM: 23
SJD: 25
MLS: 57 in person + 1 online
BA: 445 in person + 2 online
Micro-campus students: 289

College of Law FTE Faculty
Full-time faculty: 50
Non-full-time faculty: 117
Total: 167

The College of Law faculty teaches across the different graduate and undergraduate programs.

d. Give the proposed numbers of FTE students (graduate and undergraduate) and FTE faculty for the next three years in the department or unit in which the certificate is offered.

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<thead>
<tr>
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<th>Year One</th>
<th>Year Two</th>
<th>Year Three</th>
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<td>FTE students</td>
<td>1,202</td>
<td>1,364</td>
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<tr>
<td>FTE faculty</td>
<td>50</td>
<td>53</td>
<td>56</td>
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e. Provide a copy of the budget for the certificate including start-up costs and the anticipated costs for the first three years. Include some indication of how this fits with the overall department budget.
Please see attached 3-Year Budget Projection Form from 2018 to 2021. The College of Law is committed to growing in the area of regulatory science. We believe this initial investment will pay off substantially as well provide a needed curriculum resource that has been requested by students in the health sciences, law, and those currently working in the regulatory science sector.

X. Contacts and Administration

a. List the name and contact information for the primary point of contact for the certificate.

Christopher Robertson  
Professor; Associate Dean for Research & Innovation  
James E. Rogers College of Law  
Email: robertson@email.arizona.edu  
Office Phone: (520) 621-1289

b. List the name and contact information for the person or persons who will serve in the role of Director of Graduate Studies (DGS) for the certificate. (This is not always the same as the DGS for affiliated programs or head of the managing academic unit.)

Keith Swisher  
Professor of Legal Ethics; Director, BA in Law and Master of Legal Studies Programs  
James E. Rogers College of Law  
Email: keithswisher@email.arizona.edu  
Office Phone: (520) 626-8373
March 22, 2018

To: Graduate College, University of Arizona

From: Douglas Taren, Mel and Enid Zuckerman College of Public Health

Subject: Memo of Support for the Graduate Certificate in Regulatory Science

The Mel and Enid Zuckerman College of Public Health has closely worked with the James E. Rogers College of Law in developing the proposed Graduate Certificate in Regulatory Science. We have shared resources in terms of faculty and course offerings, particularly in regards to the Colloquium entitled, ‘Hot Topics and Emerging Issues in Regulatory Science.’ The Graduate Certificate in Regulatory Science builds on this course, which we have offered together since 2015, to bring in internationally renowned experts in regulatory science.

Together with the College of Law, we have also connected with industry groups, including the Critical Path Institute and Roche Group, to help ensure the curriculum being developed is the most current and needed for the future workforce. We are committed to continuing to develop these industry partnerships so that public health students will have the opportunity to apply their newly gained knowledge and skills to real-world issues.

We have committed ongoing resources in terms of faculty time to ensure that the course instruction is of the highest quality for this exciting new and needed certificate.

Please do not hesitate to contact me, if you have any further questions.

With my best wishes,

Douglas Taren, PhD
Associate Dean for Academic Affairs
Professor of Public Health
Director, Western Region Public Health Training Center
March 20, 2018

MEMORANDUM

TO: Graduate College
The University of Arizona

FR: Rick G. Schnellmann, Ph.D.
Dean, College of Pharmacy
Howard J. Schaeffer Endowed Chair
Professor of Pharmacology and Toxicology
schnitt@pharmacy.arizona.edu

RE: Support for the Graduate Certificate in Regulatory Science

On behalf of The University of Arizona College of Pharmacy, we are in support of the proposed creation in developing the Graduate Certificate in Regulatory Science. The College has worked closely with the James E. Rogers College of Law and have shared resources in terms of faculty and course offerings, particularly in regards to the Colloquium entitled, ‘Hot Topics and Emerging Issues in Regulatory Science.’ The Graduate Certificate in Regulatory Science builds on this course, which we have offered together since 2015, to bring in internationally renowned experts in regulatory science.

Together with the College of Law, we have also connected with industry groups, including the Critical Path Institute and Roche Group, to help ensure the curriculum being developed is the most current and needed for the future workforce. We are committed to continuing to develop these industry partnerships so that students in the College of Pharmacy will have the opportunity to apply their newly gained knowledge and skills to real-world issues.

We have committed ongoing resources in terms of faculty time and funding to ensure that the program administration, student advising, and course instruction is of the highest quality for this exciting new and needed certificate.

I offer the full and enthusiastic support of the College for this endeavor and I am confident the Graduate Certificate in Regulatory Science will continue to build upon the successes of existing programs. Please do not hesitate to contact me, if you have any further questions.
Date: April 23, 2018

To: Graduate College, University of Arizona

From: Vincent J. Del Casino, Jr., Ph.D., Vice President for Academic Initiatives and Student Success

RE: Memo of Support for two Graduate Certificates in Health Law offered by the James E. Rogers College of Law

UA Online supports the James E. Rogers College of Law proposal to offer two Graduate Certificates, including the Graduate Certificate in Health Law for Health Professionals and the Graduate Certificate in Regulatory Science. We believe the coursework they have developed with the Colleges of Pharmacy and Public Health are exciting interprofessional course offerings.

We expect both Graduate Certificates will be attractive to students interested in expanding their health professional or health sciences education to become more aware of the legal, regulatory, and ethical issues in the rapidly growing health care and regulatory science industries. We believe the College of Law’s interest in making these courses available online is an excellent idea for time-strapped early and mid-career professionals to have optimal flexibility in their coursework schedule.

Members of our UA Online team, Joshua Steele and Stephanie Adamson, have been in regular contact with the College of Law faculty on developing these certificates. We look forward to continuing to work with them on bringing these new and needed course offerings to the market.
April 26, 2018

Professor Christopher Robertson, JD, PhD
Associate Dean for Research and Innovation
James E. Rogers College of Law
The University of Arizona

Dear Professor Robertson:

The Critical Path Institute supports The University of Arizona's proposal to develop a 13-credit Graduate Certificate in Regulatory Science. We have actively worked with the James E. Rogers College of Law on developing the curriculum in this proposed certificate to provide real-world examples throughout the coursework and would serve as an ongoing resource for career advising for future students.

Members of our team are very involved in this certificate, with a small working group consisting of Dr. John-Michael Sauer, Dr. Mabel Crescioni, Dr. Jennifer Burkey, and Dr. Marco Schito providing their expert advice on each of the courses offered. As an institution, we are particularly interested in supporting LAW 598A Regulatory Capstone, which will provide students with a practical project to apply their newly gained knowledge and skills from the certificate coursework and give them an opportunity to work with leaders in the field at the Critical Path Institute. We have been, and plan to continue, periodically presenting in the colloquium course, LAW 695D Regulatory Science, to help inform students of the current and emerging topics in regulatory science.

We believe the Graduate Certificate in Regulatory Science will open doors to gainful employment by providing students with specialized skills for this rapidly growing area of the economy. We genuinely appreciate efforts by The University of Arizona to develop a stronger, local workforce, and are committed to working with the College of Law on this exciting new and needed certificate.

Please do not hesitate to contact me, if you have any further questions.

With my best wishes,

Martha Brumfield, PhD
President and CEO
May 1, 2018

Professor Christopher Robertson, JD, PhD
Associate Dean for Research and Innovation
James E. Rogers College of Law
University of Arizona

Dear Professor Robertson:

Ventana Medical Systems, Inc. (“VMS”), a member of the Roche group, wholeheartedly supports the University of Arizona's proposal to develop a 13-credit Graduate Certificate in Regulatory Science. We have actively worked with the James E. Rogers College of Law to develop curriculum in this proposed certificate that will provide real-world examples throughout the coursework. We, further, look forward to opportunities, as mutually agreed from time to time, to strengthen our ties with the local community, University, and prospective regulatory professionals through this program.

We are particularly interested in supporting LAW 598A Regulatory Capstone, as we may mutually agree from time to time, which will provide students with a practical project wherein capstone students may apply their newly-acquired knowledge and skills from the certificate coursework and give them an opportunity to work with leaders in the field. We also anticipate periodic invitations for VMS to present in the colloquium course, LAW 695D Regulatory Science, to help inform students of the various roles and career opportunities in regulatory science.

We believe the Graduate Certificate in Regulatory Science will open doors to gainful employment by providing students with specialized skills for this rapidly growing area of the economy. We genuinely appreciate efforts by the University of Arizona to develop a stronger, local workforce, and look forward to working with the College of Law as an ongoing resource for this exciting new and needed certificate.

Please do not hesitate to contact me, if you have any further questions.

With my best wishes,

[Signature]

Fatima Pereira
Director, Regulatory Affairs
Ventana Medical Systems, Inc.
Tucson, AZ 85735
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<tr>
<th>Legend</th>
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**Table: Courses and Learning Activities**

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**Certificate in Regulatory Science**

**Demo Area**

University of Arizona, Ann...
### Financial Summary

**Graduate Certification in Regulatory Science**

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<td>$327.46</td>
<td>$327.46</td>
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<tr>
<td>RCM Tax Rate</td>
<td>30%</td>
<td>31%</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>Approx. Split Ownership of Classes between Law &amp; Other Colleges</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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</table>

**Sources of Funds to UA**

<table>
<thead>
<tr>
<th></th>
<th>Gross AISS Revenue</th>
<th>84,500</th>
<th>169,000</th>
<th>338,000</th>
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</thead>
<tbody>
<tr>
<td>Less AISS Share</td>
<td>(25,350)</td>
<td>(50,700)</td>
<td>(101,400)</td>
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<tr>
<td>Gross RCM SCH Revenue</td>
<td>29,062</td>
<td>46,499</td>
<td>58,124</td>
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<tr>
<td>Less RCM Share</td>
<td>(8,684)</td>
<td>(14,591)</td>
<td>(18,239)</td>
<td></td>
</tr>
<tr>
<td>Gross RCM Major Revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Gross RCM Program Fee Revenue</td>
<td>-</td>
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**Sources of Funds to Law**

<table>
<thead>
<tr>
<th></th>
<th>Net AISS Revenue</th>
<th>59,150</th>
<th>118,300</th>
<th>236,600</th>
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<tbody>
<tr>
<td>Net RCM SCH Revenue</td>
<td>20,378</td>
<td>31,907</td>
<td>39,884</td>
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</tr>
<tr>
<td>Net RCM Major Revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
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<tr>
<td>Net RCM Program Fee Revenue</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Less Tuition Discounting</td>
<td>-</td>
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**Total Sources of Funds**

<table>
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<tr>
<th></th>
<th>0</th>
<th>79,528</th>
<th>150,207</th>
<th>276,484</th>
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**Uses of Funds**

<table>
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<tr>
<th></th>
<th>Course Development</th>
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<tr>
<td>Course Instruction</td>
<td>-</td>
<td>68640</td>
<td>68640</td>
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<td>Program Coordinator/Director</td>
<td>12250</td>
<td>33000</td>
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<tr>
<td>Advising &amp; Career Services</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
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<tr>
<td>Advertising</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Operational Expenses</td>
<td>-</td>
<td>-</td>
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**Total Uses of Funds**

<table>
<thead>
<tr>
<th></th>
<th>115,210</th>
<th>101,640</th>
<th>101,640</th>
<th>101,640</th>
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</thead>
</table>

**Overall Net Proceeds (Deficit)**

| | (115,210) | (22,112) | 48,567 | 174,844 |

Cumulative Balance/(Shortfall) 86,090
## Appendix - Graduate Certificate in Regulatory Science

Comparable Curricula at Peer Institutions for Graduate Curriculum Requests
Top 3 Competitor Certificate Programs in Regulatory Science

<table>
<thead>
<tr>
<th></th>
<th>George Washington University</th>
<th>University of Southern California</th>
<th>University of Rochester</th>
</tr>
</thead>
</table>
| **1. Host College / Program Name** | School of Medicine and Health Sciences / Grad Cert in Regulatory Affairs  
LINK: https://healthsciencesprograms.online.gwu.edu/graduate-certificate/regulatory-affairs | College of Pharmacy / Regulatory Science Graduate Certificate  
LINK: https://regulatory.usc.edu/programs/certificates/ | School of Medicine and Dentistry (administered by Department of Public Health Science) / Advanced Certificate in Regulatory Science  
LINK: https://www.urmc.rochester.edu/education/graduate/certificate/advanced-certificate-in-regulatory-science.aspx |
| **2. Program Focus** | - Domestic and international foundations in regulatory affairs  
- Interdisciplinary approach (law, science business)  
- Global outlook  
- Experienced faculty from public sector and industry | 6 Certificate options  
1) Medical Product Quality  
2) Clinical Research Design and Management  
3) Food Safety  
4) Patient and Product Safety  
5) Preclinical Drug Development  
6) Regulatory and Clinical Affairs | In-depth training in fundamental skills, methodology, and principles necessary for a future career in Regulatory Science through:  
1) Didactic course work  
2) Capstone project/competition  
3) Mentorship program  
4) Introduction to relevant career paths  
5) Assistance in identifying experiential training opportunities  
- Competency-driven curriculum (based on Regulatory Science core thematic areas and associated competencies developed by Clinical and Translational Science Awards (CTSA), Regulatory Science Workgroup, and PhRMA Foundation |
| **3. Target Audience** | - Healthcare professionals entering field of regulatory affairs or who wish to increase their knowledge and skills to advance to a leadership position  
- Working professionals seeking career advancement  
- Potential online students from around the world | - Working professionals wishing to take 1-2 courses per term in convenient weekend or distance formats | N/A |


### 4. Number of Units and Courses

- 18 units (5 core courses; 1 research course)
  - Yes, credits can be applied to master’s degree:
    1) Online Master of Science in Health Sciences (MSHS) in Regulatory Affairs

- 12 units (4-5 courses)
  - Yes, credits can be applied to master’s degree:
    1) Online Master
    1) MS: Regulatory Science;
    2) MS: Management of Drug Development;
    3) MS: Medical Product Quality
    4) DRSc: Professional doctorate program in Regulatory Science

- 16 units; 7-8 courses (plus capstone)

### 5. Courses offered

#### I. Major Courses

1) RAFF 6201: Introduction to Global Regulatory Affairs (3)
2) RAFF 6202: Regulatory Strategy in the Development of Drugs and Biologics (3)
3) RAFF 6203: Regulatory Strategy in the Development of Devices and Diagnostics (3)
4) RAFF 6204: Clinical Research for Regulatory Affairs (3)
5) RAFF 6205: Regulatory Compliance (3)
6) RAFF 6275: Leadership and Change in Regulatory Affairs (3)

#### II. Research

1) HSCI 6263: Biostatistics for Clinical and Translational Research (3)
2) HSCI 6264: Epidemiology for Clinical and Translational Research (3)

#### III. Professional

1) HSCI 6223: Topics in Health Care Leadership (3)
2) HSCI 6240: Issues and Trends in Health Systems (3)

#### I. Medical Product Quality

**Requirements:** 12 units; 4 courses
1) 1 Quality Systems course (3)
2) 1 Quality Tools course (3 units)
3) Managing Complex Projects: RSCI603 (3 units)
4) Optional Quality or Regulatory course (3)

#### II. Clinical Research Design and Management

**Requirements:** 12 units; 4 courses total
1) MPTX 517—Structure & Management of Clinical Trials (4)
2) MPTX 522—Clinical Design Course (3)
3) MPTX 602—Science, Research & Ethics (2)
4) Elective (3)

#### III. Food Safety

**Requirements:** 12 units; 4 courses
1) MPTX 514—Regulation of Food & Dietary Supplements (3)
2) MPTX 524—Food Science & Technology (3)
3) RSCI 525—Introduction to Drug & Food Toxicology (3)

#### I. Required

1) BME 431: FDA Regulatory Processes & Intellectual Property (2)
2) BME 432: Navigating FDA Regulatory & Commercialization Landscapes (2)
3) PM 487: Fundamentals of Science, Technology & Health Policy (2)
4) PM 488: Experimental Therapeutics (3)
5) BST 463: Introduction to Biostatistics (3)
6) IND 501: Ethics in Research (1)
7) Capstone: Regulatory Science Student Competition

#### II. Options (one or more courses below totaling at least 3 units)

1) PHP 404: Principles of Pharmacology (4)
2) PM 415: Principles of Epidemiology (3)
3) BST 465: Design of Clinical Trials (3)
4) MBI 403: Drug Discovery (2)
5) IND 417: Workshop in Scientific Communication (1)
<table>
<thead>
<tr>
<th>3) HSCI 6241: The Health Care Enterprise (3)</th>
<th>4) Optional: MPTX515, MPTX526, MPTX511 (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IV. Elective</strong></td>
<td><strong>IV. Patient and Product Safety</strong></td>
</tr>
<tr>
<td>1) Chosen with academic advisor (3)</td>
<td><strong>Requirements:</strong> 12 units; 5 courses</td>
</tr>
<tr>
<td></td>
<td>1) RSCI 520 — Introduction to Risk Management for Health Care Products (2)</td>
</tr>
<tr>
<td></td>
<td>2) RSCI 527 — Medical Product Safety (3)</td>
</tr>
<tr>
<td></td>
<td>3) RSCI 528 — Safety in Health Care Environment (3)</td>
</tr>
<tr>
<td></td>
<td>4) RSCI 529 — Application of Risk Management Tools &amp; Techniques (2)</td>
</tr>
<tr>
<td></td>
<td>5) MPTX 602 (2)</td>
</tr>
<tr>
<td></td>
<td><strong>V. Preclinical Drug Development</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Requirements:</strong> 12 units; 4 courses</td>
</tr>
<tr>
<td></td>
<td>1) RSCI 530 — Translational Medicine — An Overview (2)</td>
</tr>
<tr>
<td></td>
<td>2) RSCI 531 — Drug Discovery (4)</td>
</tr>
<tr>
<td></td>
<td>3) RSCI 532 — Early Stage Drug Development (3)</td>
</tr>
<tr>
<td></td>
<td>4) Elective: MPTX 511/RSCI 525/RSCI 526 (3)</td>
</tr>
<tr>
<td></td>
<td><strong>VI. Regulatory and Clinical Affairs</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Requirements:</strong> 12 units</td>
</tr>
<tr>
<td></td>
<td>1) 1 introductory course: MPTX 511, RSCI 530, or RSCI 531</td>
</tr>
<tr>
<td></td>
<td>2) 1 Advanced Regulation course: MPTX 512, MPTX 513, or MPTX 514</td>
</tr>
<tr>
<td></td>
<td>3) 1 Clinical Course: MPTX 522 or MPTX 517</td>
</tr>
<tr>
<td></td>
<td>4) 1 Quality Assurance Course: MPTX 515, RSCI 526</td>
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</table>

| 6. Practicum or internship required | None | None | None (but assistance available to identify experiential learning opportunities) |
### 7. Tuition

<table>
<thead>
<tr>
<th>Unit/Year</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 units</td>
<td>$16,110</td>
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<tr>
<td>12 units</td>
<td>$21,960</td>
</tr>
<tr>
<td>16 units</td>
<td>$25,536</td>
</tr>
</tbody>
</table>

### 8. Admissions Requirements

1. Bachelor’s degree or higher from a regionally accredited college or university
2. 3.0 minimum cumulative GPA
3. Relevant work experience in health care or clinical institutions

1. Earned bachelor’s degree
2. Suggested overall GPA of 3.0 or higher (3.0 minimum undergraduate GPA preferred)
3. Official transcripts from all colleges/universities attended
4. English language proficiency and excellent communication skills
5. Two reference letters
6. One-page statement of purpose (i.e. “Why do you want to pursue a graduate certificate program in Regulatory Science?”; “What attributes do you have that distinguish you as a good candidate for our program?”)

*GRE not required

### 9. Target Careers

- Regulatory Affairs Specialist
- Regulatory Affairs Manager
- Chemistry, Manufacturing and Controls (CMC) Manager
- Consumer Officer
- Technical Engineer
- Medical Affairs Associate
- Quality Assurance Engineer

- Specialist in medical product development

- Researcher/scientist
- Reviewer
- Regulatory Science professional in academia, industry, government
### Speakers and Topics for Regulatory Science Colloquium Series
**University of Arizona**

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Background</th>
<th>Topic</th>
<th>Semester(s)</th>
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<tbody>
<tr>
<td>Abraham, Ivo (PhD, MS, RN)</td>
<td>Professor, Department of Pharmacy Practice and Science, College of Pharmacy, University of Arizona; Professor, Department of Family and Community Medicine, College of Medicine, University of Arizona Center for Health Outcomes and PharmacoEconomic Research and the Cancer Center</td>
<td>The Federal Regulatory Scheme: Drug Approval, Biosimilars, GXP’s and Lab Regulations</td>
<td>Fall 2015, Spring 2017</td>
</tr>
<tr>
<td>Armstrong, David G. (DPM, MD, PhD)</td>
<td>Professor of Surgery and Director of Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona College of Medicine-Tucson</td>
<td>Cyber Security and Regulatory Implications</td>
<td>Fall 2016</td>
</tr>
<tr>
<td>Aspinall, Mara</td>
<td>President, CEO, Health Catalysts</td>
<td>Biomedical Diagnostics and Healthcare Companies</td>
<td>Fall 2017</td>
</tr>
<tr>
<td>Bambauer, Derek (JD)</td>
<td>Professor of Law, University of Arizona, James E. Rogers College of Law</td>
<td>Gene Patenting</td>
<td>Fall 2015</td>
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<tr>
<td>Bambauer, Jane (JD)</td>
<td>Associate Professor of Law, University of Arizona James E. Rogers College of Law</td>
<td>Privacy Versus Research in Big Data</td>
<td>Fall 2015, Spring 2017</td>
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<tr>
<td>Berlin, Rob (JD, MPH)</td>
<td>Senior Policy Advisor, Office of the Commissioner, Food and Drug Administration</td>
<td>FDA Overview: Regulatory Policy, Product Authorization, and Enforcement; E-Cigarettes: Science, Policy, and Practice</td>
<td>Fall 2016, Spring 2017</td>
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<tr>
<td>Boyer, Leslie (MD)</td>
<td>VIPER Institute, University of Arizona</td>
<td>Antivenom in the USA</td>
<td>Spring 2017, Spring 2018</td>
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<tr>
<td>Name</td>
<td>Title</td>
<td>Topic</td>
<td>Term</td>
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<tr>
<td>Calhoun, Elizabeth</td>
<td>Associate Vice President for Population Health Sciences and Executive Director of Center for Population Science and Discovery, University of Arizona Health Sciences</td>
<td>Ethics of Conducting Research with Vulnerable Populations</td>
<td>Fall 2016, Fall 2017</td>
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<tr>
<td>Courtney, Brooke</td>
<td>Senior Regulatory Counsel, FDA's Office of Counterterrorism Threats</td>
<td>Emergency Use Authorizations for Medical Countermeasures</td>
<td>Upcoming in Spring 2018</td>
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<tr>
<td>Ernst, Kacey</td>
<td>Associate Professor, University of Arizona Mel &amp; Enid Zuckerman College of Public Health</td>
<td>Science in the Time of Zika</td>
<td>Fall 2016</td>
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<tr>
<td>Dennis, Eslie</td>
<td>Vice President Medical Affairs, Ventana Medical Systems</td>
<td>Cancer, Pathology, and Precision Medicine: Virchow Revisited Through Grogan’s Lens</td>
<td>Spring 2016</td>
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<tr>
<td>Friese, Randall</td>
<td>Professor of Surgery and Physiological Sciences, University of Arizona; Arizona State Representative, District 9; Assistant Democratic Leader</td>
<td>Meds and Free Speech: A Medical, Legal, and Policy Discussion</td>
<td>Fall 2017</td>
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<tr>
<td>Garcia, Francisco</td>
<td>Director and Chief Medical Officer, Pima County Health Department; Professor, University of Arizona Mel &amp; Enid Zuckerman College of Public Health</td>
<td>Science in the Time of Zika</td>
<td>Fall 2016</td>
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<tr>
<td>Georger, Katherine</td>
<td>HIPAA Privacy Officer, University of Arizona</td>
<td>HIPAA for Researchers: Why Does it Apply to Research and Common Misconceptions</td>
<td>Fall 2017</td>
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<tr>
<td>Gillette, Epiphanie</td>
<td>COI Officer, University of Arizona</td>
<td>Institutional Research Regulations: IRBs, Conflicts of Interest, and Privacy</td>
<td>Spring 2016</td>
</tr>
<tr>
<td>Hodge, James G. Jr.</td>
<td>Professor of Public Health Law and Ethics, ASU Sandra Day O’Connor College of Law; Director of Western Region Office, Network for Public</td>
<td>Science in the Time of Zika</td>
<td>Fall 2016</td>
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<tr>
<td>Name</td>
<td>Title</td>
<td>Topic</td>
<td>Date</td>
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<tr>
<td>Humble, Will (MPH)</td>
<td>Division Director for Health Policy and Evaluation, Center for Population Science and Discovery, University of Arizona Health Services; Director, Arizona Department of Health Services</td>
<td>Impact of Scientific Research on the State Regulatory Process</td>
<td>Spring 2017</td>
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<tr>
<td>Hutt, Peter Barton (JD)</td>
<td>Senior Counsel, Covington &amp; Burling; Former Chief Counsel for the Food and Drug Administration</td>
<td>FDA Regulation of New Drugs Since 1950</td>
<td>Spring 2016</td>
</tr>
<tr>
<td>Joiner, Keith (MD, MPH)</td>
<td>Director, Center for Mgt. Innovations in Health Care, Eller College of Management</td>
<td>Clinical and Translational Science as an NIH Priority</td>
<td>Fall 2015</td>
</tr>
<tr>
<td>Kleidermacher, David</td>
<td>Chief Security Officer, BlackBerry</td>
<td>Cyber Security and Regulatory Implications</td>
<td>Fall 2016</td>
</tr>
<tr>
<td>Laurion, Victor (MD)</td>
<td>Resident/Fellow, Department of Emergency Medicine, Department of Pediatrics, University of Arizona College of Medicine</td>
<td>Meds and Free Speech: A Medical, Legal, and Policy Discussion</td>
<td>Fall 2017</td>
</tr>
<tr>
<td>Mahler, Andrew (JD)</td>
<td>HIPAA Privacy Officer, University of Arizona</td>
<td>Institutional Research Regulations: IRBs, Conflicts of Interest, and Privacy</td>
<td>Spring 2016</td>
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<tr>
<td>Marcus, David (JD)</td>
<td>Professor of Law, University of Arizona James E. Rogers College of Law</td>
<td>Administrative Law</td>
<td>Spring 2017</td>
</tr>
<tr>
<td>Marsh, Mariette (MPA, CIP)</td>
<td>Director, University of Arizona Human Subjects Protection Program</td>
<td>Institutional Research Regulations: IRBs, Conflicts of Interest, and Privacy; Human Subjects Protection, Updates to the Common Rule</td>
<td>Spring 2016, Fall 2016, Spring 2017, Fall 2017, Spring 2018</td>
</tr>
<tr>
<td>McBride, Ali (PharmD)</td>
<td>Clinical Coordinator, University of Arizona Cancer Center</td>
<td>Pharmaceutical Dollars and Sense: A Facilitated Discussion Among Experts</td>
<td>Spring 2017</td>
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<tr>
<td>Name</td>
<td>Position and Affiliation</td>
<td>Topic</td>
<td>Date</td>
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<tr>
<td>-----------------------------</td>
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<tr>
<td>Mitchell, Andi</td>
<td>Officer, University of Arizona Animal Care &amp; Use Committee (IACUC)</td>
<td>Animal Use in Research</td>
<td>Upcoming in Spring 2018</td>
</tr>
<tr>
<td>Nair, Uma S. (PhD)</td>
<td>Assistant Professor, Department of Health Promotion Sciences, Mel and Enid Zuckerman College of Health, University of Arizona</td>
<td>E-Cigarettes: Science, Policy, and Practice</td>
<td>Spring 2017</td>
</tr>
<tr>
<td></td>
<td>Assistant Director of Arizona Smokers’ Helpline (ASHLine), University of Arizona</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nelson, Daniel (MSc, CIP)</td>
<td>Director, Human Research Protocol Office (HRPO), National Health and Environmental Effects Research Laboratory (NHEERL), Environmental Protection Agency; Adjunct Professor, Social Medicine and Pediatrics, Faculty Associate, Center of Bioethics, University of North Carolina Chapel Hill</td>
<td>Environmental Protection Agency Human Subjects Policy</td>
<td>Spring 2017</td>
</tr>
<tr>
<td>O’Brien, Patrick (JD)</td>
<td>General Counsel, Arrowhead Research Corporation</td>
<td>Labeling</td>
<td>Upcoming in Spring 2018</td>
</tr>
<tr>
<td>Ramos, Ken (MD, PhD, PharmB)</td>
<td>Associate Vice President for Precision Health Sciences, University of Arizona Health Sciences; Interim Dean, University of Arizona College of Medicine-Phoenix</td>
<td>Precision Medicine</td>
<td>Fall 2016</td>
</tr>
<tr>
<td>Romero, Klaus (MD, MS, FCP)</td>
<td>Director of Clinical Pharmacology, Critical Path Institute</td>
<td>Applying Quantitative Medicine to Regulatory Science: A Case Study in Alzheimer’s Disease</td>
<td>Spring 2016</td>
</tr>
<tr>
<td>Sage, William (Bill) (MD, JD)</td>
<td>James R. Dougherty Chair for Faculty Excellence, Texas Law</td>
<td>Health Law and Health Policy: A Frictional Account</td>
<td>Fall 2015</td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
<td>Topic</td>
<td>Term</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>----------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Professor, Department of Surgery and Perioperative Care, Dell Medical School</td>
<td>Sauer, John Michael (PhD) Executive Director, Predictive Safety Testing Consortium (PSTC), Critical Path Institute; Research Professor, Department of Pharmacology, University of Arizona College of Medicine</td>
<td>Good Research Practices The Federal Regulatory Scheme: Drug Approval, Biosimilars, GXP's and Lab Regulations</td>
<td>Fall 2015 Fall 2016</td>
</tr>
<tr>
<td>Sax, Joanna (JD, PhD) Professor of Law, California Western School of Law</td>
<td>Sax, Joanna (JD, PhD) Professor of Law, California Western School of Law</td>
<td>Are We What We Eat? Proposals for Science-based Regulation of Genetically Engineered Food and Dietary Supplements</td>
<td>Fall 2016</td>
</tr>
<tr>
<td>Sharfstein, Joshua M. (MD) Associate Dean, Public Health Practice and Training; Faculty in Health Policy and Management, Johns Hopkins Bloomberg School of Public Health; Board of Population Health and Public Health Practice of the Institute of Medicine; previously Commissioner of the U.S. Food and Drug Administration</td>
<td>Sharfstein, Joshua M. (MD) Associate Dean, Public Health Practice and Training; Faculty in Health Policy and Management, Johns Hopkins Bloomberg School of Public Health; Board of Population Health and Public Health Practice of the Institute of Medicine; previously Commissioner of the U.S. Food and Drug Administration</td>
<td>Pharmaceutical Dollars and Sense: A Facilitated Discussion Among Experts (Pharmaceutical-Pricing Panel Discussion)</td>
<td>Spring 2017</td>
</tr>
<tr>
<td>Silva, Rick (PhD, MBA) Executive Director, Biomedical Corporate Alliances, University of Arizona Health Sciences</td>
<td>Silva, Rick (PhD, MBA) Executive Director, Biomedical Corporate Alliances, University of Arizona Health Sciences</td>
<td>Precision Medicine</td>
<td>Fall 2016</td>
</tr>
<tr>
<td>Sorooshian, Armin (PhD, MS) Associate Professor, Chemical and Environmental Engineering, College of Engineering, University of Arizona</td>
<td>Sorooshian, Armin (PhD, MS) Associate Professor, Chemical and Environmental Engineering, College of Engineering, University of Arizona</td>
<td>E-Cigarettes: Science, Policy, and Practice</td>
<td>Spring 2017</td>
</tr>
<tr>
<td>Throckmorton, Douglas (MD) Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration</td>
<td>Throckmorton, Douglas (MD) Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research, Food and Drug Administration</td>
<td>FDA Approaches to Opioid Epidemic</td>
<td>Fall 2017</td>
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<tr>
<td>Tsosie, Regents' Professor of Law, University of Arizona</td>
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<td>Ethics of Conducting Research with</td>
<td>Fall 2017</td>
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<tr>
<td>Name</td>
<td>Institution</td>
<td>Topic</td>
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<tr>
<td>Rebecca (JD)</td>
<td>James E. Rogers College of Law; Faculty Co-Chair, Indigenous Peoples Law and Policy Program; Special Advisor to the Provost for Diversity and Inclusion</td>
<td>Vulnerable Populations</td>
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<td>Voss, Gerie</td>
<td>Center for Tobacco Products, Food and Drug Administration</td>
<td>FDA &amp; Tobacco</td>
<td>Fall 2017</td>
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<tr>
<td>Winiecki, Scott (MD)</td>
<td>Center for Biologics Evaluation and Research, Food and Drug Administration</td>
<td>FDA Approaches to Opioid Epidemic</td>
<td>Fall 2017</td>
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MEMORANDUM OF UNDERSTANDING

Graduate College, College of Pharmacy, College of Law

June 14, 2018

BACKGROUND: The College of Pharmacy's PharmD program is a 142-credit, four-year professional degree, which does not require a bachelor's degree for admission. In partnership with the College of Pharmacy, the College of Law has created two new graduate certificates, one in Health Law for Health Professionals and one in Regulatory Science. For students choosing to go further, this coursework may also contribute towards a Masters in Legal Studies (MLS). These programs could be valuable for PharmD students, enriching their education and enhancing their career prospects.

PROBLEM: The Graduate College normally requires a completed bachelor's degree to be eligible for admission into a graduate program. Enforcing that rule would prevent PharmD students from participating in these new programs designed to serve them.

SOLUTION: Upon discussion, the Graduate College has agreed that when a PharmD professional student without a bachelor's degree accumulates a total of 120 credits of undergraduate and PharmD professional coursework, that student would be eligible for admission to the graduate certificate in Health Law for Health Professionals and the graduate certificate Regulatory Science at the University of Arizona. This solution was discussed in a May 2018 meeting with Interim Provost Jeff Goldberg.

SIGNED:

Dean Andrew Carnie
Graduate College

Dean Rick Schnellmann
College of Pharmacy

Dean Marc Miller
College of Law