



INDIANA UNIVERSITY

SCHOOL OF MEDICINE

Graduate Division

Date: June 30, 2016

To: Janice S. Blum, Ph.D.
Associate Vice Chancellor for Graduate Education at IUPUI
Associate Dean of the University Graduate School, Indiana University

From: Randy R. Brutkiewicz, Ph.D. *RRB*
Associate Dean for Research and Graduate Studies, IU School of Medicine

Re: Updates to the Business of Biomedical Sciences doctoral minor

This memo requests changes to the Business of Biomedical Sciences doctoral minor, originally approved by the IUPUI Graduate Affairs Committee (GAC) in May 2014, with approved modifications in March 2016. Since the March 2016 modifications, one required course will no longer be offered (GRAD-G672), requiring the Division to find a replacement course. The replacement course (BUS-W511 – Venture Strategies) is 3 credits, whereas the previous course (GRAD-G672) was 2 credits. This will increase the required number of credit hours for the minor from 9 hours to 10 hours.

Additionally, the required internship for this minor currently uses the GRAD-G718 Research in Biomedical Sciences course, designed for student laboratory rotations. We are proposing a new course designed for an internship, GRDM-G791 (Internship in Biomedical Science), to replace GRAD-G718 in this particular minor.

Previous Requirements (Approved March 2016):

Required Courses (9 credits total):

- GRAD-G718 – Research in Biomedical Science (2 cr.)
- BUS-X518 – Global Trends and Events (1.5 cr.)
- BUS-X519 – Business of Life Sciences (1.5 cr.)
- GRAD-G672 – Translational Research and Entrepreneurship (2 cr.)
- LAW-D/N 698 – Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)

Proposed (New) Requirements:

Required Courses (8 credits total):

- GRDM-G791 – Internship in Biomedical Science (2 cr.)
- BUS-X518 – Global Trends and Events (1.5 cr.)
- BUS-X519 – Business of Life Sciences (1.5 cr.)
- BUS-W511 – Venture Strategies (3 cr.)

Choose one of the following courses (2 credits total):

[Note: these four courses are normally offered for 2 or 3 credit hours. Students should register for 2 credits.]

- LAW-D/N 693 – Life Sciences Compliance Law (2 cr.)
- LAW-D/N 698 – Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)
- LAW-D/N 635 – Drug Innovation and Competition Law (2 cr.)
- LAW-D/N 838 – Bioethics and Law (2 cr.)

Attached is our internal doctoral minor information sheet, for your records. If you have any questions, please contact me at rbrutkie@iupui.edu.

Doctoral Minor: Business of Biomedical Sciences

Minor Contact: Dr. Randy Brutkiewicz, PhD

Minor Description

The “Business of Biomedical Sciences” minor allows our trainees to be highly competitive for the careers in the 21st century biomedical workforce that require doctoral education. We take advantage of the existing structure of the IBMG Program for PhD study for the minor. The ten (10) credit hour “Business of Life Sciences” minor requires that students utilize existing courses in the Schools of Business, Law and Medicine. These courses are listed below in the doctoral minor plan of study.

Plan of Study

Required Courses (8 credits total):

- GRDM-G791 – Internship in Biomedical Science (2 cr.)
- BUS-X518 – Global Trends and Events (1.5 cr.)
- BUS-X519 – Business of Life Sciences (1.5 cr.)
- BUS-W511 – Venture Strategies (3 cr.)

Choose one of the following courses (2 credits total):

[Note: these four courses are normally offered for 2 or 3 credit hours. Students should register for 2 credits.]

- LAW-D/N 693 – Life Sciences Compliance Law (2 cr.)
- LAW-D/N 698 – Intellectual Property of Pharmaceutical Products and Medical Devices (2 cr.)
- LAW-D/N 635 – Drug Innovation and Competition Law (2 cr.)
- LAW-D/N 838 – Bioethics and Law (2 cr.)

Admission Requirements

To be admitted to the Ph.D. minor in Business of Biomedical Sciences, you must be a currently enrolled doctoral student in good academic standing in any IU or IUPUI school. Students in any IU school or department are also welcome to apply.

Application Procedure

Students who would like to apply to the Ph.D. minor in the Business of Biomedical Sciences, must submit via email to Dr. Randy Brutkiewicz, Associate Dean for Research and Graduate Studies and minor contact for this minor, the following:

- Documentation of the approval of the student’s pursuit of this minor by his/her PI and advisory committee.
- A one-page personal statement explaining the student’s reason for pursuing this minor, including the relevance of the minor to their program and goals

Accepted students will be notified promptly via email by the minor contact.

Grading Policy

A minimum of B (3.0) is required in each course that is to count toward the minor. If a minimum of B (3.0) is not earned in a course, that course must be retaken. A course may only be retaken once. Students who fail to achieve the minimum grade of B (3.0) the second time they take a course will not be able to earn the Ph.D. minor.

Qualifying Exam

The Ph.D minor in Business of Biomedical Science does not require a Qualifying Exam

anticompetitive effects in the biomedical industry. Coursework or related experience in intellectual property, patent law or copyright law is required to enroll. No background in pharmaceuticals or medical technology will be necessary, but some knowledge of any of the life sciences or of chemistry will be helpful. Students will be expected to write and present a research paper of adequate length to satisfy the advanced writing requirement when the course is taught as a seminar. This course may be taught either as a seminar or as a regular course.

3. **LAW-D/N 635 - Drug Innovation and Competition Law (2 or 3 cr.)** provides an understanding of the processes by which pharmaceutical exclusivity is obtained and challenged on a global scale. The course examines the interplay between patents, data package exclusivity, pediatric exclusivity, and orphan drug exclusivity; and surveys the procedural and substantive aspects of US Hatch-Waxman litigation, drug reimportation/parallel trade, and exceptions to exclusivity. Finally, it addresses the influence of public policy on the evolution of pharmaceutical exclusivity law.
4. **LAW-D/N 838 - Bioethics and Law (2 or 3 cr.)** D/N 838 examines how the law in bioethics is shaped by the interplay of ethical principles, medical considerations, and social forces. Topics that will be covered include: the refusal of life-sustaining treatment, physician-assisted suicide, organ transplantation, abortion, the balance between individual liberty and protection of the public health, access to health care, and rationing of health care. An important theme of the course will be to consider the extent to which individuals have--and should have--control over medical decision making.

Course Descriptions – Business of Biomedical Science Doctoral Minor

IUSM Graduate Division Courses

1. **GRDM-G791 - Internship in Biomedical Science (2 cr.)**

An internship course allowing incoming basic science doctoral graduate students enrolled in programs (minors, etc.) that require internships. Permission of instructor required.

Kelley School of Business Courses

1. **BUS-W511 - Venture Strategies (3 cr.)**

Prerequisite: J 501 (Contact the IUSM Graduate Division for assistance with waiving the prerequisite, with supplemental pre-course work)

This course is designed for those individuals interested in creating a new business venture, acquiring an existing business, working in industries that serve the entrepreneur, or students wishing to familiarize themselves with concepts, issues, and techniques of new venture creation and entrepreneurship. There is also a strong focus on intrapreneurship, or innovation within a corporate environment. Because the sources of entrepreneurial and intrapreneurial motivation are often quite diverse, the learning goals and objectives of the students in this course are often similarly diverse. Therefore, the course is designed to offer a broad range of educational experiences, including case analyses, presenting and negotiating a financial deal, and creating a business plan or corporate change initiative.

2. **BUS-X518 - Life Sciences Global Events and Trends (1.5 cr.)**

This course exposes students to a variety of trends driving change within the life sciences industry. Topics to be reviewed include increasing worldwide cost pressures, shifts in population demographics, regulatory compliance and approvals, privacy and data protection, emerging market opportunities and ethical issues currently being faced. Discussions will include how different companies are responding to these trends.

3. **BUS-X519 - The Life Sciences Industry from Research to Patient (1.5 cr.)**

This course introduces students to the different parts of the life sciences industry and highlights some of the challenges and opportunities currently being faced. Sections of the industry included are basic science, medical devices, pharmaceuticals/ generic/biologics, distributors, health care providers, insurers, contract services and specialized suppliers. The business of life sciences is made more successful when those involved in the industry recognize and understand the value added at each stage. A Kelley student interested in a life science career will benefit from a deeper understanding of how the whole value chain/network functions.

McKinney School of Law Courses

1. **LAW-D/N 693 - Life Sciences Compliance Law (2 or 3 cr.)** The course examines law and regulation pertaining to the initiation of research projects involving human and animal subjects by both universities and manufacturers. It examines the pertinent government regulations, guidance documents and enforcement initiatives forming the framework for the conduct of clinical trials and focuses upon the practical aspects of clinical trial contracting, application of regulatory guidelines, quality system compliance and corresponding documentation requirements. The course will provide experience in drafting and negotiating clinical trial contract provisions, addressing publication rights, intellectual property ownership, indemnification and confidentiality.

2. **LAW-D/N 698 - Intellectual Property of Pharmaceutical Products and Medical Devices (2 or 3 cr.)** This seminar/course will offer a detailed and high-level analysis of intellectual property law as it applies to medical devices and medical therapeutics, including pharmaceuticals, genetics, proteomics, etc. Topics to be covered are patent law, copyright law and trademark law, as well as some discussion of their potential