

New Course Request

Indiana University

Indianapolis Campus

Check Appropriate Boxes: Undergraduate credit Graduate credit Professional credit

1. School/Division Law 2. Academic Subject Code LAW-D/N

3. Course Number 637 (must be cleared with University Enrollment Services) 4. Instructor _____

5. Course Title International and Comparative Pharmaceutical and Medical Device Law

Recommended Abbreviation (Optional) Intl Comp Pharm Med Devise Law
(Limited to 32 Characters including spaces)

6. First time this course is to be offered (Semester/Year): Spring 2010

7. Credit Hours: Fixed at _____ or Variable from 2 to 3

8. Is this course to be graded S-F (only)? Yes _____ No X

9. Is variable title approval being requested? Yes _____ No X

10. Course description (not to exceed 50 words) for Bulletin publication: This course addresses the major legal issues in bringing pharmaceutical products and medical devices to market, including intellectual property rights, new product approvals before regulatory agencies, regulation of human subjects research and coverage decision-making by third party payers. It compares the regulatory regimes of different countries and supranational organizations such as the European Union.

11. Lecture Contact Hours: Fixed at _____ or Variable from 2 to 3

12. Non-Lecture Contact Hours: Fixed at _____ or Variable from _____ to _____

13. Estimated enrollment: 35 of which 100 percent are expected to be graduate students.

14. Frequency of scheduling: annually Will this course be required for majors? No

15. Justification for new course: Enrichment of curriculum

16. Are the necessary reading materials currently available in the appropriate library? Yes

17. Please append a complete outline of the proposed course, and indicate instructor (if known), textbooks, and other materials.

18. If this course overlaps with existing courses, please explain with which courses it overlaps and whether this overlap is necessary, desirable, or unimportant.

19. A copy of every new course proposal must be submitted to departments, schools, or divisions in which there may be overlap of the new course with existing courses or areas of strong concern, with instructions that they send comments directly to the originating Curriculum Committee. Please append a list of departments, schools, or divisions thus consulted.

Submitted by: [Signature] Date 10/12/09
Department Chairman/Division Director
Academic Affairs Committee Chair

Approved by: [Signature] Date 10/18/09
Dean

Date _____
Dean of Graduate School (when required)

Date _____
Chancellor/Vice-President

Date _____
University Enrollment Services

After School/Division approval, forward the last copy (without attachments) to University Enrollment Services for initial processing, and the remaining four copies and attachments to the Campus Chancellor or Vice-President.