

Final Report of the Task Force on the Bachelor of Science in Pharmaceutical Sciences (BSPS) Program

Submitted to the faculty of the Purdue University School of Pharmacy and Pharmaceutical Sciences, February 3, 2010.

Approved by the faculty of the Purdue University School of Pharmacy and Pharmaceutical Sciences, February 19, 2010

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The Task Force affirms the importance of the BSPS program to the overall mission of the School of Pharmacy and Pharmaceutical Sciences. In the current Strategic Plan, the School's mission includes a focus to "educate and train students to become leading pharmacists and scientists," and further to produce "world class scientists for academia and industry." The continuation of the BSPS provides the School with:

1. An undergraduate program that is consistent with the land-grant undergraduate mission of Purdue University.
2. An opportunity to train entry-level (BS) pharmaceutical scientists.
3. A program from which our undergraduates may pursue advanced professional or graduate education.

Mission Statement

To provide students interested in the multidisciplinary basic sciences that relate to drug discovery, development, and commercialization with classroom and experiential education that spans the pharmaceutical sciences and liberal arts, thus, imparting skills and knowledge that allow pursuit of diverse opportunities in pharmaceutical or related applications, research, or professional/graduate education.

Program Learning Outcomes:

Students of the Purdue University Bachelor of Science in Pharmaceutical Sciences program will be able to demonstrate:

1. A broad knowledge of pharmaceutical and related sciences

The student will demonstrate:

- a basic understanding of chemistry, biology, physics, and mathematics relevant to pharmaceutical sciences
- an understanding of pharmaceuticals, pharmacology, toxicology, medicinal chemistry, therapeutics, and pharmacokinetics.

2. An understanding of drug discovery, development, and commercialization

With this knowledge, the student will:

- be able to demonstrate a high-level understanding of the key stages in drug discovery, development, and commercialization.
- demonstrate an ability to relate applicable scientific disciplines to each stage of drug discovery, development, and commercialization.

- be able to identify the legal and regulatory issues that affect: a) development, b) conduct of research studies used in each phase of drug product development, and c) commercialization.
- be able to identify the questions addressed by research studies used in each phase of drug product development, and the decision-makers who use this information.
- be able to synthesize this information to create a preliminary drug development research plan for all phases of a new compound's life cycle.
- be able to identify the potential roles of BSPS graduates in drug discovery, development, and commercialization.

3. Effective written and oral communication skills

For all students in the pharmaceutical sciences, the ability to effectively communicate via both written and oral media is essential. The need to integrate knowledge and learning in this field requires students to be able to share technical concepts and information with colleagues as well as non-experts. Mastery of oral/written communication will be achieved through a multifaceted approach in both the classroom as well as through practical experiences. Students will be required to apply their technical skill base to produce written documents and oral presentations demonstrating an ability to be clear, concise and show a logical progression of thought. Both individually generated and team-produced documents and presentation skills will be developed and evaluated.

The student will:

- demonstrate proficiency in technical writing and presentations.
- demonstrate knowledge and proficiency with current audio-visual presentation technologies.
- demonstrate an ability to communicate scientific knowledge in non-expert/lay terms.
- develop examples of scientific communications (e.g., abstract, manuscripts, reports, poster presentations).
- demonstrate an ability to critically and constructively evaluate the presentations of others.

4. An ability to integrate and apply knowledge to solve problems

The program will provide opportunities for the student to develop basic problem solving skills including the use of statistical analysis. The curriculum will utilize individual and team projects to strengthen skills in issue identification, root cause analysis, and solution development.

The student will:

- demonstrate the ability to solve technical problems by integrating multi-disciplinary scientific knowledge and interpersonal skills developed through classroom and team project experiences.
- develop interpersonal skills such as influencing others, negotiating and working with others, conflict management, and informal/formal leading others through the problem solving process.

5. An ability to contribute in various roles on effective teams

The student will:

- demonstrate a road-map level understanding of the interconnection between the scientific, clinical, and filing processes that in parallel constitute the backbone of pharmaceutical development
- demonstrate a general understanding of how different areas of expertise must come together in order to discover and develop pharmaceutical products at the level of multi-participant collaboration
- demonstrate an ability to engage in productive professional/technical interactions with specialists from different areas that come together in pharmaceutical development
- demonstrate an ability to become a leading specialist in at least one of the areas of the pharmaceutical sciences that are integral part of pharmaceutical development.

6. Ethical and socially responsible conduct

Evidence of this conduct will come from an ability to identify and exhibit ethical, socially responsible, and socially aware behaviors in the classroom, workplace, and society in general.

The student will:

- demonstrate awareness of cultural and social diversity through interactions with others.
- demonstrate a sense of self, community, and citizenship.
- demonstrate sensitivity to personal values and ethical principles in professional and social contexts.
- develop an understanding of social, economic, and professional responses to change in the pharmaceutical industry.

Proposed Curriculum

The Task Force defined the following topic areas as “core” content for the BSPS program: General Biology, General Chemistry, Plane Anly. Geometry, Calculus, English Composition, Technical Writing, Communication, Anatomy & Physiology, Organic Chemistry, General Physics Basic Statistical Methods, Analytical Chemistry, Basic Pharmaceutics, Biochemistry, Physical Chemistry, Pathophysiology, Drug Development, Medicinal Chemistry, Pharmacology/therapeutics, Basic Pharmacokinetics, Toxicology, Regulatory issues.

Areas such as Immunology, Pharmaceutical Processing, Business Management, Entrepreneurship, Economics, Clinical Development were defined as important, but suitable for elective offerings.

Overview of Proposed Revised Curriculum:

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| Semester 1 | Semester 2 |
| (4) CHM 115 General Chemistry I | (4) CHM 116 General Chemistry II |
| (4) BIOL 110 Fundamentals Biology I | (4) BIOL 111 Fundamentals Biology II |
| (4) MA 165 Analytic Geometry And Calculus I | (4) MA 166 Analytic Geometry And Calculus II |
| (4) ENGL 106/108 First Year Composition (108 Acc) | (3) COM 114 (or other comm. Course) |
| (1) IPPH 100 Pharm Sci Orientation | (3) Humanities/Soc Science elective* |
| (17) | (18) |
| Semester 3 | Semester 4 |
| (4) CHM 255 Organic Chemistry I | (4) CHM 256 Organic Chemistry II |
| (4) MA 261 Multivariate Calculus | (4) BIOL 221 Intro to Microbiology |
| (4) PHYS 220 General Physics I | (3) Humanities/Soc Science elective* |
| (3) BIOL 230 Biology Of The Living Cell | (4-6) Electives |
| (3) Humanities/Soc Science elective* | |
| (18) | (15-17) |
| Semester 5 | Semester 6 |
| (3) BCHM 561 General Biochemistry I | (3) BCHM 562 General Biochemistry II |
| PHRM XXXXX Pharmaceuticals I | (4) CHM 372 Physical Chemistry |
| (2-3)BIOL 301/201/203 Anatomy and Physiology I | PHRM XXXX Pharmaceuticals II |
| (3) ENGL 421 Technical Writing | (3) STAT 511 Statistical Methods |
| (3-6) Electives | (2-3) BIOL 302/202/204 Anatomy and Physiology II |
| (14-17) | (0-3) Elective |
| | (15-18) |
| Semester 7 | Semester 8 |
| (4) PHRM XXX Princ of pathophys and drug action | MCMP XXX Drug Classes/Mechanisms |
| PHRM XXX Drug Discovery & Development I | PHRM XXX Drug Discovery & Development II (Regulatory/Marketing/Business Case) |
| (5-8) Electives | (5-8) Electives |
| (13-16) | (13-16) |
| Graduation requirement: 128 credit hours | |

Red indicates new course or revised course.

*6 credit hours of humanities/social science electives required.

Analytical chemistry requirement: Student must take either CHM 321 Analytical Chemistry I, 4 cr. hrs (recommended for students interested in pharmaceutical manufacturing OR industrial and physical pharmacy research) OR MCMP 514 Advanced Medicinal Analysis, Modules 1 (Energetics,Equilibria,Binding) and 2 (Bioseparations & Applications), 2 cr. hrs (suggested for those students interested in graduate school in biomedical research). These courses may be taken anytime in semesters 5-8.

An alternative “accelerated” chemistry sequence has been proposed to meet the pre-pharmacy pre-requisites, and the Task Force endorses this sequence as an alternative to the traditional chemistry sequence.

Semesters 1-6 with the accelerated chemistry sequence:

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| Semester 1 | Semester 2 |
| (5) CHM 109 General Chemistry I | (4) MCMP 204 Organic Chemistry I |
| (4) BIOL 110 Fundamentals Biology I | (4) BIOL 111 Fundamentals Biology II |
| (4) MA 165 Analytic Geometry And Calculus I | (4) MA 166 Analytic Geometry And Calculus II |
| (4) ENGL 106/108 First Year Composition (108 Acc) | (3) COM 114 (or other comm. Course) |
| (1) IPPH 100 Pharm Sci Orientation | (3) Humanities/Soc Science elective |
| (18) | (18) |
| Semester 3 | Semester 4 |
| (4) MCMP 205 Organic Chemistry II | (4) MCMP 304 Biological Chemistry I |
| (4) MA 261 Multivariate Calculus | (4) BIOL 221 Intro to Microbiology |
| (4) PHYS 220 General Physics I | (3) Humanities/Soc Science elective* |
| (3) BIOL 230 Biology Of The Living Cell | (4-6) Electives |
| (3) Humanities/Soc Science elective | |
| (18) | (15-17) |
| Semester 5 | Semester 6 |
| (2) MCMP 305 Biological Chemistry II | (4) CHM 372 Physical Chemistry |
| PHRM XXXXX Pharmaceuticals I | PHRM XXXX Pharmaceuticals II |
| (2-3)BIOL 301/201/203 Anatomy and Physiology I | (3) STAT 511 Statistical Methods |
| (3) ENGL 421 Technical Writing | (2-3) BIOL 302/202/204 Anatomy and Physiology II |
| (4-6) Electives | (3-6) Electives |
| (14-16) | (15-18) |

Semesters 7-8 remain the same in this sequence.

Suggested electives for all students:

MA 262 Linear Algebra And Differential Eq.

PHYS 221 General Physics II

IPPH 583 Advanced Biopharmaceutics

Suggested electives for those students interested in pharmaceutical manufacturing.

STAT 512 Applied Regression Analysis: Very strongly recommended

STAT 514 Experimental design: Very strongly recommended

IPPH 562 Intro to Pharm Manuf. And Processes: Strongly recommended

IPPH 580 Physical Chemical Principles: Strongly Recommended

IPPH 522 Regulatory affairs: Recommended if desired.

Suggested Electives for those students interested in graduate school.

MCMP/IPPH49000 Research for credit, very strongly recommend a minimum of 6 credits.

MCMP 570 Basic Principles Of Chemical Action On Biological Systems

Other potential electives for the BSPS students are provided in the Appendix.

NOTE: Students should be encouraged to meet with their academic advisers to discuss completion of time-sensitive courses, particularly those courses that meet programmatic and/or minor requirements.

Year 1 (Semesters 1-2)

- Input from alumni consistently indicated a need for rigorous math requirements. The MA 165/166 sequence allows for MA 261 in year 2.
- English composition and a communications course (most likely COM 114) achieve basic needs around written and oral communication.
- IPPH 100 provides an opportunity to orient students to potential career paths, but additional career path counseling should occur in years 2 and 3.
- Humanities/Soc science electives in years 1 and 2 fulfill the overarching undergraduate (BS) mission of this program.

Year 2 (Semesters 3-4)

- Completion of MA 261 sequence meets need and desire for additional math; MA 262 is a suggested course (especially for those interested in manufacturing and IPPH-related graduate programs), but is not required. This course could be taken in years 3 or 4 as well.
- PHYS 221 is considered elective to provide flexibility in the program. Students considering Pre-Med should be advised that two semesters of physics is typically required for entry to medical school.
- BIOL 230 provides a basic overview of cell biology.

Year 3 (Semesters 5-6)

- Basic and intermediate pharmaceuticals should be offered in these semesters:

PHRM XXX Pharmaceuticals I. Maybe compatible with Dosage Forms I in the revised Pharm.D. curriculum. This course provides principles of physical pharmacy and pharmaceutical sciences applied to dosage form design and performance. Overview of traditional dosage forms and manufacturing processes and introduction to kinetics. Topic areas include: Overview of molecular properties and intermolecular interactions, Solid-liquid/solutions and liquid-liquid/emulsions equilibria, Routes of drug administration (oral, topical, parenteral, transdermal, mucosal delivery systems) and overview of dosage forms, Solid formulations, Liquid formulations, Semisolids, Suspensions and other dispersed systems, Basics of manufacturing processes, Overview of chemical kinetics, Basics of dissolution and drug release

PHRM XXX Pharmaceuticals II. May be compatible with Dosage Forms II or Principles of Pharmacokinetics in the revised Pharm.D. curriculum. This course provides principles of pharmacokinetics. Overview of biopharmaceutics and advanced drug delivery systems. Topic areas include: ADME concepts (Drug absorption, distribution, metabolism, pharmacogenomics and excretion), Compartmental/non-compartmental analysis, quantitative training on PK concepts (half-life, T_{max}, C_{max}, volume of distribution, clearance, AUC, bioavailability) with an emphasis on application of PK and ADME concepts to drug development, Passive and active transport, drug transporters, BCS classification, Controlled drug delivery, Autoinjectors, self-injectors and parenteral delivery, Pulmonary delivery, Targeted drug delivery, Nucleic acid therapeutics delivery

- The program will allow considerable flexibility in meeting the Anatomy and Physiology requirement. Any of the BIOL 301/302, 201/202, or 203/204 course sequence will satisfy the program requirement.
- While Technical Writing is offered (and may be taken anywhere in semesters 5-8), it is highly recommended that this course be completed during semesters 5 or 6.
- Analytical Chemistry (CHM 321 Analytical Chemistry I) is elective (but highly recommended for those interested in pharmaceutical manufacturing). An alternative is to take “analytical” modules in MCMP 514 Advanced Medicinal Analysis.

Year 4 (Semesters 7-8)

Four new or revised courses would need to be developed.

PHRM XXX Principles of Pathophysiology and Drug Action. This is a new course in the revised Pharm.D. curriculum. This course will introduce principles of pathophysiology, medicinal chemistry, drug action, ADME, and toxicology. Topics will include: Pathophysiology (Cell Injury, Adaptation, and Death, Acute and Chronic Inflammation, Tissue Repair, Wound Healing, Cell Regeneration, and Fibrosis), Medicinal Chemistry (Classification of drugs by source, chemical type, and therapeutic use, Impact of chemical and physical properties of drugs & structure/activity relationships, Sources and production of drugs), Pharmacology (Receptor binding equilibrium theory, Affinity and potency, Efficacy; full and partial agonists; antagonists, Principles of enzyme inhibition), ADME (Absorption, Biodistribution, Metabolic activation and inactivation/pharmacogenomics, Secretion and excretion), Toxicology.

MCMP XXX Drug Classes/Mechanisms. This course will involve the integration of basic concepts in organic chemistry, biochemistry, and physiology in order to gain an understanding of how drugs act at the molecular level. It will provide a survey of representative examples drawn from various drug classes with emphasis on mechanism of action and therapeutic uses. This should provide students with an understanding of the relationship between chemical structure and biological activity and it should also provide insights of value in drug design. Topics will include: Introduction to Medicinal Chemistry, Introduction to Pharmacology, Autonomic Agents, Other Cardiovascular Drugs, CNS Agents, Anti-infective Agents Anti-cancer Agents, Endocrine Drugs, and Diabetes Drugs.

PHRM XXX Drug Discovery & Development I. This course will cover issues and topics related to early-stage development of pharmaceuticals. Topics would include: Discovery, drug screening, target validation, synthetic medicinal chemistry, preclinical safety and toxicology, early formulation, ethics, intellectual property, evaluation in humans (IND, Phase I, Phase II).

PHRM XXX Drug Discovery & Development II. The course will provide a review of the regulatory framework within which the drug development process occurs. It will also present the impact of marketing and business considerations on the process. Topics would include: Regulatory Landscape – FDA, ICH, USP, PhEur, etc., Good Laboratory Practices, Investigational New Drug application, Good Clinical Practices, Good Manufacturing Practices, New Drug Application, New Indications, Line Extensions, Role of Marketing in Development, Business Case Development (product differentiation, value proposition, stakeholders, etc.), Tailored therapeutics (Pharmacogenomics).

Other Considerations:

Recruitment. The BSPS committee should work with OSS staff to create a comprehensive marketing plan for the BSPS program targeted to high school students. The program, if it is to be successful, needs to be marketed to high schools along with the Pharm.D. program. It is important that career options be accurately communicated including entry-level technical professional positions in industry as well options to pursue advanced study (graduate school/research or professional school). The success of BSPS alumni in achieving technical/professional leadership positions should be highlighted.

Admissions. The Task Force supports direct admission of freshman to the BSPS program. This provides a recruiting advantage (no second admissions process), perhaps assisting in attracting top quality students. As space and over-enrollment issues are not apparent, removing the admissions process in year 2 seems reasonable. The Task Force supports a requirement for students meeting a minimum 3.0 GPA to advance into semester 5. The BSPS Committee for the SoPPS may wish to consider whether additional requirements for moving into years 3-4 are justified.

Immunology and Biotechnology. As these courses are developed or revised for the new Pharm.D. curriculum, they should be reviewed by the BSPS committee to determine whether they should be included in the BSPS core curriculum.

Research and Internships. The Task Force endorses the continued use of research for credit or internships as elective options to gain “real world” experiences in the pharmaceutical sciences.

Capstone Project. A Capstone Project/Experience, similar to those found in other programs (e.g., BME 405, NUR 409, HORT 425) was considered. Capstone projects are typically designed to assess learning outcomes and the overall curriculum. They rely on student application projects or research that is unique and may have previously undetermined solutions, requiring students to integrate all of their learning, from both classroom and “outside” exposures, to research, analyze, solve problems, propose solutions, and defend their proposals. The Task Force is interested in such a requirement for the BSPS program, but would recommend further development by faculty to fully consider such a component for the BSPS program. After full development, the Capstone Project/Experience requirement should be considered by the faculty as a whole. The Task Force encourages consideration of a broad range of experiences including laboratory research projects for the Capstone Project/Experience.

Tracks. The Task Force endorses a single core curriculum. Suggested electives will be provided for students interested in either pharmaceutical manufacturing or graduate school.

Minors. BSPS students should have sufficient flexibility in their schedules to pursue minors. The most common minors would include biology, biotechnology, chemistry, communication, economics, management, organizational leadership/supervision, and statistics. Those students who are primarily interested in medical school have been inclined toward philosophy, psychology, and foreign languages.

Graduate Degrees. The development of the proposed M.S. in Pharmaceutical Sciences and Engineering may provide additional opportunities for BSPS students. The Task Force encourages the consideration of a 4+1 option between these programs.