



Request for Proposals: A baseline evaluation of the integration of the
“Science of Safety” into the curriculum of the Doctor of Pharmacy degree in
U.S. colleges and schools of pharmacy

Submitted to the Membership of the American Association of Colleges of Pharmacy on
November 11, 2008

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Background

The Food and Drug Administration (FDA) is interested in improving its understanding of how pharmacy professionals are educated in the “science of safety.” This assessment of the knowledge and skills of pharmacy professionals related to medication safety will determine the extent to which these professionals might be utilized to assist the FDA in meeting its strategic goals. The FDA is interested in learning how the concepts of the drug life-cycle are integrated into the pharmacy curriculum.

The public expectations of the FDA have increased substantially over the last decade. These expectations are both a challenge and opportunity for the FDA. The FDA is actively engaged in determining which of its stakeholders can assist the agency in successfully meeting these expectations. The agency has taken the opportunity to address these expectations internally through a variety of mechanisms including the FDA Strategic Plan [<http://www.fda.gov/consumer/updates/strategicplan022908.html>] and initiatives implementing the legislative mandates of the Food and Drug Administration Amendments Act (FDAAA).

The current FDA strategic plan includes four main goals:

1. Strengthen the FDA for Today and Tomorrow:
Pharmacy professionals and academic research can actively participate to enhance the science knowledge of the FDA through programs such as Sentinel [<http://www.fda.gov/oc/initiatives/advance/#sentinel>], Critical Path [<http://www.fda.gov/oc/initiatives/criticalpath/>], and the Adverse Event Reporting System (AERS) [http://www.fda.gov/cder/aers/potential_signals/].
2. Improve Patient and Consumer Safety:
The FDA recognizes that an essential role for improving patient and consumer safety is effective communication of the risk associated with medications, devices and biologics. Pharmacy faculty and pharmacists are well positioned to help create effective communication tools as well as using these tools to improve patient safety. Knowledge about the science of safety for drug development and use is crucial to developing tools and messages that will enable pharmacists to more effectively communicate drug safety issues to patients and consumers. Detailed information about this goal can be found at [<http://www.fda.gov/consumer/updates/strategicplan022908.html>].
3. Increase Access to New Medical and Food Products:
The demand for new, safe and effective medical and food products has never been greater. The Critical Path Initiative is an opportunity for academic pharmacy and pharmacists to be engaged in meeting this demand. The desire to improve the utilization of drug products requires heightened communication among prescribers, pharmacists and patients. Direct to consumer advertising presents an additional opportunity for the pharmacist and is highly dependent on significant communication skills and the ability to translate new knowledge.

4. Improve the Quality and Safety of Manufactured Products and the Supply Chain: Continued improvement of the quality and safety of products and maintaining this quality in the supply chain requires the FDA to seek vigilant partners competent to detect sentinel events and report them. Pharmacists are positioned to be a vigilant, front-line partner; success as a partner is dependent on his or her pharmacoepidemiologic knowledge, familiarity with adverse event reporting programs and effective communication.

The FDA is also focused on implementing the Food and Drug Administration Amendments Act of 2007 [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110]. For example, in 2007 the agency announced the Safety First/Safe Use Initiative. *Safety First* refers to steps FDA's Center for Drug Evaluation and Research (CDER) can take to strengthen and modernize its internal policies and processes to manage significant drug safety issues. *Safe Use* describes CDER's mission to collaborate with stakeholders in the healthcare system to devise effective, efficient steps to ensure drugs are used as appropriately as possible and in ways that minimize medical errors and manage risks aggressively. Many of the legislation's provisions recognize the importance of the FDA seeking the input of academic institutions for comprehensive implementation.

The totality of the FDA's initiatives, strategic goals and legislative requirements, many of which are focused on the drug life cycle, can be described as the science of safety.

Project Overview

The American Association of Colleges of Pharmacy (AACP) seeks proposals for an assessment of U.S. colleges and schools of pharmacy's curricular inclusion of patient safety concepts described by the Food and Drug Administration (FDA) as the science of safety. The FDA is interested in knowing how the concepts of the drug life-cycle are integrated into the pharmacy curriculum.

Interested individuals must submit their proposals to AACP by 5:00 p.m. EST on December 19, 2008. Proposals are to be submitted via e-mail to wlang@aacp.org.

Project Details

The goal of this proposal, through survey and case study development, is to determine the extent to which the science of safety is integrated into the pharmacy curriculum. The information from this project will provide the FDA with the necessary information to continue to build its expectations and utilization of academic and professional pharmacy to accomplish the agency's strategic goals and legislative mandates. This baseline assessment of the pharmacy curriculum regarding the science of safety will provide a platform for continued collaboration between AACP and the FDA.

The baseline assessment is to be determined through a survey sent to all accredited U.S. colleges and schools of pharmacy. The survey will be constructed in such a manner that analysis of the input will allow for a determination of the extent to which the science of safety is addressed in the professional degree program. Consideration should be given to

how this survey might lend itself to future application to assessing other health professions and the integration of the science of safety into their curricula.

Additionally, the project will seek to determine how the science of safety can be mapped throughout a professional degree curriculum. This determination will be accomplished through case studies based on the input of five (5) accredited U.S. colleges and schools of pharmacy that have recently mapped their entire professional degree curriculum. This will provide the opportunity for best-practice identification and possible future collaboration between AACCP and the FDA.

The results of this project will also be beneficial to increasing the opportunities for collaboration between U.S. colleges and schools of pharmacy and entities eligible for the 340B drug discount program supported through the Pharmacy Services Support Center, which is managed by the American Pharmacists Association (APhA), and those engaged in the Health Resources and Services Administration Office of Pharmacy Affairs Patient Safety Collaborative [<http://www.hrsa.gov/patientsafety/>]. These opportunities for collaboration include improving the teaching of the science of safety so that patient safety is improved across our healthcare delivery system including those sites serving underserved and underinsured populations.

Dissemination of the project analysis and results will be an important component of this project. The successful investigator must demonstrate a record of success in having his or her research accepted for publication in world-class peer-reviewed journals including the *American Journal of Pharmaceutical Education* (AJPE). The successful investigator will also be expected to present the results of this project to national audiences.

Submission Instructions

Interested individuals must submit their proposals to AACCP by 5:00 p.m. EST on December 19, 2008. Proposals are to be submitted via email to wlang@aacp.org. Proposals should be no more than eight single-pages in length. The document should be formatted with 1 inch margins and a font size of no less than 11-point. Proposals will include:

1. Telephone number, mailing and e-mail address of the primary investigator.
2. Budget and justification for each aspect of the investigators project including personnel, travel and supplies. The investigator must indicate the total amount of funding, including indirect costs, they are requesting to complete the project.
3. Timeline for completion of the tasks listed in this RFP.
4. Describe survey methodology and the primary investigator's ability to coordinate input from within the Academy.
5. Biographic information of the primary investigators and any other individual working with the primary investigator. The bios will not count toward the proposal page total.
6. Description of primary investigator's research portfolio related to patient safety and the application of this research to pharmacy curriculum.
7. Description of the primary investigators demonstrated capacity to create, collect and analyze survey and other qualitative data.

8. List of articles in peer-reviewed publications.
9. Description of relationships with patient safety organizations such as Centers for Education and Research on Therapeutics (CERTs), the HRSA Patient Safety Collaborative and/or Institute for Safe Medication Practices (ISMP).

Timeline

November 11, 2008	Request for proposals is made public
November 24, 2008	Conference call to clarify project to interested individuals
December 19, 2009	Proposal submission deadline to AACP
December 24, 2009	AACP announces awardee
January 6, 2009	Awardee begins work
January 12, 2009	Advisory Group/Awardee call prior to work initiation
February/June 2009	Progress conference calls with awardee, and Advisory Group
September 23, 2009	Project completed and submitted to AACP

Review Criteria

All proposals that comply with the above submission instructions will be reviewed by a team consisting of AACP and FDA staff. Individual critiques of submitted proposals will not be available. Proposals will be reviewed using the following criteria:

1. Compliance with submission instructions
2. Strength of submitters prior patient safety research experience and its application to the pharmacy curriculum
3. Clearly defined methods and description of how submitter will meet deliverables time table
4. Strength of the budget and justification.

Requests for Additional Information

All questions related to this RFP should be directed to wlang@aacp.org.