

FOR IMMEDIATE RELEASE

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Industry expert provides real life drug and device development experience to Kelley School of Business

INDIANAPOLIS, Indiana – Life Sciences is a growing industry in the state of Indiana. Recognizing this, Indiana University’s Kelley School of Business has created the course “The Business of Life Sciences: Life Science Global Events and Trends.” The focus of this course is to overview the key trends shaping the future of life sciences companies – demographics, globalization, regulation, cost controls, mergers and acquisitions, scientific discovery, and technological innovation.

As a part of the impressive lineup of industry speakers that will present throughout the semester, Gretchen Bowker, Director of Regulatory Affairs and Compliance Services for Safis Solutions, will be speaking on January 27, 2009. Bowker is a protein chemist who has spent her career in product development, regulatory, and quality roles at large companies such as Lilly, Roche, and for the past three years, at Safis Solutions leading their team of regulatory and quality specialists. Utilizing her extensive industry experience, she will present on the topic of “Government Regulation at Home and Its’ Use as a Trade Barrier.” During this session she will be discussing the implications of regulatory approval, inspection, compliance, and quality standards on the product development life cycle. “In order to succeed in a pharmaceutical, biotech, or device company, scientists and business leaders must appreciate and understand the regulatory hurdles and quality compliance standards required in this industry. Safis Solutions is pleased to support the Kelley School in their efforts to educate students on the nuances of life sciences,” adds Diana Caldwell, Director, Sales and Marketing for Safis Solutions.

About Safis Solutions: Safis Solutions, LLC is a regulatory compliance consulting company serving pharmaceutical, medical device and biotech companies worldwide to ensure health authority requirements are met. Areas of expertise include regulatory approval, clinical strategies, quality systems, validation, IT services, auditing, and post-market surveillance programs. Visit us online at www.safis-solutions.com.

To learn more about Indiana University Kelley School's *The Business of Life Science* course, visit online <http://newsinfo.iu.edu/web/page/normal/6770.html> .

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