As the competition among life science companies intensifies, it is becoming increasingly important to find ways to reduce the costs of product development—in terms of both money and time spent getting products to market. Project management has greatly improved the productivity in aerospace and in software development, and is poised to engender the same successes in the life sciences industry.

The University of California, Irvine Extension’s certificate program, Project Management for Life Sciences, focuses on the application of project management best practices to life science industries that produce pharmaceuticals, medical devices, and other biomedical products used by the medical profession.

**Target Audience**
The Project Management for Life Sciences certificate program is designed for product managers and research directors responsible for moving new product concepts through the development, regulatory approval, and marketing processes. The program is also of interest to others who have a vested interested in seeing new products move quickly through the development lifecycle. This program has also been created for students who already have an understanding of fundamental project management principles, such as project managers with experience in other industries who wish to make a transition to the life sciences field.

**Program Benefits**
- Learn to apply project management best practices to the pharmaceutical or medical device product areas with goals of achieving shorter times-to-market, better-designed products, and smoother regulatory approvals
- Apply facilitative leadership skills to improve project management effectiveness
- Develop and lead teams of diverse individuals from both within the organization, and among different organizations (including international teams)
Course Offerings:

The Project Management for Life Sciences certificate program targets both the pharmaceutical and medical device industries. Most of the courses are appropriate for both industries while others are specific for one or the other, as specified below each course title.

Required Courses:

Overview of Project Management for Life Sciences

BOTH INDUSTRIES

Learn to apply fundamental, widely-used project management principles to the pharmaceutical and medical device industries, taking into account regulatory requirements, clinical trials, and other unique aspects of their product development lifecycles. Review fundamental project management concepts with special attention to biological science industries, examination of project scope, planning, and risk in the development of FDA-regulated products and exploration of the importance of project managers with some technical knowledge in order to be effective.

Facilitative Leadership in Project Management

BOTH INDUSTRIES

Become an effective and productive leader in your pharmaceutical company. Learn how to apply facilitative leadership techniques in the management of pharmaceutical product projects. The workplace environment and the nature of the pharmaceutical product are unique to this industry and warrant specialized treatment. Topics of study include leadership vs. management, approaching your leadership challenges from a global perspective, negotiating and influencing, effective communications, and building high-performance teams.

Global Aspects of Team Leadership and Alliance Management

BOTH INDUSTRIES

Today, many pharmaceutical and medical technology companies have workers scattered around the globe. Project teams may have members in geographically diverse locations, posing interesting challenges for the project management process. This course shows you how to lead a culturally and geographically diverse team taking into consideration different cultural norms, working styles and educational backgrounds. You'll also explore tools for managing your team virtually (over the Internet).

Elective Courses:

Regulatory Requirements for Medical Devices

BOTH INDUSTRIES

Increase your understanding of essential U.S. medical device regulations, including device classification, organizing pre-market notification 510(k), and planning and submitting a Pre-market approval (PMA). Enhance your knowledge of topics such as global vigilance requirements and labeling requirements, European Medical Device Directive 93/42/EEC (MDD), E.U. conformity assessments, meeting E.U. essential requirements, and developing a technical file for the E.U. Get a review of device registrations in Canada, Australia, Japan and Latin America.

Regulatory Requirements for Pharmaceutical Products

BOTH INDUSTRIES

Get a detailed overview of the regulatory requirements necessary for the development and manufacture of pharmaceutical products. Individuals involved in manufacturing, quality control, research and development, and clinical studies will learn the latest information. Explore topics from the product development process through commercialization; product characterization and pre-clinical evaluation; pharmaceutical industry requirements; clinical trial requirements and good manufacturing practices (GMPs); good laboratory practices (GLPs); FDA inspections, labeling, and advertising of medical products; and preparing Food and Drug Administration (FDA) submissions.

Research Project Management

BOTH INDUSTRIES

Project and functional managers in today’s highly competitive biotechnology industry must possess key managerial and technical competencies, business knowledge and strategic insight in order to perform both individually and as members of a team contributing to the success of their organizations. This course focuses on the special aspects of project management in the research & development and discovery phases of product development. This highly interactive course encourages active participation in the learning process, and immediate application of the tools and skills learned in the course for improved project performance.

Pre-Clinical Project Management

BOTH INDUSTRIES

This course is in development.

Clinical Project Management

BOTH INDUSTRIES

Learn to implement project management principles as they apply to pharmaceutical or medical device clinical trials. Coursework covers project strategies, scope definition, schedule and budget creation, enrollment forecasting, project tracking tools and applied risk management techniques relevant to the industry. Discussion covers differing trial requirements for investigational product development phases, and various regulatory approaches to market approval. Real-world case studies will be presented, and students will have an opportunity to work as a team to create a complete clinical trial project plan.

Chemistry, Manufacturing, and Control (CMC) Project Management

BOTH INDUSTRIES

Learn to implement project management principles as they apply to pharmaceutical or medical device clinical trials. Coursework covers project strategies, scope definition, schedule and budget creation, enrollment forecasting, project tracking tools and applied risk management techniques relevant to the industry. Discussion covers differing trial requirements for investigational product development phases, and various regulatory approaches to market approval. Real-world case studies will be presented, and students will have an opportunity to work as a team to create a complete clinical trial project plan.

Medical Device Project Management

BOTH INDUSTRIES

Medical device project managers must understand hardware and software development practices, and how to apply project management methodologies to both areas. Learn how to approach a medical device project—from the business proposal to justify the project, to evaluating and mitigating risks, and executing quality assurance processes. Discover the impact of regulatory requirements and explore the application of project management best practices on the development process.

Organizational Change and Process Improvement

BOTH INDUSTRIES

The pharmaceutical and medical device industries are enjoying a period of rapid growth and change—bringing both opportunities and challenges. This course looks at change from the perspectives of organizational governance and process improvement. Learn to establish effective governance for a change or process improvement project; apply Six Sigma concepts and lean principles to a process improvement project; and effectively manage. Discover how to ensure that a project that effects change through business process improvement is completed successfully.
“Life Science projects are unique in that they are typically capital intensive, long term, high risk, and require human resources from various functional areas. To obtain the most business value it is critical to manage projects in a systematic way using good project management principals. The entire project team should be versed in project management to be most effective. The value of project management to a company is in maximizing project success and to an individual is in developing transferable leadership skills.”

-- Tom Smagala
Engineering Specialist, B. Braun

ADVISORY COMMITTEE

The following professionals contributed their knowledge and time to the development of this certificate program:

- Nancy Belford, Senior Project Manager, Advanced Medical Optics
- Anna Crici, Vice President, Project Management & Business Process Development, Amylin Pharmaceuticals, Inc.
- Sue Fisher, Senior Consultant, Project Performance Services, Inc.
- Greg Kohler, Senior Program Manager, Biogen Idec
- Eric Morphey, Partner, Critical Skills, Inc.
- Aileen Morgan, Senior Global Project Manager, Allergan
- Tom Smagala, Engineering Specialist, B. Braun Pharma
- Marty Wartenberg, Chief Inventor, Zero Boundary
- Graeme Wilson, Head of R&D Project Management, Amylin Pharmaceuticals Inc.

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Certificate Requirements
Students must complete all required courses and four elective courses for a total of 16 units. Students must earn a grade of “C” or better in each course in order to be eligible for the certificate. (One unit corresponds to 10 hours of classroom time or the equivalent amount of content in an online course.)

About UC Irvine Extension
As the continuing education arm of UCI, UC Irvine Extension is dedicated to providing a university-level learning experience for students, offering thousands of exciting courses and programs to local, regional, and global constituencies. UC Irvine Extension offers a rich array of academic and community programs to support a diverse audience, from a wide selection of academic programs to numerous campus activities.

For More Information
Please visit extension.uci.edu, or email Brian Breen at Brian.Breen@unx.uci.edu