

Xavier Health

Medical Device Leadership Certificate

Course Syllabus

A. Course Description

The Medical Device Leadership Certificate is offered through Xavier Health of Xavier University in Cincinnati, Ohio. The certificate is completed during a 10-month period. During the 10-month period students will receive approximately 50 contact hours of content, including two 2-day on-campus events. The course is evaluated with PASS/FAIL criteria. The student must also demonstrate application of learning by completing a Capstone Project. Upon successful completion of the course the student will earn a certificate of completion worth five (5.0) Continuing Education Units (CEUs) as well as a waiver for three (3) Credit Hours toward a Xavier University Masters in Business Administration (MBA) or two (2) Credit Hours toward a Xavier University Health Economics and Clinical Outcomes Research (HECOR) Degree.

B. Course Objectives

The certificate is designed to accelerate the development of High Performers with immediate business impact. As a result of this certificate program, students will be able to implement and execute successful business strategies tied to positive patient impact throughout the Total Product Lifecycle (TPLC) - aligned with the global mission and vision of their company.

C. Course Topics

The certificate is broken down into 10 Modules:

1. **Setting the Foundation:** Pre-requisites, assignments, and readings to prepare you for subsequent Modules and the course as a whole.
2. **Industry Structure and Stakeholders:** Gain an understanding of the Medical Device Industry Landscape and how stakeholders impact one another and the business.

3. **Your Company Game Plan:** Gather insight on the competitive environment of your business in the global market and how you fit-in to the business plan of your company.
4. **Leadership in Balance:** Interact with other cohort members during this on-campus Module. Receive 1-on-1 professional coaching sessions based on the results from your Leadership Self-Assessment and 360 Review.
5. **TPLC Roadmap:** Begin the technical portion of the course by learning from FDA and Industry Experts about expectations and implementation of the Total Product Lifecycle.
6. **Stage Gate Model Application:** Introduction to the Stage Gate Model that you will use to successfully complete the Case Study Project in Modules 7-9.
7. **TPLC—Design and Development Stage:** Critical aspects of the design and development stage will be put into action using the Case Study Project, incorporating the Stage Gate Model, and understanding outcomes of FDA interaction.
8. **TPLC—Quality Operations:** In this module, you will work through scenarios related to the device in the Case Study Project that require effective leadership and broader company and regulatory awareness.
9. **TPLC—Production and Post-Production Stage:** Exposure to the on-going responsibilities and expectations after product launch will be put into action through technical and ethical challenges that must be resolved, and applied to the Case Study Project.
10. **Capstone:** Formal Capstone Projects are presented to an outside panel of experts that require the students to apply all learning related to Leadership awareness, Technical competency and FDA interaction. A final professional coaching session leaves students armed with transformational action plans.

D. Texts and Materials

You will be required to purchase one textbook. Other materials will be sent to you via email. Required and suggested support for the course is listed below:

- **Textbook—Leadership in Balance: New Habits of the Mind** by John F. Kucia & Linda S. Gravett, ISBN-13: 9781137394330
- **Management Sponsor**—It is highly encouraged, but not required, for you to have a management sponsor at your company throughout the course. The sponsor's purpose is to answer questions, discuss action plans, and provide insight. We believe the support of a sponsor will greatly increase the value of the course for you.

- **Transportation to and lodging in Cincinnati, OH for the two on campus modules**—If you would like recommendations on travel arrangements (airports, hotels, etc.) and the location of the Cintas Center on Xavier University’s campus, where the on-campus events will be held, please review the document titled “Travel Logistics to Xavier University.” For a special rate at the Hilton Netherland Plaza Hotel in Downtown Cincinnati please view the “Hilton Discount Flyer” document in your welcome packet. If you have questions about logistics please contact Stacie Ball at balls2@xavier.edu or 513-745-3483. The dates for the two on-campus modules are:
 - **May 23-24, 2017 (8:00am to 5:00pm EST)**
 - **November 23-24, 2017 (8:00am to 3:00pm EST)**

E. Grading and Reporting

This course is graded on a PASS/FAIL basis. In order to receive a “PASS” in the course you must complete the following:

1. View 100% of all on-demand material.
2. Complete all assignments as prescribed by the syllabus. No more than two assignments can be completed late and they must be completed within two weeks of the due date.
3. Submit the Leadership Self-Assessment by the due date as prescribed by the syllabus.
4. Submit the 360 Review by the due date as prescribed by the syllabus.
5. Attend both on-campus events. If a conflict arises, arrangements can be made to attend a subsequent cohort’s on-campus event.
6. Complete the Capstone Project.
7. Complete evaluation forms.

Note: Xavier Health faculty reserve the right to adjust this criteria for unique situations on a case-by-case basis.

F. Course Schedule

Format	Schedule	Session Description	Faculty	Notes
1a Assignment	Date Available 3 January 2017 Date Due 27 January 2017	Meet and Greet Slides- Each student is to update the Meet and Greet slide template with their picture and bullet points on their bio as prompted in the template. This will be used to introduce you during the Meet and Greet Virtual Meeting where students and board members will meet each other, and students will have a chance to ask questions about the program.		
1b Assignment	Available 3 January 2017 Due 27 January 2017	Leadership Self-Assessments- Complete a short and long self-assessment to evaluate how you think as a leader. Results from the self-assessments will be reviewed on campus when you will receive a professional one-on- one coaching session and create action plans. Submit completed assignments via email to balls2@xavier.edu		Complete before reading <u>Leadership in Balance</u> excerpts and articles
1c Assignment	Date Available 3 January 2017 Due Date 3 March 2017	360 Review. Participants have their colleagues fill out and submit the 360 review. Please choose colleagues consisting of; 1) at least one report (direct or indirect), 2) at least two peers (one cross functional and one within your discipline) and 3) at least one superior or supervisor. If you interact with external stakeholders, have them complete the online 360 review. A link for the form is: http://www.gravett.com/qara Share the link with those who are reviewing you.		Issue to specified respondents a sample cover memo that is included in your welcome packet to better explain the intent of their input.

1d Reading Assignment	Available 3 January 2017 Due 1 May 2017	Read the text book; <u>Leadership in Balance: New Habits of the Mind</u> by John Kucia and Linda Gravett Read the entire book prior to first on-campus session		Do not begin readings until you have submitted
2a Reading Assignment	Available 3 January 2017 Due 28 February 2017	Read Fortune Article titled “ Humans are Underrated ” by Colvin Read the <i>New York times</i> Corner Office Articles (5 one-page articles in one PDF) and complete the Interview Assignment included in your Welcome Packet. Submit completed assignments via email to balls2@xavier.edu		
2b Web-Meeting (60 min)	Date of Meeting 10 February 2017	Meet and Greet Virtual Meeting- The students and Board members will join a virtual Meet and Greet web meeting to meet each other. The Board will have an opportunity to explain the vision for the program, and the students will have an opportunity to ask questions.		
3a On-Demand (20 min)	Date Available 1 March 2017 Due Date 31 March 2017	Industry Landscape Gain a deeper understanding of the medical device industry landscape and history.	Jim O’Reilly	
3b Assignment	Date Available 1 March 2017 Due Date 31 March 2017	O’Reilly Landscape question Submit completed assignment via email to balls2@xavier.edu		

3c On-Demand (20 min)	Date Available 1 March 2017 Due Date 31 March 2017	Industry Stakeholders. Gain a better understanding of external and regulatory stakeholders and how they impact your company and each other.	Susan Rolih	
3d Assignment	Date Available 1 March 2017 Due Date 31 March 2017	Rolih Stakeholder question Submit completed assignment via email to balls2@xavier.edu		
3e On-Demand (20 min)	Date Available 1 March 2017 Due Date 31 March 2017	CEO Perspective- CEO Jack Kraeutler (Meridian Bioscience) shares with you what a CEO expects from leaders throughout the organization.	Jack Kraeutler	
3f On-Demand (20 min)	Date Available 1 March 2017 Due Date 31 March 2017	Funding Strategy- Jason Barkeloo shares the various sources of funding so you as a senior leader will better understand the stability of your organization, potential acquisition and merger companies, and suppliers. The insight will help you make strategic decisions within and outside your organization.	Jason Barkeloo	Slides not available
4a Assignment	Date Available 1 April 2017 Due Date 30 April 2017	Elevator Pitch #1. Prepare (write and record) a short elevator speech about something important enough to deliver to your supervisor. "Ask" for something or include a "call to action." Submit written and recorded versions to balls2@xavier.edu		

4b On-Demand (46 min)	Date Available 1 April 2017 Due Date 30 April 2017	Getting to know your Company Game Plan. Learn how your company makes money and where they compete. Recognize the vital role internal stakeholders play and how external events affect your business.	Cecilia Kimberlin	
4c Assignment	Date Available 1 April 2017 Due Date 30 April 2017	Assessment of Objectives Worksheet. Discover how well your objectives align with the company's vision, mission, and strategy. Compare your objectives to those of your cross functional partners. Submit completed assignment via email to balls2@xavier.edu.		Requires interaction with cross-functional partners
4d On-Demand (52 min)	Date Available 1 April 2017 Due Date 30 April 2017	Objective Setting Strategies. You are a Strategic Partner within your company, now find out why. Explore ways to collaboratively work with cross functional stakeholders and include their objectives in your objective setting process.	Cecilia Kimberlin	
5a On-Campus	Start Date 23 May 2017 End Date 24 May 2017	On Campus Event 1. During this interactive session you will receive professional one-on-one coaching, gain an appreciation for the balancing act a CEO performs among employees, customers, and shareholders with market demands. Take part in ethical business decision situational analysis and learn how to become a better leader in a time of crisis.	Linda Gravett John Kucia	Travel to Cincinnati, OH required. Please refer to "Travel Logistics to Xavier University" for travel

5b Assignment	Start Date 23 May 2017 Due Date 16 October 2017	Capstone Project – Presentation Outline. You and your partner will begin preparations for your capstone presentation to a panel of outside executives. You must prepare an outline of preliminary information regarding your presentation to be sent by October 16 th . Submit completed assignment via email to balls2@xavier.edu.		
6a Assignment	Date Available 1 June 2017 Due Date 30 June 2017	Decision Making Worksheet. Determine how critical decisions are being made at different levels and by cross functional employees. Characterize how your company is making decisions and identify if dysfunction exists. Submit completed assignment via email to balls2@xavier.edu		Requires interaction with cross-functional partners
6b Assignment	Date Available 1 June 2017 Due Date 30 June 2017	TPLC Map. You and your assigned partner will complete portions of the Total Product Lifecycle map together. Submit completed assignment via email to balls2@xavier.edu.		The next two sessions are dependent on the completion of

6c On-Demand (1 hr, 58 min)	Date Available Do not view until you have completed assignment 6b Due Date 30 June 2017	TPLC Explained. Faculty will explain critical activities during development, production, and post-production to be conducted when the target is to achieve “Right First Time”. Importantly, the TPLC process needs to include an understanding of inputs and outputs, triggers for escalation, and what requires the need to go back to design. Ultimately, the goal is to have the device meet the intended use, which includes patient safety; therefore, post-production indicators need to feedback into the process. Participants will also gain a greater understanding of what constitutes the Cost of Poor Quality.	Gina Brackett Steve Niedelman Monica Wilkins	
6d On-Demand (13 min)	Date Available Do not view until you have completed assignment 6b Due Date 30 June 2017	TPLC Check on Learning. Compare your TPLC Map in assignment 6b with the one presented in this session.	Bill Brodbeck	

July sessions and assignments are suspended for the summer

7a On-Demand (20 min)	Date Available 1 August 2017 Due Date 31 August 2017	Clinical strategy - trial design. Clinical trials are time consuming and costly. This session prepares you as a senior leader to understand how best to design clinical trial studies to support the success of your product.	Sheryl Helsinger Lisa Allgood	Slides not available
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7b On-Demand (20 min)	Date Available 1 August 2017 Due Date 31 August 2017	How to build a successful Regulatory Strategy. This session provides an overview of key elements needed to develop a successful US-based regulatory strategy, from the perspective of: research on predicates, studies/data needed, timing, cross-functional groups to include and when, FDA meetings to have and why.	Michael Morton	
7c On-Demand (20 min)	Date Available 1 August 2017 Due Date 31 August 2017	Global regulatory strategy while considering the requirements and expectations from global regulators, students will be exposed to the key elements that are critical to building a truly global regulatory strategy.	Rainer Voelksen	
7d On-Demand (57 min)	Date Available 1 August 2017 Due Date 31 August 2017	Stage Gate Model Application. This tool will be used to navigate the Case Study Project in modules 7-9. It guides you through the discussions that must be made during the TPLC and who to involve in the decision making process.	Monica Wilkins	Slides not available
7e On-Demand (33 min)	Date Available 1 August 2017 Due Date 31 August 2017	The Plan and Inputs—Part I. In this session you are introduced to the Design and Development plan for the case study product. You will gain insight into customer inputs and begin filling out the Product Requirement Document (PRD). Exercises built into sessions. Look for yellow boxes within the presentation and pause the recording to complete the given task.	Michael Jodon	Use supporting documents to go through exercises. No assignments need to be turned in.

7f On-Demand (6 min)	Date Available 1 August 2017 Due Date 31 August 2017	The Plan and Inputs—Part II. Finish filling out the PRD with customer inputs and go back to the Design Plan and ensure the inputs meet the user needs. Exercises built into sessions. Look for yellow boxes within the presentation and pause the recording to complete the given task.	Tricia Cregger	Use supporting documents to go through exercises. No assignments
7g On-Demand (41 min)	Date Available 1 August 2017 Due Date 31 August 2017	FDA Interaction for The Plan and Inputs. Gain exposure to FDA's request for classification, predicate device, 513(g), and classification processes. Here from FDA how to interact with FDA, what to prepare and what the expected outcomes are during the plan and inputs stage.	Geeta Pamidimukkala	
7h On-Demand (22 min)	Date Available 1 August 2017 Due Date 31 August 2017	Design Outputs, Verification, Validation, and Reviews. Continue to build your case study PRD. Now you will verify and validate your inputs by reviewing the design. Exercises built into sessions. Look for yellow boxes within the presentation and pause the recording to complete the given task.	Tricia Cregger	Use supporting documents to go through exercises. No assignments need to be
7i On-Demand (49 min)	Date Available 1 August 2017 Due Date 31 August 2017	FDA Expectations for Design V&V, and Outputs. Hear from FDA about their expectations for design verification, validation, and outputs. Learn more about regulatory requirements and the pitfalls and challenges FDA sees in application of those requirements. FDA will also discuss interactions that can/should occur during this stage of product development.	Bill MacFarland	

7j On-Demand (16 min)	Date Available 1 August 2017 Due Date 31 August 2017	Design Transfer. Use the Stage Gate Model to discuss who should have been involved in the design development. You will be shown examples of Device Master Records (DMR). Exercises built into sessions. Look for yellow boxes within the presentation and pause the recording to complete the given task.	Tony Piotrkowski	Use supporting documents to go through exercises. No assignments need to be turned in
8a On-Demand (1hr, 18 min)	Date Available 1 September 2017 Due Date 30 September 2017	Risk Management. Update new risks to your case study device. Fill out a Hazard Analysis and FMEA. Develop risk controls and a risk management report. You will also conduct risk/benefit analysis. Exercises built into sessions. Look for yellow boxes within the presentation and pause the recording to complete the given task.	Bill Brodbeck	Use supporting documents to go through exercises. No assignments need to be turned in
8b On-Demand (45 min)	Date Available 1 September 2017 Due Date 30 September 2017	Quality Systems. Former Chief Quality Officer for J&J Devices shares complex quality challenges with the students and provides scenarios for the students to work through during the session. Students will experience the challenges faced by senior leaders. Exercises built into the sessions.	Donna Godward	Walk through exercises during webinar, there are no supporting
8c On-Demand (1 hr,16 min)	Date Available 1 September 2017 Due Date 30 September 2017	Supplier Quality. An industry expert will discuss the critical aspects of a robust Supplier Management Program to apply to suppliers and contract manufacturers. The Stage Gate Model will provide a roadmap for what activities need to be done throughout the Total Product Lifecycle.	Monica Wilkins	

<p>9a Assignment</p>	<p>Date Available 1 October 2017</p> <p>Due Date 14 November 2017</p>	<p>Revised Elevator Pitch – Revise elevator pitch to deliver to class during Capstone on-campus session.</p>		
<p>9b On-Demand (17min)</p>	<p>Date Available 1 October 2017</p> <p>Due Date 31 October 2017</p>	<p>Senior Management Role Play and Check on Learning. You will play the role of senior management. After given a scenario you need to identify trends that require action, what additional information you can/should request, what triggers are important and when you should escalate.</p> <p>Pause the recording when answering questions and receive instant feedback; no submission of a written document is necessary.</p>	<p>Bill Brodbeck</p>	
<p>9c On-Demand (20 min)</p>	<p>Date Available 1 October 2017</p> <p>Due Date 31 October 2017</p>	<p>FDA Expectations for the Role of Senior Management. This session addresses what FDA has observed as trends of failures at the executive management level that has led to inadequate product quality, impact to patient safety, and failures to comply with regulations. Address expectations FDA has for how executive management can successfully develop a culture of quality.</p>	<p>Robin Newman</p>	

<p>9d Assignment</p>	<p>Date Available 23 May 2017</p> <p>Due Date 7 November 2017</p>	<p>Capstone Project Due. You and your partner will finalize preparations for your capstone presentation. Prepare presentation slides to be sent no later than November 7th to Stacie Ball. Please save your presentation slides using the file naming convention: “Capstone Project—Your Last Name”.</p> <p>Submit completed assignment via email to balls2@xavier.edu.</p>		
<p>10 On-Campus</p>	<p>Start Date 14 November 2017</p> <p>End Date 15 November 2017</p>	<p>On Campus Event 2.</p> <ul style="list-style-type: none"> • Formal Capstone Projects are presented to an outside panel of experts that require the students to apply all learning related to Leadership awareness, Technical competency and FDA interaction. • Students will deliver their revised Elevator pitches to the class • A final professional coaching session leaves students armed with transformational action plans. 	<p>Marla Phillips</p> <p>Panel of Industry Experts</p> <p>Coaching: Kucia, Gravett and Beigh</p>	<p>Travel to Cincinnati, OH required. Please refer to “Travel Logistics to Xavier University” for travel accommodations and</p>