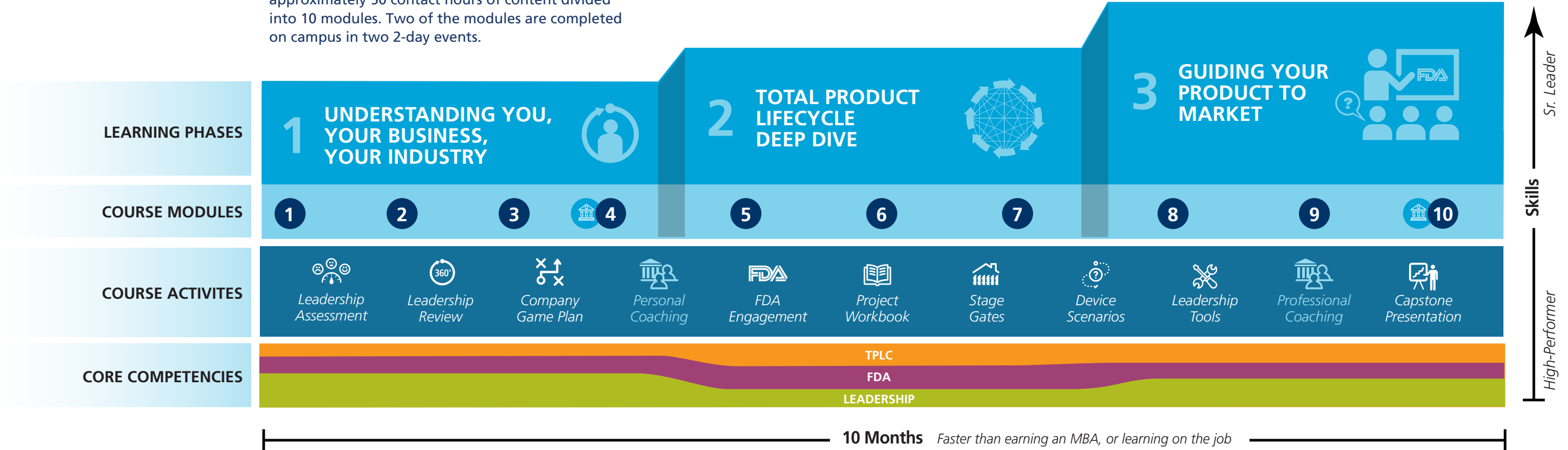


Roadmap to Leadership

During the 10-month period students will receive approximately 50 contact hours of content divided into 10 modules. Two of the modules are completed on campus in two 2-day events.



Module Descriptions:

- 1 Setting the Foundation**
 Leadership Self Assessment and 360° Review involving management, peers, and direct reports, used with professional coaching in Module 4 to develop a personal leadership action plan.
- 2 Industry Structure and Stakeholders**
 Discussion of external stakeholders, regulatory authorities, competitors, and other business influencers across the industry.
- 3 Your Company Game Plan**
 Impact of product profile diversity and global economics for unique competitive advantages, with focus on revenue streams, business measures, key strategies of your CEO, and potential effects of major news events.
- 4 Leadership in Balance**
 On-campus experience (2 days) with in-depth sessions on executive management decision making, ethical business situational analyses, professional coaching, and personal action plans with tools.
- 5 TPLC Roadmap**
 Introduction of case study and total product lifecycle process to explore technical, regulatory, and leadership aspects required for patient and business success.
- 6 Stage Gate Model Application**
 Explanation of best practice stage gate model, using case study to illustrate critical aspects of tool and how it can be used.
- 7 Design and Development Stage**
 Continued involvement with case study, exploring design and development stage through plans, inputs, and risk management while using stage gate model to drive decisions and measure success; FDA interaction, including planning and implementation of outcomes, device classification, and verification/validation expectations.
- 8 Operations Stage**
 Interaction with other participants and FDA, working through case study device scenarios to ensure understanding of necessary quality systems for operations, effective leadership, and broader company and regulatory awareness.
- 9 On-Market Stage**
 Exploration of leadership requirements after product launch using scenarios, including technical and ethical challenges, organizational expectations, and FDA interactions and expectations.
- 10 Capstone**
 On-campus experience (2 days) where Formal Capstone Projects are presented to an outside panel of experts which requires 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.

One-on-one coaching occurs in Modules 4 and 10 during the 2-day on-campus sessions