MQM 718QH: Life Sciences Strategy
Masters in Quantitative Management: Health Analytics

Faculty

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Course Overview

We will examine business strategy in the biotech, device, and pharmaceutical industries, with a focus on product development and competition. Life science companies face new challenges and opportunities. Developed markets are experiencing changes in regulatory oversight and reimbursement, including emphasis on value-based reimbursement. Emerging markets are growing rapidly. Patient populations are shrinking as diagnostics become better able to identify which patients respond best to which medicines. Many companies are focusing on rare diseases, moving away from the old blockbuster model.

To succeed, industry professionals need to understand corporate strategy, financing options, product development, innovation management, marketing, reimbursement, and customer needs. However, health care is different from other industries in important ways, including regulation and reimbursement.

In the synchronous portion of the class, we will begin each class with a discussion of a case. Some people in the class will have little background in the life sciences. Please feel free to ask us to clarify unfamiliar terms. Also, for those with less background in the life sciences, the videos and readings will be helpful.

Businesses and foundations active in health care support research by our faculty. This industry interaction can provide helpful insights, but also may be a source of bias. We genuinely hope to encourage vigorous discussion about the life science industry and welcome diverse views.

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Objectives

By the end of the class, we will better understand how life science companies

- acquire knowledge and products
- raise capital funds
- commercialize innovative products
- evaluate product safety and efficacy
- use clinical trials to persuade not only regulators but also payers and providers
- manage intellectual property
- justify the value of products
- determine price
- market to providers and patients
- shift from blockbuster to niche product strategy
- compete following patent expiration

Grading

Executive students generally focus on learning rather than grades, but it is nevertheless important to outline the grading criteria.

- 30% participation
- 30% assignments
- 15% midterm exam
- 25% final exam

The Fuqua School of Business Honor Code applies to the course.

Participation

Please attend class and participate. We grade on the quality, not the quantity, of class participation.

You are welcome to use the on-line discussion board to clarify and extend discussions from class. You can access the discussion board through the course site.

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It is not necessary to E-mail us about absences, unless you will have an unusually high number of absences. Other obligations arise, including health, family, and career. These are all important. Fortunately, you can still submit your answers even if you cannot attend class.

Assignments

For each class, there will be an assignment on the class web page. We will drop the lowest assignment score for each student. Past students reported working 3 hours per assignment. The assignments are "open" meaning that you can use class readings and other readings to answer the questions. The assignments are formatted as quizzes, but have no time limit, other than a deadline.

Assignments are due 15 minutes before the start of class. Assignments are not accepted after class, because i) the primary objective of the homework is to encourage preparation for class, ii) answers are included in the slides posted on the web page after class, (iii) each assignment matters little to the total grade, and (iv) it is generally better to work on future rather than past assignments.

Exams

The exams are online and consist primarily of multiple-choice questions. Exams will take less than an hour to complete (adjusted for those with disabilities). Exams are "closed", meaning that you cannot consult materials or other people. The midterm covers content from the first half of the class. The final exam focuses mainly on the second half of the course but includes a few questions from the first half. Exams are based primarily on material in the video lectures, class slides, and readings. Class materials marked "optional" will not be tested.

Schedule

See the next page.

Unit	Theme	Videos	Live Session	Case
1	Introduction to Medical Device Industry	• Introduction to medical device industry • Industry challenges and opportunities • Regulatory pathways	23-Jan-21	Heartport, Inc.
2	Medical Device Innovation	• Reimbursement • Research & development • Manufacturing • Fundraising	6-Feb-21	Fred Khosravi & Access Closure
3	Medical Device Commercialization, Digital Health	• Orthopedic segment • Sunshine Act • Commercialization • Digital Health	20-Feb-21	Zimmer: Gender-Specific Knee
4	Bio-Pharma Research & Development	• R&D • Make or buy • Incentives • Priority Review Voucher	5-Mar-21	Vertex Pharma: R&D Portfolio
5	Bio-Pharma Commercialization	• Flow of funds • Medicare • Medicaid • Patient cost sharing • Global reimbursement	19-Mar-21	Merck: Pricing Gardasil
6	Bio-Pharma Competition	• Forecasting market share • Drug prices • Lifecycle management • Generics & biosimilars	2-Apr-21	Teva Pharmaceuticals

Deliverables	
Midterm exam	Opens 20-Feb-21 Closes 22-Feb-21
Final exam	Opens 12-Apr-21 Closes 18-Apr-21

Unit 1: Introduction to Medical Device Industry

Videos:

- Introduction to medical device industry
- Industry challenges and opportunities
- Regulatory pathways

Case: Heartport, Inc.

Additional Resources:

- Understanding MedTech Markets Today, MedTech Strategist, 3.31.17
- Optional: Technologies to Watch in 2018, Part 1, MedTech Strategist, 3.27.18
- Optional: Technologies to Watch in 2018, Part 2, MedTech Strategist, 4.20.18
- FDA video: An Introduction to FDA's Regulation of Medical Devices

Case Discussion Questions:

1. What do you think of the underlying innovation?
2. What has Heartport done to date? Why?
3. What does the adoption process look like?
4. How should Heartport define success?

Case Discussion Dynamics (be prepared to answer questions in class)

We are in Heartport's board of directors meeting at the end of September 1999. You have been the new CEO for four weeks. The chairman of the board turns to you and asks the following questions: "As the new CEO of the company what are your top priorities for the Q4

1999? How will your strategy help us regain positive momentum? Why is this the best course of action now?"

Unit 2: Medical Device Innovation

Videos:

- Reimbursement
- Research & development
- Manufacturing
- Fundraising

Case: Fred Khosravi & Access Closure

Additional Readings:

- Can Innovative Value-Based Pricing Models Relieve Pricing Pressure in MedTech Industry, MedTech Strategist, 4.3.19

Case Discussion Questions:

1. What is your assessment of Fred's Khosravi's career and his record as a medical device entrepreneur?
2. What rules or generalizations, if any, about medical device start-ups can you draw from Khosravi's experiences?
3. What is your assessment of the AccessClosure venture? Do you have any criticisms of how the venture has been managed to date?

Case Discussion Dynamics (be prepared to answer questions in class)

You are holding a conference call with the partners of your largest venture capital investor wanting an update on the strategic direction of the company. During the conversation the senior partner asks: "What decision have you made regarding the future direction of the company? Will you recommend to sell now, wait one year then sell or build a stand-alone company?" What are the pros and cons of the strategic option you have selected? Why are you confident this is the best course of action?"

Unit 3: Medical Device Commercialization, Digital Health

Videos:

- Orthopedic segment
- Sunshine Act
- Commercialization
- Digital Health

Case: Zimmer: Gender-Specific Knee

Additional readings:

- Analytics 4 Life: Using AI to Diagnose Coronary Artery Disease at the Point-of-Care, MedTech Strategist, 10.12.17
    - The future of Healthcare in a Robotics World: An interview with Scott Huennekens, MedTech Strategist, 6.13.19
    - Optional: The Role of Physicians in Device Innovation: Critical Success Factor or Conflict of Interest? Stanford Graduate School of Business, IOT-105, 8.4.11

Case Discussion Questions:

1. Is this a good business?
2. How significant are the threats to the industry?
3. How will the gender-specific knee build profits?
4. How will the competitors respond?

Case Discussion Dynamics (be prepared to answer questions in class)

You are in a senior executive team meeting to discuss the gender-specific knee. The president of the division turns to you and asks: "Should we launch the gender-specific knee? What is your rationale for this recommendation? What are the potential risks with this launch and what steps would you take to minimize the risks?

Unit 4: Pharmaceutical Research and Development

Videos:

- Research and development
- Make or buy
- Incentives for innovation
- Priority Review Voucher

Case: Vertex Pharmaceuticals: R&D Portfolio Management (A)

Additional Readings:

- Optional: DiMasi et al., "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," Journal of Health Economics, 2016

Case Discussion Questions:

1. CEO "Josh Boger announced that Vertex would commit to developing and commercializing two of its drug candidates on its own". Why only 2 candidates?
2. What factors should Vertex consider when choosing candidates?
3. Which 2 candidates should Vertex develop?
4. What should Vertex do with the candidates that it does not develop? Hold or license?
5. If scientists continue to work on a disease that management asked them to stop, what should management do?
6. Approval probability for VX-148:
   - According to your case, what is the probability that VX-148 is approved? (Hint: "Prob. Approval" in Exhibit 7 is conditional on completing Phase III.)
   - According to industry averages below (based DiMasi et al. 2016), what is the probability that VX-148 is approved?
   - Does the VX-148 probability differ from the industry average? If so, why?
7. Probability that at least 1 compound:
   - Based on the probability from your case, what is the probability that at least one compound is launched if Vertex pursues all 4 compounds?
   - Based on the industry averages, what is the probability that at least one compound is launched if Vertex pursues all 4 compounds? If Vertex pursues 2 compounds?

If entering stage	Probability successfully completes stage	Probability approved

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I	0.60	0.12
II	0.36	0.20
III	0.62	0.56
submission	0.90	0.90

Unit 5: Pharmaceutical Commercialization

Videos:

- Flow of funds
- Medicare drug reimbursement
- Medicaid drug reimbursement
- Patient cost sharing
- Global drug reimbursement

Case: Merck: Pricing Gardasil

Additional Readings:

- Optional: Frakt, "Low Prices for Vaccines Can Come at a Great Cost," New York Times, Blog.

Case Discussion Questions:

1. What factors should Merck consider when setting the price?
2. What launch price would you recommend for Gardasil in the USA? Why?
3. What launch price would you recommend for Gardasil in emerging markets?
4. At a price of $120 per dose, what is the cost per quality-adjusted life year?
5. How should Merck support Gardasil, in terms of market and non-market (lobbying) strategies?

Unit 6: Pharmaceutical Competition

Videos:

- Forecasting market share

- Drug prices
- Lifecycle management
- Generic drugs and biosimilars

Case: Teva Pharmaceutical Industries, Ltd

Additional Readings:

- Optional: Grabowski et al., "Entry and Competition in Generic Biologics."
- Optional: ParagraphFour.com

Case Discussion Questions:

1. If you were CEO of Teva, where would you focus: U.S. generic drugs, global generic drugs, innovative drugs, or biosimilars?
2. If you were CEO of a branded pharmaceutical firm, would you diversify to generics? Can a firm have successful brand and generics units? Why or why not?
3. Do you agree with the following quote from the case? Why or why not? "Generics were typically priced significantly lower than their original versions because the drug makers did not need to recoup the massive costs of the initial research and development associated with drug discovery nor support the massive sales and marketing costs associated with introducing a new drug."
4. What is a "paragraph IV" certification?