



Author: Shreefal Mehta

COLLECTION OF LEARNING POINTS FROM BEGINNING OF EACH CHAPTER

Chapter 1 The biomedical device and drug industry and their markets

- Description of types of products covered in this book
- Understand the technological base and application for each product type
- Description of functions/processes involved in commercialization activities for each product type
- Analysis of industry sector competitiveness by value chain model and Porter's five forces analysis
- Understand the technology trajectories for the biomedical industry

Chapter 2 Markets of interest and market research steps

- Goals and methods of market research
- Segment the market and estimate the market size for the new biomedical products
- Assess general drivers and hurdles that help or hinder market growth
- Define the product concept and market positioning
- Identify the various stakeholders in the patient referral chain and the impact of the new biomedical technology intervention on them
- Assess economic impact and adoption hurdles for the new biomedical product in context of the referral chain
- Use market research to help new product development planning and product characteristics

Chapter 3

- What are the different types of intellectual property and what is their purpose?
- What is a patent and how does one interpret a patent?
- What is patentable material ?
- What is the process of filing and obtaining a patent ?
- What are the different models used to manage or make money from patents by licensing?
- What are the key terms in a licensing or a technology transfer agreement?
- What is the value of a patent?
- What is a reasonable "royalty rate" and other financial terms for licensing my patent?
- What are the damages I can claim if someone infringes my patent?

- What are the various business models around commercialization of biomedical technology patents or products?

Chapter 4 New Product Development (NPD)

- Product definition at the beginning of a biomedical product development plan through endpoints and indications.
- How do drug, device and diagnostic development processes differ?
- Why will most drugs, devices and diagnostics fail in development stages?
- How to build a product development plan for drugs, diagnostics and devices
- How to construct a preliminary budget
- When to kill a project
- How to prepare for clinical trials – what are specific issues for diagnostics and devices?
- Successfully make a pitch for a project to senior management for funding
- What ethical issues must be recognized during product development activities?
- When should you outsource?
- Compliance to specific certifications and laboratory regulations when setting up a new laboratory

Chapter 5 The regulated market: Gateway through the FDA

- What are the functions of the FDA ?
- What is the importance of indications and endpoints in mapping a regulatory route ?
- How do FDA regulations impact preclinical and clinical product development planning?
- Identify a path through the regulatory process for a drug, device or diagnostic product idea
- What are the contents of the submissions required by the FDA at various points?
- How does a product with a combination of diverse technologies get approved?
- How are personalized medicines developed through the regulatory process?

Chapter 6 Manufacturing

- What controls and systems are needed to comply with regulatory oversight of manufacturing processes?
- What standards apply to manufacturing processes ?
- What are the timing and quantity requirements for scale up of production for drugs devices and diagnostics?
- What key issues typically arise in the production or scale-up processes for biological or synthetic drugs?
- How does Design for Manufacturability and Assembly prepare for device manufacturing?

Ch 7 Reimbursement, Marketing, Sales and Product Liability

- Who are the purchasers and who are the payers in the health system in the US?
- Describe the overall flow of products and payments in the US health care system
- What steps can a biomedical product company (drugs, devices, diagnostics) take to maximize revenues in the US healthcare system?
- What specific payer perspectives should be taken into account during product development / how can product development be planned for maximum reimbursement benefit?
- How do new products gain recognition and reimbursement in the healthcare payment system ?

EXERCISES FROM END OF EACH CHAPTER

(Samples from Ch 1, 2)

Chapter 1 Exercises

- 1.1. Map your technology or product idea on an S-curve for the overall industry and for your own technology platform. Are you close to maturity in that technology platform? Is the industry segment you are approaching growing rapidly or just taking off? How would you now qualify your product opportunity?
- 1.2. What new opportunities might arise if you look at the technology trajectories in other industries and their intersection with the biomedical technology industry segment of interest?
- 1.3. Can you plan for the next generation technology that might replace or threaten your product?
- 1.4. Analyze the components of the value chain for your industry (see one of the figures in the chapter) and understand where your organization fits in currently and in the future. Who holds the maximum value (highest margins) in the value chain?
- 1.5. Do you understand the functions, information and materials from the other parts of the value chain that feed into the processes your organization performs? Is there a strong positioning statement for your organization? Are the investments being made now appropriate to maintain the strategic advantage in the current position in the value chain?
- 1.6. Given the trends for biological research and development identified here, are there specific areas that you should consider investing in to gain competitive advantage in the future value chain.

Chapter 2 Exercises

- 2.1. In simple terms, briefly describe the invention and summarize the significance of the underlying technology innovation
- 2.2. Define clearly the specific market need or core problem that your technology addresses
- 2.3. Identify the specific indication for your product and identify other potential indications for future development
- 2.4. Also brainstorm to identify non medical or non-regulated applications (animal health, other industries) for your technology (if so needed in the business and financial model, the product can be commercialized in a market where time to market may be shorter and revenues might help fund medical product development).
- 2.5. Describe the referral chain for the indication and the economic context (costs)
- 2.6. Describe the patient population and identify the payers (see Chapter 7)
- 2.7. Identify the purchaser, user, prescriber and other stakeholders who are affected in the value chain (e.g. nurses who will see the patient each week for 4 hour infusion of the drug).
- 2.8. Describe the benefit from the new product to each stakeholder or to the primary purchasing decision maker
- 2.9. Describe the savings in the entire referral chain from the intervention made by the new product. This will also help define the actual economic value proposition for the insurers/payers/purchasers.
- 2.10. Write, in one sentence, why your technology will be purchased over others and over current treatment options –in other words, define the value proposition for your technology/product for the chosen indication

- 2.11. Identify competitors based on the specific problem the new product/technology is addressing. Describe very briefly why a certain competing solution is a competing technology/product
- 2.12. Classify alternatives and competition in a comparison table highlighting advantage of your product considering appropriate parameters – efficacy, safety, price etc.
- 2.13. Collect specific value propositions that the stakeholders will value and translate those into product characteristics that would be appreciated by the stakeholders. Give more weight to the primary purchaser's perspectives. This list of preferred product characteristics will serve as input to a product design.
- 2.14. For a market research project follow these steps
 - a. Define the specific goals of the market research program – Examples include: i) Define and segment markets in order to clarify reimbursement strategy; or ii) Define potential market opportunity in order to drive investment decision or iii) Provide input on specific market needs for better defining desirable product characteristics
 - b. Decide on the extent of primary vs. secondary research to be carried out and make sure adequate resources are available
 - c. Collect data and tabulate results without any bias entering the summary tabulation
 - d. Analyze the data and then present the specific output required – based on the defined goals of the market research project.