Book Review

Biodesign: The process of innovating medical technologies

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Gerard Piel, once publisher of *Scientific American* magazine, said that it might be good if there were complaints about too few articles in a given field (Gerard Piel, private communication to R. T. (then a high-school senior) at a Phillips Andover Board of Trustees luncheon). This would mean that the magazine introduced readers to the full breadth of science. The same can be said of *Biodesign*. While an experienced practitioner in a field of engineering, medicine, business or law might wish for more depth in a given specialty, the 778-page text provides a thorough and balanced tour of the essentials of biomedical device innovation that will inform practitioners from many backgrounds. The close interplay of clinical needs, technical feasibility, development cycles, intellectual property, regulation, reimbursement, business planning and strategy is repeatedly stressed throughout the book.

We consider the book from the point of view of several types of readers.

A student in a biomedical engineering design course will find that each chapter cleanly meets the learning objectives summarized at the chapter's beginning. The totality of these objectives gives a first-time learner just enough knowledge to be 'dangerous'. We mean this in the positive sense where a student can contribute to a real biomedical device project, but under caution that further expertise and experience is required. These cautionary statements, such as the advisability of hiring an intellectual property attorney, are clearly set out through the text.

A seasoned professional in high-technology business with an MBA degree can use this book to gather the facts of life of the biomedical device industry. Many aspects of product development carry over from other fields as delineated in a standard text like Ulrich & Eppinger's *Product Design and Development*.[1] However, the book also treats elements unique to biomedicine such as FDA regulatory requirements, medical insurer reimbursement codes and biodesign strategy. Again, a proper sense of 'Here there be dragons' is conveyed, whereas crucial 'Where to look' sections provide entry points into literature, associations and websites for more detailed exposition.

An engineer, scientist or medical clinician who is now becoming an innovator will find the book packed with essential tables of information, lists of key questions to ask in various parts of the process, entry-points into technical data and so on. The chapter summaries called 'Getting Started' are very good encapsulations of the material that, when read by themselves, could give the time-pressed practitioner a rapid but effective connection to the field. Several pointers to journal databases, disease surveys, cost studies, financial analysis formats, etc. are interspersed for just-in-time access. The book is a pragmatic how-to guide to all aspects of the biomedical device development process and to business and economic success as a biodesign innovator.

A teacher of biomedical device design will find the book to be a readable, well-organized textbook. It does not have exercises *per se*, but the chapter sections and the 'Getting Started' sections provide lots of hooks for assigning exercises, both for individuals and groups. There are numerous supplements on the book's web site ebiodesign.org.

The book is rich in examples set apart in sections called 'From the field'. These examples are often told from the first-person point of view of experienced device developers and entrepreneurs. A running example throughout the book deals with the development of an alternative to functional endoscopic sinus surgery. The example links together all of the components of the book into a coherent story about one of the authors' experiences in meeting a clinical need for safer and less traumatic procedures.

A researcher will gain insight on how to look for and follow avenues for translational research. The journey from a vibrant new possibility in the laboratory to an actual clinical device is a long and tricky one. Nonetheless, the book can be used to find the critical path that ensures more effective and less risky attempts to go from lab bench to bedside. Note that this book does not deal with pharmaceuticals, except with devices like drug-eluting stents. The examples are also mostly based on therapeutic rather than diagnostic devices.

Finally, a physicist (who said anything about physicists?) will see the book as a checklist for how to become aware of clinical, market, regulatory and business realities. The reason we mention physicists, aside from the fact that one of us is running an undergraduate program in biophysics, is that biomedical devices usually require technical versatility. Multi-disciplinary teams bring expertise from different sub-domains, but a physicist is trained to have an integrative view of technology running the gamut of mechanics, electronics, electromagnetic fields, optics and so on. Thus a physicist is a good advance scout for unusual technical approaches and novel combinations of ideas. A physicist is also adept at sophisticated quantitative modeling as a tool to anticipate performance characteristics.

From this last viewpoint, we might suggest that a future edition of the book include greater discussion of quantitative thinking and numerical modeling. For example, in designing devices that use catheters to introduce polymeric liquids into the heart (one of the 'From the field' examples), one wants to know answers to: How long? How strong? What volume? What flow pattern? We especially advocate some back-of-the-envelope calculations in the needs screening and early prototyping stages. We also suggest that the prototyping chapter include an appendix on optical systems design to augment the existing topics of materials selection, mechanical design and electronics. More in-depth lists of reference books could be provided including Horowitz and Hill's *The Art of Electronics*.[2] A practitioner will also want technical guides such as Bronzino's *Biomedical Engineering Handbook*[3] in addition to specialized texts in fields critical to a particular project.

In summary, this is an essential guide, desk reference and practitioner's handbook on the biomedical device design process with emphasis on the comprehensive business framework needed for solid market success.

REFERENCES

1. Ulrich, K.T. and Eppinger, S.D. (2007) *Product Design and Development*, 4th edn. New York, NY: McGraw-Hill.
2. Horowitz, P. and Hill, W. (1989) *The Art of Electronics*, 2nd edn. Cambridge, UK: Cambridge University Press, A new edition appears to be forthcoming in 2012.
3. Bronzino, J.D. (ed.) (2006) *The Biomedical Engineering Handbook*, 3rd edn. Boca Raton, FL: CRC Press.

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