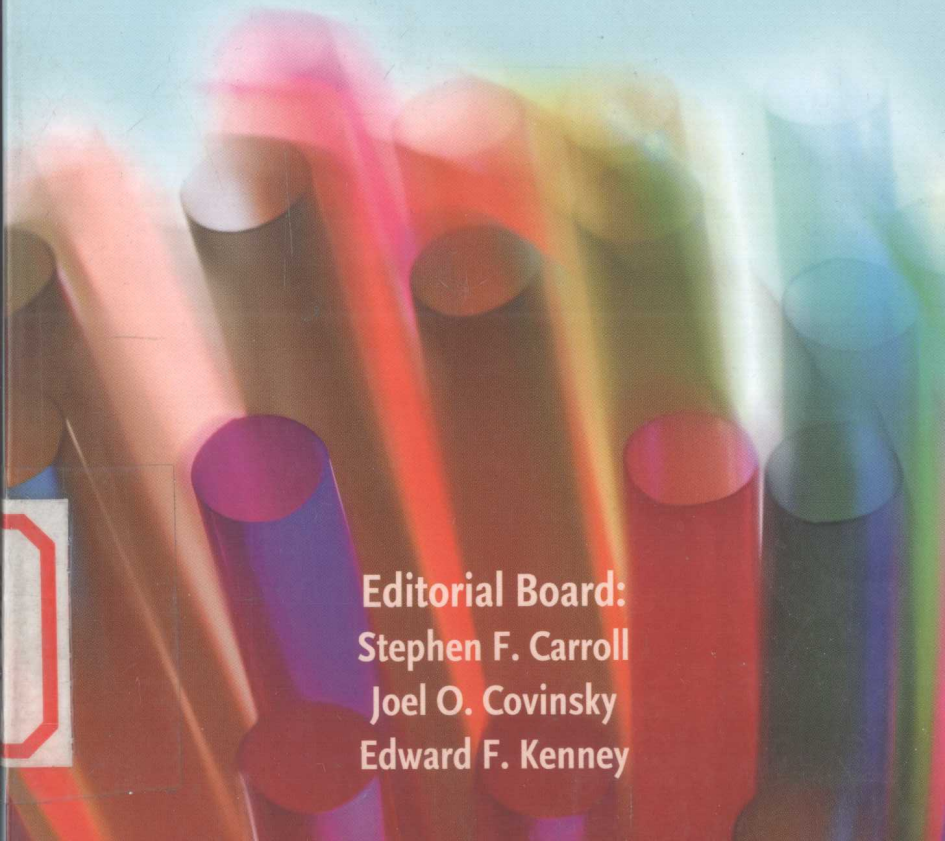
Handbook of

Biopharma Industry Acronyms & Terms

Ronald P. Evens



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Handbook of Biopharma Industry Acronyms & Terms

The Acronyms, Terms, and Phrases for the Science and Business of the Pharmaceutical and Biotechnology Industries

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Overview and Introduction

Language can be either a facilitator or barrier to effective communication and is a cornerstone of any successful work environment, whether it is in research or business practices, or in collaborations between different types of workers, or even in an interpersonal relationship. In most of the world, languages are unique to each country, and cross-border collaboration requires translation and interpretation of words and phrases, along with their meanings and appropriate context. Ultimately, the learning of the other language itself is needed for fully effective communication.

Business worlds can also have their own language with distinct phrases and terms, based on the unique features of their technologies, science, products, employees, customers, and government relationships. The business worlds of home construction, agriculture, and space exploration are easy to recognize as unique from each other in technologies, products, and terminology. Certainly, the pharmaceutical and biotechnology industries (here-to-fore called the biopharma industry) have such special circumstances in at least seven areas: (1) their sophisticated and complex science base, (2) the medical practice and patient care context, (3) a research-intensive environment on at least four levels (basic laboratory, animal, clinical, and economic), (4) substantial government engagement and regulatory oversight, (5) highly varied and complex healthcare systems along with the related customer relationships, (6) the global nature of business and health care, and (7) the basic business world challenges, as well. This book provides over 3,200 acronyms and over 850 terms and phrases, representing the biopharma industry language.

Customers of the Biopharma Industry

The complex customer environment and players involved in and with the industry warrant additional introduction. The spectrum of customers and their needs is exceptionally broad for the biopharma industry with at least 11 different categories, each of them both a recipient of communications and a contributor to the biopharma language:

1. Patients with a disease consume the products, along with their families that provide support. Patient support groups are further customers for the biopharma industry.
2. Health care professionals ("providers," i.e., physicians, pharmacists, nurses, and allied healthcare workers) decide upon, guide, and monitor the products' use. They also congregate in national professional associations for communication, education, clinical practice, and research discussions, comprising yet another customer base.
3. The payers in the private and public sectors cover the costs of the products, create reimbursement processes, and provide usage guidelines for products. Private payers include insurance companies, managed care organizations, and the patients. Public payers include federal, state, and local governments.
4. The healthcare systems with the many inpatient and outpatient settings (e.g., hospitals, nursing homes, clinics, physician offices, pharmacies, and laboratories) form a broad and varied context in which patients are treated and the products are used. Usage patterns are impacted by these many settings, and they both facilitate usage and create barriers.
5. The scientific community involves many basic science areas that help discover the products, for example, chemistry, biology, molecular biology, genetics, pharmacology, toxicology, pharmacokinetics, and economics. Each possesses their own terminology that needs to be understood and integrated for product development in the biopharma industry.
6. The clinical research community establishes the benefits and risks for the products in patients through the clinical studies conducted in collaboration with the biopharma industry. Diseases and study designs along with research processes create terminology for biopharma.

7. The many facets of government serve two key functions: performing oversight and regulation of the biopharma industry (the science and the business), and creating the health policies, laws, and regulations governing operations and outcomes (e.g., Food and Drug Administration, Office of Inspector General in the Justice Department, Veterans Administration, National Institute of Health, Health and Human Services, Centers for Medicare and Medicaid Services, Department of Agriculture, and Environmental Protection Agency).
8. Many contractors and vendors in science and business areas support and assist the biopharma industry in performing their work, for example, testing laboratories, contract research organizations, market research companies, sales management organizations, and advertising agencies.
9. The investment community provides the capital to perform the work, monitors the business outcomes and research advances for potential investors, and may even help set corporate goals.
10. The media monitor, report, challenge, and color the work, outcomes, benefits, and risks of the products, product development, and the biopharma business world.
11. The biopharma companies themselves interact through research and business collaborations and alliances and become customers of each other. The biopharma industry engages this breadth of players and customers, leading to substantial complexity, variety, and unique features in its communications, essentially creating a language of its own.

Acronym Usage

The language of biopharma is further complicated by the extensive use of acronyms in the worlds of the sciences, health care, business, and government, in which and with which the biopharma industry must simultaneously operate. Acronyms are used most often to facilitate communications among their user groups, but they may also confuse communication to those staff members and customers unfamiliar with them. A simple acronym (e.g., "EC" or "PC") can have many distinct meanings even within this one industry because of so many different customers, business

needs, and technologies. For example, "EC" can mean Executive Committee, or European Commission, or European Council, or Ethics Committee, or enteric coated, or e-clinical, or etoposide with carboplatin. The acronym "PC" can mean placebo control, or physicochemical, or pre-clinical, or product complaints, or primary care, or patient consent, or personal computer, or pediatric committee, or post cibum (Latin for 'after meals'). The context for the acronym is particularly important to guide the reader to the most appropriate definition of the acronym.

Biopharma Industry Department Contributors

The over 4,000 terms, phrases, and acronyms in this book comprise much of the biopharma language and include 10 different work areas of the biopharma industry itself, as noted in Figure 1

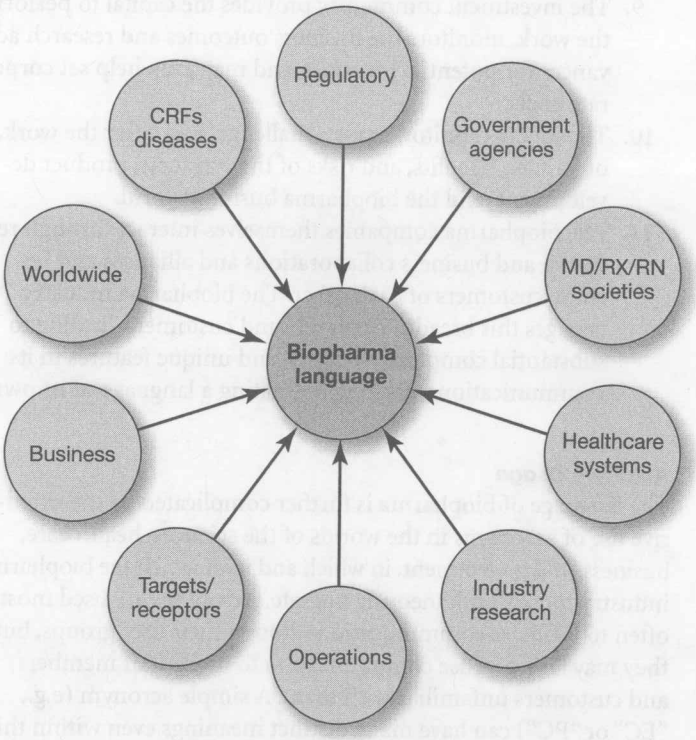

Figure 1: Content of Biopharma Language

and in the following comments. Standard business operations (1) and marketing terms (2) are presented regarding all business environments, and are adapted to the science and healthcare context and new product development. Basic research concepts (3) in the acronym and term lists focus on discovery of new molecules and the related processes. Many of the targets and receptors (4) in humans that are recognized as contributing to existing and new molecule discovery are provided. Although any of the thousands of human enzymes, substrates, proteins, metabolites, antibodies, ion channels, ribosomes, DNA/RNA units, and cell receptors could be listed as targets, the about 450 targets/receptors in the book represent current major receptor families and their prominent components. Clinical research terms (5) focus on the many different issues, such as processes, documents, study design issues, clinical assessment tools, people (roles and titles), and activities involved in clinical studies and product development. Clinical assessment tools that could be a scale, index, questionnaire, survey, exam, evaluation, interview, report, schedule, or inventory are incorporated. Government agencies (6) are manifold and varied, and their nomenclatures that impact both the business practices and product development for the biopharma industry are included. Regulatory concepts (7) cited in the book come most often from government health-related agencies that perform oversight of the work (processes and outcomes) of the biopharma industry. The associations and foundations (8) for health care and science professionals that interface with the biopharma industry are noted. Global operations (9) hallmark biopharma product development and marketing, such that many non-U.S. regulatory groups, processes, and other international-related acronyms are addressed as well. Some acronyms for diseases (10) are provided for those likely to appear in case report forms for industry-sponsored studies or in market research for disease and health care information. Drug names are found commonly elsewhere and generally are not included. It is important to note that some of the other science areas are not included, even though they may be used in the biopharma industry, because of their ready availability elsewhere in specialized dictionaries, for example, chemical and trade names for drugs and biological products, anatomic and physiologic names (e.g., muscles, bones, nerves, and blood vessels), and names of microorganisms.

Sources of Acronyms and Terms

The sources to obtain these terms, phrases, and acronyms for the *Handbook of Biopharma Industry Acronyms & Terms* are manifold (described hereafter). Also, they represent the real world environment in which the biopharma industry must operate. The first bases for the handbook are the 30 plus years of hands-on and management experience in healthcare, health education, research, and the industry of the editor and author at two prominent, fully integrated pharmaceutical companies and four start-up companies, as well as six universities, along with his extensive professional contacts through his work with many professional organizations. The book's prestigious editorial board further represents several hundred years, collectively, of healthcare, research, education, and industry experience, supplementing well the content in scope and descriptions.

Industry experience of the editorial board and editor directly involves 14 companies, both pharmaceutical and biotechnological, and both large, fully-integrated and small, start-up companies, that is, Amgen, Amylin, Aventis, Bertek, Boehringer-Ingelheim, Bristol-Myers, Cell-Pro, Cetus, CTI Therapeutics, Hoechst-Marion-Roussel, Marion, Onyx, Pharmacyclics, and Xoma. University affiliations of the editorial board and author have included esteemed research and healthcare institutions such as, Harvard University, Ohio State University, Philadelphia College of Pharmacy and Sciences, University of Buffalo State University, University of California at Los Angeles, University of Florida, University of Kentucky, University of Missouri at Kansas City, University of Southern California, University of Tennessee, and University of Texas. A further industry resource is the annual Drug Information Association meeting every June, which provides a rich, extensive, and diverse source of presentations (hundreds of presentations over four days annually) on every conceivable topic for the industry by industry experts, whether it is a science topic, an operational area, a marketing issue, or a regulatory topic. Journals and periodicals dedicated to drug development and the biopharma industry were used as sources of information for acronyms as well. These include *Nature Reviews Drug Discovery, Nature Biotechnology, Pharmaceutical Executive, Med Ad News, Genetic Engineering News, State of the Clinical Trials Industry, R&D Directions, Center for the Study of Drug Development Impact Re-*

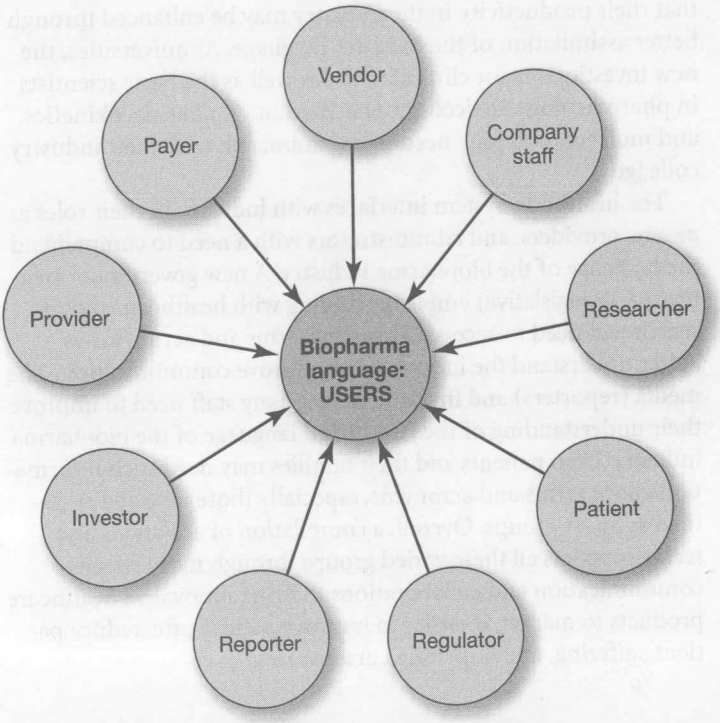

Figure 2: Users of Biopharma Language

ports, FDA Reports to the Nation, the Code of Federal Regulations (312, for drug development), reports of the Pharmaceutical Research and Manufacturers Association and the Biotechnology Industry Organization, and Ernst and Young's annual biotechnology reports.

Users of the Handbook of Biopharma Industry Acronyms & Terms

The likely users of this nomenclature and language book are quite broad, as displayed in Figure 2 and in the following commentary. This book is intended as a resource to and an educational vehicle for the new staff in the biopharma industry in many areas, for example, marketing, sales, or research, as well as their vendors in contract research, marketing, or sales organizations. We hope

that their productivity in the industry may be enhanced through better assimilation of the industry language. At universities, the new investigators for clinical trials, as well as the basic scientists in pharmacology, toxicology, pharmaceutics, pharmacokinetics, and molecular biology need to communicate with their industry colleagues.

The healthcare system interfaces with industry in their roles as payers, providers, and administrators with a need to comprehend the language of the biopharma industry. A new government (regulatory or legislative) employee dealing with healthcare and research will need to access a library of terms and acronyms to better understand the industry and improve communication. The media (reporters) and investment company staff need to improve their understanding of the jargon and language of the biopharma industry. Even patients and their families may need such information about terms and acronyms, especially those involved in patient support groups. Overall, a compilation of acronyms and terms supports all these varied groups through more effective communication and collaborations to bring innovative healthcare products to market, in order to improve patient care, reduce patient suffering, and hopefully cure diseases.

Directions for Using This Book

Two sections are presented: Acronyms of the Biopharma Language, covering over 3,300 listings, and Terms and Phrases of the Biopharma Language, covering over 850 listings.

1. The acronyms and terms are in alphabetical order based on the first letter or the first word.
2. For the acronyms, each letter of the acronym is defined in the book, and those letters are capitalized in the definitions; for example, "AP" can be Asia-Pacific (market) or Action Potential or Action Plan or Activator Protein (receptor/target) or Angina Pectoris or Adriamycin, Platinol or APproved.
3. It is important to note that an acronym or term can have very different meanings based on its use, such that the user of this book should always consider the context of the item being used in interpreting its definition.
4. The content of the terms and acronyms is the interpretation of the author and editor, along with review by the editorial board.
5. The definitions of any acronym, term, or phrase are presented in practical terms, as much as possible, for more easy understanding by the breadth of the book's readership. They are not official government or organizational definitions.
6. Many acronyms and terms relate to government regulations, and their definitions are paraphrased for readability, but they are as close as possible to publications of the respective government agency.
7. Individual pharmaceutical companies will use an acronym or term and may offer a somewhat different meaning, but the over 4,000 in this book represent commonly used examples to guide the new person working either within or with the biopharma industry.

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Biography of the Author and Editor:
Ronald P. Evens, PharmD, FCCP

Ronald Evens is CEO and President of M.A.P.S. 4 Biotec, Inc., consulting to biotechnology and pharmaceutical industries for medical affairs and product launches, especially strategy, planning, staffing, and operations for clinical trials (phases 2, 3b, and 4), medical education, publication planning, medical science liaisons, pharmacy affairs, and medical information for marketed and pipeline products (U.S. and International). Dr. Evens is also clinical professor at the University of Florida, College of Pharmacy in the Departments of Pharmaceutics and Pharmacy Practice, teaching about industry and biotechnology. He served on the board of directors for Oragenics, Inc., as well as their interim President and CEO in 2008, Cheladerm (drug company), national advisory boards for University of Florida, Biotechnology Development Incubator, and three Colleges of Pharmacy in the University of Florida, Gainesville; University of Buffalo, Buffalo, New York; and Midwestern University, Chicago, Illinois. Previous boards were HDMA Healthcare Foundation; American Society of Health-Systems Pharmacists, Research and Education Foundation; and industry advisory boards for medical societies in Hematology and Oncology and the American College of Clinical Pharmacy. He has made over 150 presentations on the healthcare industry and published over 100 publications, with 14 book chapters including "Biotechnology" in *Encyclopedia of Pharmaceutical Technology,* 2nd (2002) and 3rd (2006) editions; "Biotechnology Products in the Pipeline" in *Pharmaceutical Biotechnology for Pharmacists and Pharmaceutical Scientists,* 1st (1997) and 2nd (2002) editions. He was also editor of the book, *Drug & Biological Development, From Molecule to Product & Beyond* (2007), published by Springer.

Previously at Amgen for more than 13 years, he created and directed the Professional Services Department, which was responsible for medical information, post-marketing research, and medical communications for marketed products (staff of 140 and budget of $40 million). At Amgen, he also created the PeriApproval Research Group in Clinical Development for late-stage research for pipeline products. Dr. Evens was Associate Director of Clinical Research and Medical Services at Bristol-Myers Squibb for more than 6 years; Associate Professor and later chairman of Department of Pharmacy Practice at the University of Tennessee, Memphis. He created the Drug Information Center and was Assistant and Associate Professor at the University of Texas at Austin and University of Texas Center for Health Sciences. Faculty appointment as clinical professor also occurred at the University of Southern California, College of Pharmacy. His clinical research has been in areas of oncology, nephrology, hepatology, arthritis, infections, pain, and neurology.

Dr. Evens received a Bachelors of Science in Pharmacy at University of Buffalo in New York, and then completed an internship at E.J. Meyer Memorial Hospital in Buffalo. He attended the University of Kentucky for his PharmD and a 3-year residency and later the University of Southern California, Marshall School of Business, where he completed a certificate program for Marketing 101 for Scientists. His academic and professional awards have included Roger Mantsavinos (Biochemistry), Robert Ritz (Pharmacology), Rexall (1st in class), and the Rho Chi Honor Society at University of Buffalo; Resident's "Impact" Award at University of Kentucky; and Fellowship with American College of Clinical Pharmacy.

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