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products are therapeutics that

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Combine two or more products (drug/device, biologics/device, biologics/drugs, or drug/device/biologics), regulated and sold as a single unit. Examples of combination products include drug-coated implantable devices, drugs packaged with delivery devices in

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medical kits, and drugs and devices packaged separately but intended to be used together.

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Key to Outsourcing Method  
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Pragmatic Approach. RSSL. In an industry that is seeing an increasing level of work being outsourced, the Contract Research Organisation (CRO) of choice needs to have proven experience in both the pragmatism and flexibility of the method developer's mind set and a regulatory

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Eurofins BioPharma Product Testing.  
Pharmaceutical and biopharmaceutical  
companies face a significant challenge  
to get their drug products developed



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and launched quickly, all while keeping development costs down. One of the most common ways for companies to lower development costs is to manage fixed headcounts.

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Pharmaceutical companies will continue to fuel much of this growth as they outsource an increasing number of products and services.

Biotechnology companies, which have

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almost doubled in number over the past five years, will also contribute to this trend as they seek new ways to bring their products to market without investing heavily in building or upgrading their own manufacturing facilities.

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Pharma R&D Outsourcing Is On The

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Rise. Pharmaceutical companies are increasingly outsourcing research activities to academic and private contract research organizations (CROs) as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, increasingly sophisticated

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technologies and an unstable economic environment. The R&D tasks that firms choose to outsource include a wide spectrum of activities from basic research to late-stage development: genetic ...

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The two companies plan to work together on the creation a drug-

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development technology tool that helps in safety margin risk assessment prediction. Latest FDA updates on COVID-19 battle As the pandemic maintains a grip on the globe, the federal agency continues to offer advice and take action to guide life-sciences professionals.

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Some key players operating in the pharmaceutical analytical testing outsourcing market include Toxikon, Inc.; Intertek Group PLC; SGS SA;

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Eurofins Scientific; Boston Analytical;  
Pace Analytical Services, LLC; West  
Pharmaceutical Services, Inc.; WuXi  
AppTec, Inc.; Intertek Group Plc;  
Pharmaceutical Product Development,  
LLC; and Charles River Laboratories  
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ThermoFisher Scientific, a leading biotechnology product development company who will be exhibiting their range of spectroscopy products at Pittcon 2018, is an example of a company that provides...

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Product development company who  
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22, as industry experts with more than  
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Operations and CRO selection will share their tips and secrets for identifying the right partner.

The field of combination product development (products born of the

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Integration of medical devices, biologics, and drugs) is so new that, while literature abounds on each part individually, there are very few publications, including FDA documents, available concerning the unique challenges posed by this nascent but fast-growing area.

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Providing the first in-depth look at this breakthrough field, *Combination Products* includes practical guidelines and a detailed step-by-step process for the development of these novel technologies. It addresses the technical, scientific, regulatory, and quality issues that arise when

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Combining drugs, biologics, and medical devices into a single product. It takes a practical, readily applicable approach to discussing the challenges, victories, and pitfalls associated with merging technologies and systems and how to implement these products into the market successfully and in a

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timely manner. Specifically, this text explores the process from start to finish, establishing a workable design and development plan complete with relevant definitions. It reviews FDA and other regulatory expectations and covers resource requirements, manufacturing pitfalls, post-launch

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compliance requirements, and agency audits and challenges. Drawing on the experience and expertise of two leaders in their respective fields, Combination Products boasts the credentials of Dr. Smita Gopaldaswamy, a 20 year veteran of technical consulting responsibilities in



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medical device, biologics, and pharmaceutical industries as well as combination products, along with the support of Dr. Venky Gopaldaswamy, an expert in business improvement methodologies such as six sigma, lean, and change management, to provide a comprehensive assessment

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of the field and an efficient and effective approach to the creation and implementation of combination products.

The original edition of this text, Clinical Evaluation of Medical Devices: Principles and Case Studies, provided

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the first overview of key principles and approaches to medical device clinical trials, illustrated with a series of detailed, real-world case studies. The book is designed as a resource for clinical professionals and regulatory specialists working in the field of new medical device development and

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marketing. Since the first edition of this text was published in 1997, the rapid pace of innovation in health care technologies continues to yield exciting and important new products. The regulatory landscape has also evolved, reflecting some of the changes and needs within the medical

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device industry. The purpose of  
Clinical Evaluation of Medical Devices:  
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Edition is to provide an updated and  
expanded presentation of the scientific  
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includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this purpose as well as health care technology assessment methods; (2) information on new

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statistical methodologies applied to medical device trials; and (3) all new case studies, including examples of combination products, three-phase development models (i. e. , feasibility, FDA approval, Medicare reimbursement), and novel study designs.

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The development of a robust drug product requires juggling many competing priorities such as overcoming scientific challenges, following regulatory requirements, and managing business-related concerns. Unfortunately, despite large resources



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Spent on R&D, multifactor productivity of pharmaceuticals is on the decline for several years now. Because of this business reality, pharmaceutical companies have seen a notable change in the traditional operating model and footprint over the past couple of decades. Outsourcing, in

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Particular, has emerged as a successful business model for many pharmaceutical companies looking for ways to strategically increase their R&D capabilities and to augment their in-house resources. How to Integrate Quality by Efficient Design (QbED) in Product Development bridges the gap

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between theory and practice when it comes to strategic decision-making in a pharmaceutical research scenario. This book will introduce the concept of QbED and focus on various aspects such as patient-centric product designs, platform-based manufacturing technologies, business

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Acuity, and regulatory strategies to balance the challenges in outsourcing with the need for strategic and statistically sound experiments rooted in good science. Detailed discussions will cover pharmaceutical business models, regulatory approval process, quality by design (QbD), business

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analytics, and manufacturing excellence specifically for small molecules and solid oral dosage forms. With the addition of case studies, flowcharts, diagrams, and data visualizations, How to Integrate Quality by Efficient Design (QbED) in Product Development will be a

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Practical reference to help professionals working in the area of pharmaceutical drug development, strategy, and outsourcing management. Part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin  
Integrates pharmaceutical business

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models, economics, and outsourcing-related challenges into pharmaceutical product development Discusses relevant literature references in quality risk management, business strategy, QbD, and product development Provides decision-making flowcharts, conceptual diagrams, and data

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visualizations to make the book useful,  
easy to read, and to understand

Thanks to remarkable advances in modern health care attributable to science, engineering, and medicine, it is now possible to cure or manage illnesses that were long deemed



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untreatable. At the same time, however, the United States is facing the vexing challenge of a seemingly uncontrolled rise in the cost of health care. Total medical expenditures are rapidly approaching 20 percent of the gross domestic product and are crowding out other priorities of national

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importance. The use of increasingly expensive prescription drugs is a significant part of this problem, making the cost of biopharmaceuticals a serious national concern with broad political implications. Especially with the highly visible and very large price increases for prescription drugs that

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have occurred in recent years, finding a way to make prescription medicines—and health care at large—more affordable for everyone has become a socioeconomic imperative. Affordability is a complex function of factors, including not just the prices of the drugs themselves, but

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also the details of an individual's insurance coverage and the number of medical conditions that an individual or family confronts. Therefore, any solution to the affordability issue will require considering all of these factors together. The current high and increasing costs of prescription

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drugsâcoupled with the broader trends in overall health care costsâis unsustainable to society as a whole.

**Making Medicines Affordable** examines patient access to affordable and effective therapies, with emphasis on drug pricing, inflation in the cost of drugs, and insurance design. This

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Report explores structural and policy factors influencing drug pricing, drug access programs, the emerging role of comparative effectiveness assessments in payment policies, changing finances of medical practice with regard to drug costs and reimbursement, and measures to

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prevent drug shortages and foster continued innovation in drug development. It makes recommendations for policy actions that could address drug price trends, improve patient access to affordable and effective treatments, and encourage innovations that address

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The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable



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Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of

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Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as

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combination products. A survey of the market indicates that there is a strong need for a new book that will provide "one stop shopping" for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product

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development. The new book entitled  
Development of Biopharmaceutical  
Drug Device Products is a reference  
text for scientists and engineers in the  
biopharmaceutical industry, academia  
or regulatory agencies. With insightful  
chapters from experts in the field, this  
new book reviews first principles,

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covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to

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influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes,

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including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials). Finally, the latter half of the book reviews key considerations to ensure the

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Development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the



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product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout. The typical readership would have biology and/or engineering

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degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.

The International Conference of Harmonization (ICH) has worked on

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Harmonizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical

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concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the

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American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several

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regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from

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Presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v  
Freedom of our mind is Mother of all inventions.

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The engineering enterprise is a pillar of U.S. national and homeland security, economic vitality, and innovation. But many engineering tasks can now be performed anywhere in the world. The emergence of "offshoring"- the transfer of work from



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the United States to affiliated and unaffiliated entities abroad - has raised concerns about the impacts of globalization. The Offshoring of Engineering helps to answer many questions about the scope, composition, and motivation for offshoring and considers the

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implications for the future of U.S. engineering practice, labor markets, education, and research. This book examines trends and impacts from a broad perspective and in six specific industries - software, semiconductors, personal computer manufacturing, construction engineering and services,

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Automobiles, and pharmaceuticals.  
The Offshoring of Engineering will be  
of great interest to engineers,  
engineering professors and deans,  
and policy makers, as well as people  
outside the engineering community  
who are concerned with sustaining  
and strengthening U.S. engineering

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capabilities in support of homeland security, economic vitality, and innovation.

Bikash Chatterjee emphasizes the criticality of applying the principles of Lean and Six Sigma within the paradigm of the drug development

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process. His guide to operational excellence in the pharmaceutical and biotech industries is a focused summary of the application of Lean Six Sigma theory to the regulated life sciences. From molecule discovery to the application of PAT Applying Lean Six Sigma in the Pharmaceutical

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Industry will highlight the importance of framing these initiatives within the key deliverables of drug development manufacturing and quality.

Challenging conventional wisdom the author offers a quality and efficiency perspective as a foundation for the principles of Quality by Design, PAT

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and the new philosophies underlying  
Process Validation. Each chapter  
includes discussion around the  
considerations for applying Lean  
manufacturing and Six Sigma  
principles and their tools, culminating  
in a case study to illustrate the  
application. The book is organized to

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reflect the major work centers involved in the drug development lifecycle.

Each chapter is stand-alone but together they illustrate the necessary synergy between Lean, Six Sigma and compliance sensibilities required to be successful in the pharmaceutical industry. These design, manufacturing



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and management techniques are not without their challenges. Bikash Chatterjee's book offers the roadmap for an industry that is struggling to reinvent many of its development and business processes.

This book examines the strategic

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Aspects of outsourcing in relation to the firm. It provides a holistic view of the outsourcing process, starting with conceptualisation, through to implementation and management of the process. Although the book is based on a case study of the pharmaceutical industry, the general

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principles derived from the Strategic Sourcing Model are generic in nature and the model can be applied to instances of outsourcing in other industries.

The national immunization system has achieved high levels of immunization,

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particularly for children. However, this system faces difficult challenges for the future. Significant disparities remain in assuring access to recommended vaccines across geographic and demographic populations. These disparities result, in part, from fragmented

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publicâ€"private financing in which a large number of children and adults face limited access to immunization services. Access for adults lags well behind that of children, and rates of immunizations for those who are especially vulnerable because of chronic health conditions such as

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diabetes or heart and lung disease, remain low. Financing Vaccines in the 21st Century: Assuring Access and Availability addresses these challenges by proposing new strategies for assuring access to vaccines and sustaining the supply of current and future vaccines. The book

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recommends changes to the Advisory Committee on Immunization Practices (ACIP)-the entity that currently recommends vaccines-and calls for a series of public meetings, a post-implementation evaluation study, and development of a research agenda to facilitate implementation of the plan.

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