FUTURE ISSUES IN REGULATORY SUBMISSIONS. pdf

1: When will the courts intervene in regulatory decisions concerning future issues? - Lexology

When will the courts intervene in regulatory decisions concerning future issues? Herbert Smith Freehills LLP United Kingdom September 5 Avaaz made submissions on Fox's record in both.

Through different kinds of cooperative arrangements, biotech drug manufacturing firms outsource parts of their manufacturing processes and services. Among the motivators to practice outsourcing, economics and faster product manufacturing play major roles. FDA wants to support every effort that would facilitate the approval of safe and quality products for the American public in the United States. Therefore, it is important to gain a full understanding on the impact outsourcing has on the firms and on the FDA, along with the responsibilities for the participants of these cooperative arrangements. This understanding can facilitate compliance with FDA regulations. Introduction This article explains the impact outsourcing has in defining the Food and Drug Administration FDA activities and its resources. Different cooperative manufacturing arrangements are possible for biotech product firms through outsourcing. Understanding these arrangements and the roles responsible for these cooperative manufacturing arrangements can help improve outsourcing practices and minimize the potential for quality problems. Background Originally, there were very few biotech product manufacturers in the U. These few manufacturers were responsible for the whole manufacturing process of their products. As time progressed, the increasing complexity of manufacturing and improved, highly specialized technologies began to limit single source manufacturing. Firms who previously had performed the entire process were now only capable of performing limited aspects of the whole drug manufacturing process. Consequently, firms started to delegate certain aspects of the manufacturing process to contract services to facilitate product development. Increased market pressure for innovation fostered even further specialization by outsourcing firms. Also, data from an exploratory survey of 86 companies suggests that the outsourcing of strategic activities such as manufacturing and clinical trials continue to be outsourced at an accelerating pace [2]. Cooperative Manufacturing Arrangements A Type of Outsourcing Outsourcing involves delegation of responsibilities among different manufacturers. Accomplishing this goal via this type of outsourcing brings products to the market faster, often with less expense than if the parent company were required to develop, qualify and then implement all the manufacturing processes. Benefits from outsourcing include access to a skilled workforce without having to hire new workers [4] , higher-quality services provided by a focused and experienced external source, and being able to refocus limited internal resources on core business activities [5]. Description of the most common arrangements among firms sharing the manufacturing of a given product can be found in the FDA Guidance to Industry: For example, manufacture of the whole product might be done by one firm, with packaging or warehouse contracting performed by another. Another cooperative arrangement includes when a manufacturer might contract to have only laboratory testing performed by an outside source. A third possible cooperative arrangement is the exception of obtaining a small amount of product from a firm which is not part of the identified license holder. In summary, any type of firm participating in the manufacturing process must comply with the Law. Roles and Responsibilities Under the Law Many are the benefits of outsourcing to those companies looking for innovation and building efficiency. More agile contract manufacturers and labelers are a great alternative. However, properly managing outsourced manufacturing presents many challenges to everyone [7]. With new challenges, responsibilities also need to be defined. However, the responsibilities of license holders differ from those of contractors. Through the consistent implementation of current good manufacturing practices cGMPs the license holder can ensure compliance with product and establishment standards. FDA recommends effective and timely communication with the parties involved in the manufacturing of a product to avoid misunderstandings. Communication is extremely important in supporting the production of high-quality biopharmaceuticals. This is especially true when the results of an analysis indicate a problem with the product [8]. Reporting any test results that may adversely affect the product, informing manufacturing changes to all the parties involved in the manufacture, and informing every manufacturing participant on changes in facilities are all good examples of effective communication. There are different mechanisms available to facilitate effective communication

between firms and contractors. For example, there are two options contractors may use to notify license holders about a recent change. One option is to provide the information to the sponsor to submit as a supplement to the original biologic licensing application BLA to FDA. In practice, the latter option is the most commonly used due to confidentiality issues surrounding proprietary manufacturing changes. Outsourcing does not exempt its participants to comply with the Law, regulations, and cGMPs. Not complying with these can result in adverse action taken by FDA against the firms. A license holder is an applicant for a license assuming responsibility for ensuring compliance with applicable product and establishment standards. The applicant is not required to perform any of the manufacturing steps but may contract other firms to perform all or part of the manufacture of the product [10]. A sponsor can be a license holder and a license holder can be a sponsor. Sponsorship and license holding are not mutually exclusive or totally inclusive. Effects of Outsourcing on FDA Resources We benefit from one of the safest drug supplies and one of the highest standards of consumer protection in the world. However, the general trend toward global outsourcing of pharmaceutical products has created new challenges for the FDA. New consumer safety risks and challenges result when outsourcing the manufacturing of pharmaceutical products [11]. For example, a biological component material made in one facility may have important precursor constituents made elsewhere, and an important property of the material may be adjusted by yet another facility. The product might then be sent to an additional separate facility to be filled into containers. In this scenario multiple contractors could be involved in the manufacture of a single compound! Nowadays, modality is to have a manufacturing process shared among different participating sites. There is a positive relationship between the number of firms participating in the manufacture of a product and the number of FDA inspections. Inspections to sites, including laboratories, suppliers, labelers, storage sites, and packagers â€" in and outside the United States will be needed. Warehouses for unlabeled products may also be inspected. The increase in FDA inspections has posed new challenges to FDA, including meeting this obligation with limited resources. The need to perform inspections overseas has increased as firms have moved manufacturing outside the U. In the past, less inspectional obligations, and normally of US sites, may have been needed before approval. Increase in worldwide inspections is associated with an increase in travel time and associated expenses such as the need for multilingual staff to manage and control documentation, and interaction with a variety of international business cultures. In their interactions with manufacturing sites outside the U. These challenges translate into an increased need for effective communication and coordination of efforts with more parties. In response to these new challenges, new trends have emerged: To save time, FDA encourages early communication between the sponsor and the Agency. Including a table of contents with each submission, a list of acronyms with their definitions, background information, past history and future projections are all good time-saving practices. Another current issue that may impact the future of outsourcing is the development of Generics for DNA-derived biotech and therapeutics covered under BLAs. This issue is currently being studied by Congress and FDA. Conclusion In conclusion, FDA wants to facilitate product development and manufacturing flexibility. Manufacturers should have a clear understanding of the potential role of cooperative manufacturing arrangements for outsourcing in their manufacture process and their responsibilities in the context of such cooperative manufacturing arrangements. A well-written agreement can help avoid regulatory actions with legal consequences [13]. This article was written by the author in her private capacity. No official support or endorsement by the Food and Drug Administration is intended or should be inferred.

2: FDA to Reject eCTDs with Significant Technical Issues | The eCTD Summit

The FDA released guidance for sponsors of devices with cybersecurity risks on what they should include in their premarket submissions, as well as considerations for device design and labeling. The GMP Letter (GMP) to stay on top of the FDA's interpretation and enforcement of the quality systems.

The rapid increase of information about environmental processes, human-environment interactions, and human and environmental impacts brings new challenges to this relationship in the future. The spectrum of new information that will be available to the environmental regulatory process is vast and beyond the scope of this report. Two examples are discussed to indicate the diverse sources of information that have the potential to be available to modeling. One end of the spectrum could be considered the genomics revolution, which has enabled the analysis of all the genes in a cell at the DNA, mRNA, protein, or metabolite level NRC b. These tools can be used to better understand the susceptibility of individuals or subpopulations to chemicals, as well as their responses to chemicals toxicogenomics. For example, genomics tools provide a means to examine changes in gene expression and to examine how these indicators might be used to understand human health impacts EPA g. Although the capability to understand the potential for toxicants to impact human genes has been present for many years, the innovation of high throughput testing technologies has profoundly expanded the capability to better measure genomic changes NRC b. The dramatically increasing amounts of information from genomic technologies have spawned a new science called infomatics to enable orderly analysis of vast data sets. However, substantially more sophisticated computational toxicology methods, including the use of computational models of biological systems and phenomena, will be needed to link genomics data to quantitative estimates of human health risks before the full potential for this information will be realized NRC b. Another end of the spectrum of measurement systems that will influence regulatory modeling is the rapid increase in data from environmental satellites and weather data Foley The information from these systems provides a truly global climate observation system as well Page Share Cite Suggested Citation: Models in Environmental Regulatory Decision Making. The National Academies Press. Such measurements may help to discern information on climatic variability, water resources, ecosystem changes, air pollution episodes, and a wide array of other possible applications. Although the sheer volume of data creates unprecedented challenges for data-handling operations, a more fundamental challenge is the scientific use of this information Kahn Again, the spectrum of possible technologies and methods is vast and beyond the scope of this report. The committee discusses two areas as examples: One area is the increasing development of integrated modeling approaches. The continuum from sources to human health responses in the human health risk assessment paradigm is described in many sources e. Recent advances in modeling tools have greatly enhanced the capabilities to perform computationally intensive multiscale source-to-dose and exposure assessment for a wide range of environmental contaminants Foley et al. For example, Georgopoulos et al. The use of integrated modeling approaches for the environment is not confined to the human health risk assessment field. Page Share Cite Suggested Citation: Watershed modelingâ€”The BASINS modeling framework includes watershed nutrient loading and transport models and instream water quality models that operate with a geographical information system EPA d. FaTE model is a multimedia compartmental model to help assess multimedia chemical fate, transport, and exposure and risk of pollutants in the ambient environment Efroymson and Murphy ; EPA g. Hazardous waste risk assessmentâ€”The multimedia, multipathway, and multireceptor exposure and risk assessment 3MRA model can assess potential human and ecological health risks using transport, fate, exposure, and toxicity EPA h. Global change fieldsâ€”These models link models of energy-economic processes to environmental models e. These integrated modeling frameworks are typically written in a modular form, as discussed in Chapter 3 , which allows users to easily add or remove parts of the model to tailor individual applications to the problem at hand. Software platforms, such as the framework for risk analysis in multimedia environmental systems FRAMES , are often used to link models and databases under one integrated system. Typically, a user interface facilitates such development. However, the ever-larger and more-sophisticated models may not necessarily make better regulatory tools. Clarke and Perciasepe raise

the possibility that pursuing larger and more-sophisticated models make them less and less able to be evaluated and more impenetrable to the public and decision makers. Other modeling technologies have attempted to improve transparency and build a stronger bridge to the public and decision makers through the use of user-friendly graphic simulation software. One approach is to utilize object-oriented programming languages that allow individual components of a model to be visually and mathematically linked in a user environment that displays how different elements of a model interrelated and that allows users to easily modify the relationship among components. Known as share-vision modeling, it involves the common development of a single model or modeling framework by a diverse group of stakeholders involved in a water resources issue facilitated by object-oriented programming software Lund and Palmer This approach has been recommended by the Institute for Water Resources as a way to bridge the gap between the specialized water models and the human decision process Werick Two general approaches are weight-of-evidence and adaptive management strategies. The Air Quality Management AQM Work Group, which is composed of stakeholders from state and local governments and some industry and nonprofit organizations, endorsed the weight-of-evidence approach as a way to reduce reliance on modeling data as the centerpiece for air quality attainment demonstrations and increase the use of monitoring data and analyses of monitoring data AQM Work Group Adaptive strategies recognize the importance of improving environmental management strategies as new measurements and modeling analyses become available. The objective of this review is to decide whether the current NAAQS for that pollutant should be revised. Although the process of reviewing and implementing changes in the standards is cumbersome and has not been kept up with the 5-year review cycle mandated in the legislation, the history of the Clean Air Act has seen important revisions to air quality standards as a result of these reviews. Another example is in the cleanup of large mining megasites, where the amount and wide distribution of contaminated materials preclude complete remediation with traditional cleanup approaches envisioned under the Superfund Act. EPA recognizes that many contaminated mining megasites will require operation and maintenance in perpetuity EPA h. Under conditions where remediation is a long-term process involving many separate projects, some of which cannot be specified at the outset, the agency is forced into an adaptive approach requiring periodic progress reviews and adjustments to unsuccessful remedies. A final example of an adaptive strategy in environmental regulatory activities is the California Air Resources Board CARB process for periodic review and revision, if necessary, of California motor-vehicle emissions standards NRC c. Because of the far-reaching and long-term nature of the California standards, CARB committed to a biennial review of its motor-vehicle emissions standards program to monitor manufacturer compliance plans, to identify any problems with the feasibility of its demanding program, and to modify the standards if deemed necessary e.

3: Regulatory affairs - Wikipedia

Such recurring issues if converted to a checklist and prevented for future submissions will help to get validated in first attempt itself. Biography Jayprakash is a Senior Project Leader at Virtify Inc.

4: Banking Regulatory Outlook | Deloitte US

Study Data in Future Regulatory Submissions. Inside This Issue. FDA now requires that certain regulatory submissions conform to the electronic Issues of this newsletter are archived at.

5: Regulated Product Submissions - Wikipedia

FDA also agreed to provide written feedback on the issues raised in pre-submission requests for a minimum number of pre-submissions for each year of the MDUFA IV program.

6: Regulatory Publishing Innovation and Success | Synchrogenix

FUTURE ISSUES IN REGULATORY SUBMISSIONS. pdf

Agile Project Management Methodology. Since adopting Agile for Regulatory Submissions, Synchrogenix's regulatory publishing team has completed 75% of its projects ahead of the submission deadline.

7: Life Sciences Regulatory Outlook | Deloitte US

Given the challenges of generating revenues to fuel future, life-saving therapies while responding to growing scrutiny and evolving regulatory requirements, manufacturers must take steps to understand and manage this growing risk area that threatens their reputations (and potentially their finances).

FUTURE ISSUES IN REGULATORY SUBMISSIONS. pdf

Cs rao environmental engineering book The Photosynthetic Bacteria Guide de redaction juridique Issues in selecting, collecting, reporting, using performance measures. Global Conscius ness New treasures from the old Externalization of consciousness and the psychopathology of everyday life Evaluation of cultural action Microeconomics colander 10th edition Small-Scale Modelling Check list of American eighteenth century newspapers in the Library of Congress Early man life history Were just good friends Bridging the Expectation Gap Naming, The new rules of Structural dynamics for engineers Earth-Based Psychology Memoir of William Henry Channing Developing casework skills Kantian form and phenomenological force Introduction xxxv Using scary stories in the classroom Environmental politics and policy The Return of the Village Atheist Foundations of European Community law Andrew, the first to follow Rapid viz 3rd edition 15-minute Latin American Spanish (Eyewitness Travel Guides) Neurosciences at the Postgenomic Era (Research and Perspectives in Neurosciences) Simcoes Military Journal; A History Of The Operations Of A Partisan Corps Called The Queens Rangers Seven champions of Christendom, 1596-7 Contemporary perspectives on property, equity, and trusts law Computer programming in BASIC the easy way Indesign ument will not export to Defiance unto death : the tragic finale The heart of the monarchy Adam Zertal The God of This World to His Prophet Solomon Among the Postmoderns Jaguars and electric eels Faux Finish Secrets