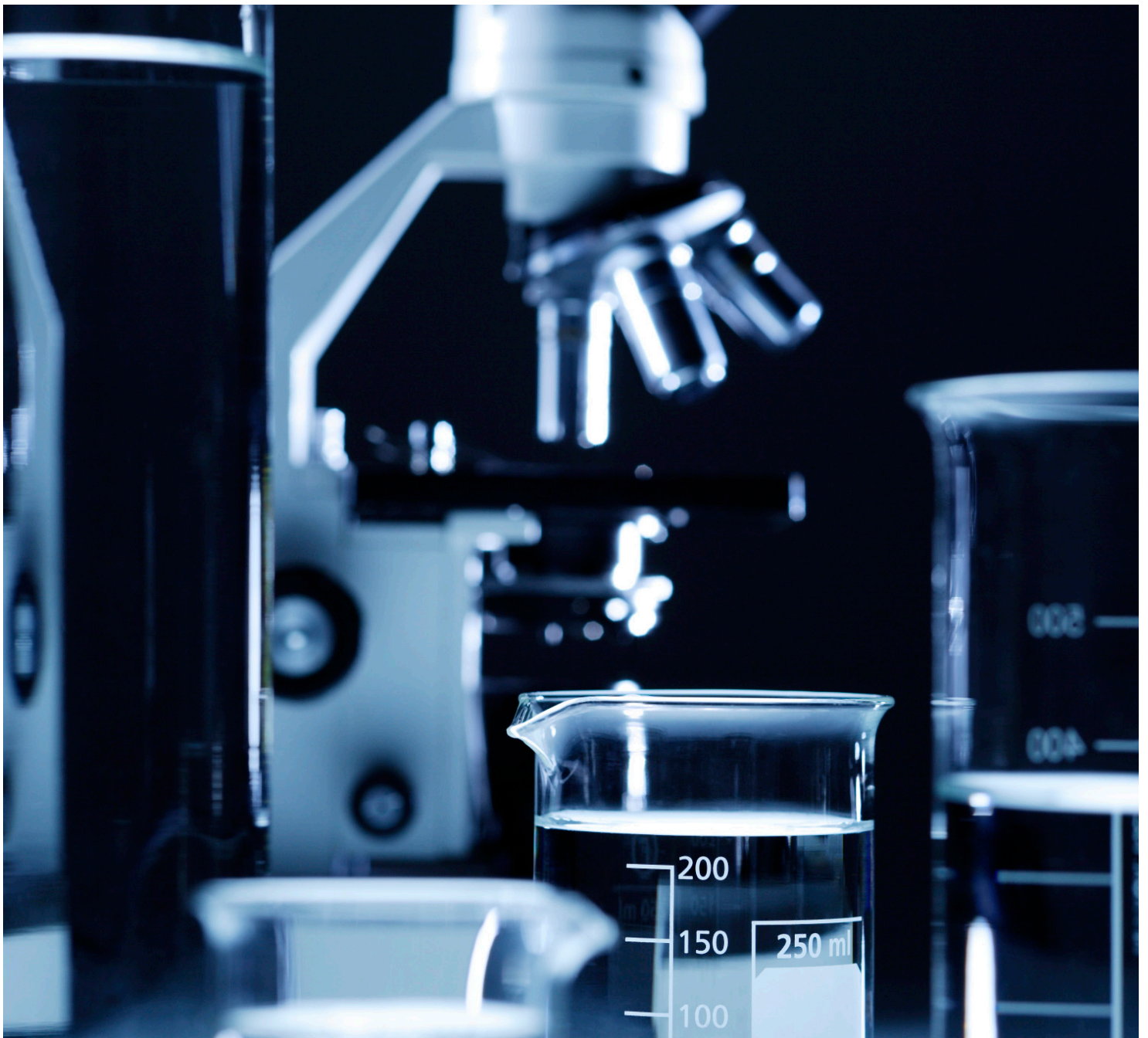


Improving America's Health IV

A survey of the working relationship between
the life sciences industry and the FDA



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Foreword

For more than a decade, PricewaterhouseCoopers has periodically surveyed the life sciences industry on its relationship with the United States Food and Drug Administration (FDA). The surveys conducted in 1995, 1997 and 1999 provided a clear picture of the process FDA and the industry engage in to ensure the safety of new pharmaceutical, biologic and medical device products. The picture then was mixed, with a regulatory review process viewed by many as slow and bureaucratic.

In 2006, PricewaterhouseCoopers, in partnership with BIOCOM, the world's largest regional life sciences association, conducted the fourth survey in this series. In *Improving America's Health IV: A Survey of the Working Relationship Between the Life Sciences Industry and the FDA*, we see a regulatory process that has been greatly improved by the changes it has undergone since enactment of the Food and Drug Administration Modernization Act of 1997.

The 1997 legislation, the impacts of which were only beginning to be felt at the time of the last survey in 1999, has helped make the evaluation of new products significantly more efficient. Products that save lives and enhance the quality of life are making their way to physicians and patients faster and more efficiently than ever before.

Despite the progress made during the past half-dozen years, substantial issues remain and further improvements are needed. The 2006 update of *Improving America's Health* examines these issues and offers perspectives on improvements that can be made to the regulatory review process and the working relationship between FDA and industry. We hope that it can advance the long-term dialogue between FDA and the life sciences industry on how best to improve processes, and it also serves as a source of ideas for examining how new products are vetted.

During the past generation, there have been few improvements to public health that have had more dramatic impact than the introduction of new medicines, medical devices and diagnostics. Lives have been saved and improved as a result of scientific advances that have been brought into the nation's hospitals, clinics, doctors' offices and pharmacies. Introducing new products as rapidly as possible, while ensuring their safety and effectiveness, is among the most important steps the federal government can take to improve America's health.

We trust that this report will help bring greater understanding of the working relationship between FDA and the life sciences industry and continue the improvements that have been made to date in the regulatory review process.

Joseph D. Panetta
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Michael Mentesana
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Executive summary

Introduction

Some of the most important developments in human health have been the discovery of new medicines and man's ability to prevent, cure or eliminate disease. By its very nature, there is urgency for scientific discovery, especially that which can save a life, reduce pain or restore health. This urgency is manifested in the tension between the desire to develop new medicine as quickly as possible and the obligation to protect those who use them. It is a tension that has long characterized the relationship between life sciences companies and FDA.

While some believe that the advance of science should not be bridled, the decision to move discovery efforts from the lab to commercial use is a tightly controlled, rigorous process, designed to assure the public that the safety and effectiveness of biologics, drugs and medical devices are based on science not whim.

The US FDA is the gatekeeper of this process and ultimately decides whether to permit a new drug, biologic or medical device to be marketed. The rigor of its review and approval process is one reason that US citizens generally have had a high degree of confidence in the safety and efficacy of their food and drugs.

In sharing a similar goal to bring the safest, most effective new drugs, biologics and medical devices to market, one would expect that FDA and life sciences companies would have a cooperative working relationship. But, historically, their relationship has been more contentious than collegial, described over the years at times as adversarial. Some firms have argued that FDA has stifled innovation and that bureaucracy within the resource-constrained agency has led to the delay or rejection of viable medicines and treatments and the loss of US competitiveness. On the opposite end of the spectrum, other critics have accused FDA of being too cozy with industry, succumbing to pressure to fast-track certain drugs or suppress vital information about others.

In truth, FDA and life sciences companies have a symbiotic relationship.

- Introducing new products as rapidly as possible, while ensuring their safety and effectiveness, is among the most important steps the federal government can take to improve America's health.
- At the same time, FDA is essential to the development of a strong life sciences sector, and it interjects structure into what otherwise might be a chaotic, costly and risk-prone process.

Since 1995, PricewaterhouseCoopers has been tracking the relationship between FDA and life sciences companies. What's clear is that the relationship has changed over the years as new pressures and opportunities have emerged and science has advanced.

Surveys conducted in 1995, 1997, 1999 and now 2006 show the evolution of the relationship between life sciences companies and FDA, pointing out a stark contrast between their relationship today and 15 years ago. In the early 1990s product submissions were

backlogged in lengthy review queues; the relationship between the industry and the agency was strained; expectations were unclear and communications were poor.

Fortunately, Congress passed Food and Drug Administration Modernization Act of 1997 (FDAMA). The legislation, which included scores of regulatory measures to modernize and improve the FDA review process, was intended to (1) enhance the public health; (2) make the regulatory processes more effective and efficient; and (3) increase consumer and industry confidence through open, transparent processes and collaboration.

At the time of the 1999 survey update, there were clear signs as early as one year since passage of FDAMA that overall communication between FDA and product sponsors had begun to improve. However, frustration over approval process delays persisted.

Now, nearly ten years since FDAMA and six years since the last update, we revisit the relationship between FDA and the life sciences industry with a survey that received responses from 66 drug, biologic and medical device companies. It is a critical time for all. New questions about FDA relationships have intensified following recent safety issues that led to warnings and even the withdrawal of widely marketed drugs. And amid calls for greater transparency and accountability, life sciences companies and FDA are facing scrutiny from politicians, consumer health advocates and the media.

The first three surveys focused on issues that were important at the time, such as factors that were delaying or impeding the product approval process. They were, in effect, a report card on FDA. Unlike earlier surveys that focused primarily on FDA's effectiveness, this survey recognizes that the relationship goes both ways. The question cannot be solely, "What is FDA doing to provide better guidance and improve processes?" but "Are life sciences companies making proper use of FDA guidance and resources?"

Ultimately, the goal of this survey is to identify ways to make the development and approval process for new product submissions more efficient without compromising patient safety.

To this end, the emphasis in 2006 changed from analyzing the details of individual products to providing a broad perspective on industry interactions with the three FDA centers that oversee the reviews of life sciences industry product submissions:

- Center for Biologics Evaluation and Research (CBER, which regulates biological products for blood screening and vaccines for disease prevention)
- Center for Drug Evaluation and Research (CDER, which regulates prescription and over-the-counter drugs)
- Center for Devices and Radiological Health (CDRH, which regulates medical devices including diagnostics)

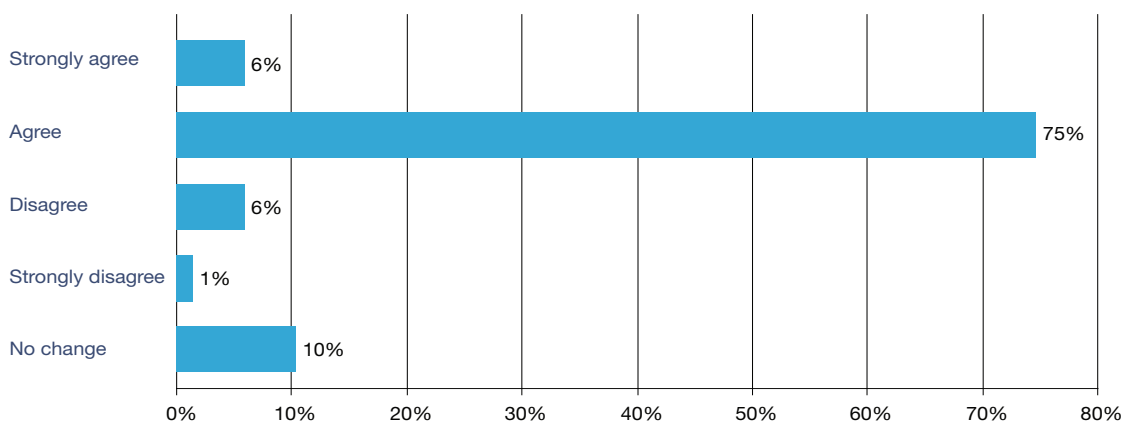
Major survey findings

In the nearly ten years since passage of FDAMA, both FDA and life sciences companies have met somewhere in the middle, both making great strides to improve communication and effectiveness of their working relationship.

Two steps forward: better guidance and clearer expectations

Eight in ten (81 percent) life sciences companies responding to the survey agreed that FDA has made significant improvements since FDAMA was enacted, and seven in ten (70 percent) indicated that their working relationship with FDA has indeed improved in that time.

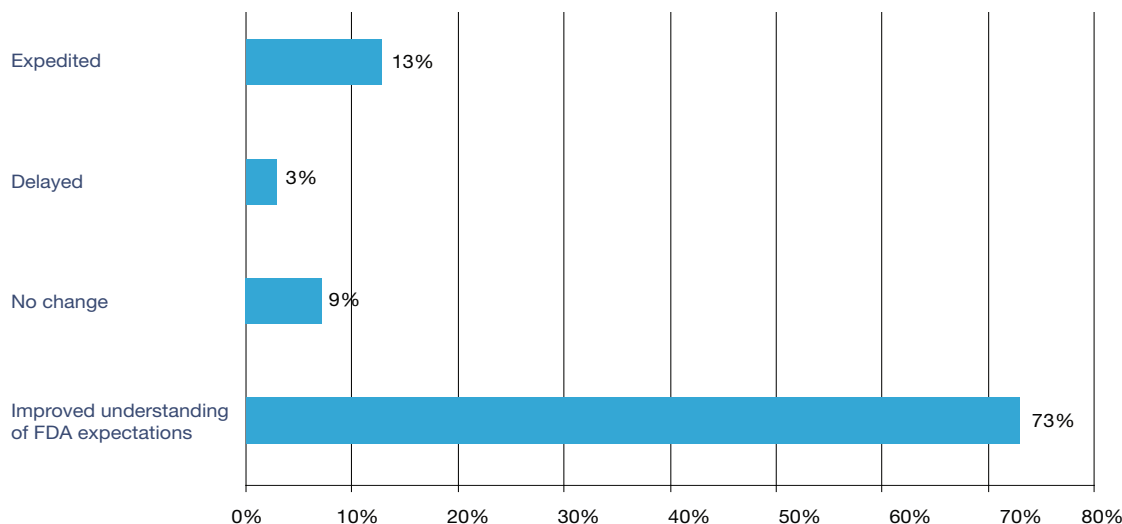
Based on your company's experience since FDAMA, the FDA has made significant improvements.



For their part, two-thirds (66 percent) of life sciences companies surveyed said that they have focused on building internal regulatory expertise, and that doing so has helped improve their relationship with FDA.

The industry also gave FDA high marks for providing more valuable feedback at the beginning of the development process and better guidance during the process itself. Overall improvements in the development process are attributed to the combination of increased or clearer FDA guidance, the accessibility and use of guidance documents by industry, and greater FDA willingness to meet with companies to provide feedback during the development process.

What do you think has been the overall impact of FDA guidance documents on the product development process?



Nearly three-quarters (73 percent) indicated that FDA guidance documents have improved their understanding of the Agency's expectations and, as a result, improved the quality of their submissions.

A majority (69 percent or greater) of the life sciences companies surveyed agreed that FDA promptly facilitated requests for clarification from the reviewers, the Agency contact was extremely knowledgeable about their submission status and promptly responded to requests. However, four in ten (43 percent) biologic and medical device companies that responded agreed that it was necessary to escalate the request above the original level of discussion compared to three in ten drug companies (29 percent). In addition, eight in ten drug (82 percent) and biologic (86 percent) companies agreed that FDA provided clear and specific answers, compared to just 62 percent of responding medical device companies.

Nearly nine of ten (88 percent) life sciences companies surveyed agreed that new FDA guidance related to risk mitigation and management of product life cycles has enhanced their comprehension of submission requirements. Furthermore, seven in ten drug companies (70 percent) and eight in ten biologic companies (77 percent) agreed that FDA is making better decisions because of these guidance tools. Medical device companies didn't feel quite as strongly about this; only 52 percent agreed.

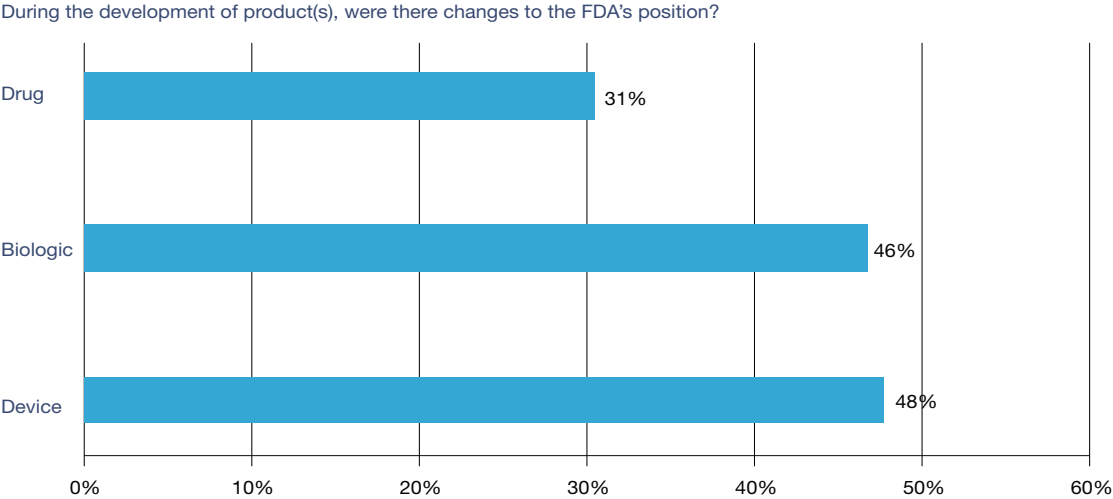
Industry consensus is that the Fast-Track program is working. More than two-thirds of biologic and drug companies indicated that the Orphan Drug or Fast-Track designation facilitated better communications with FDA and review processes.

One step back: resource constraints continue

Despite significant progress, however, there are still areas where greater improvement is needed on both sides. The life sciences companies surveyed identified faster turnaround times as the area where FDA improvement is most needed. At the same time, life sciences companies appear to not be taking full advantage of feedback when it is provided by the FDA.

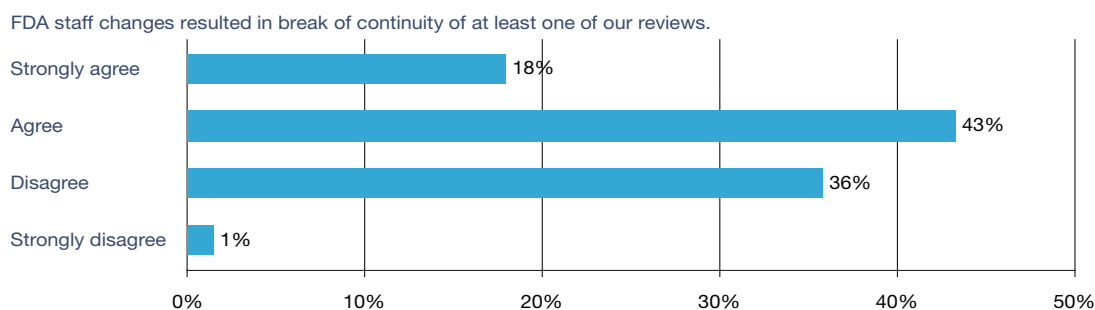
One-half of the surveyed life sciences companies overall admitted that they often are not incorporating FDA feedback into their product development progress. By ignoring FDA recommendations, they increase the likelihood of delays later in the approval process, a point at which mistakes become more costly from the standpoint of time and resources.

A small number of companies surveyed indicated that the Agency changed its position during the review of product submissions. While the number was small, the impact of FDA changing its position can be significant on a company's development program. Responding companies perceived that FDA changes were not based on new information or sponsor position changes. Furthermore, they indicated that FDA generally did not provide reasonable, scientific explanations for the changes in position.



The majority of biologic, drug and medical device company respondents indicated that meetings with FDA are important and useful for progression through the development process. Surprisingly, a significant number of them said they do not participate in stage-review meetings, especially later in the product approval process. Only 42 percent of drug companies had an end of Phase 2 meeting with FDA. Additionally, only 50 percent of drug companies indicated that CDER strongly encouraged having a post-Phase 2 pre-market filing meeting, which is low considering the importance industry says it places on these meetings.

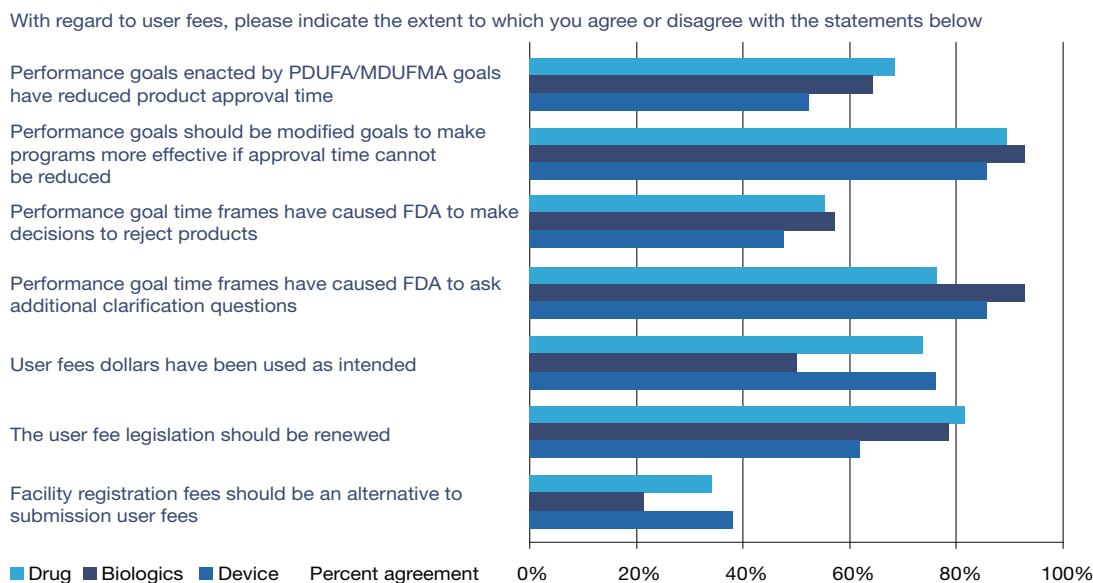
Staffing shortages and turnover within FDA remain the biggest ongoing issues in the relationship between FDA and life sciences companies. Six in ten (61 percent) companies surveyed agreed or strongly agreed that FDA personnel changes resulted in a break of continuity in at least one of their reviews.



User fees, introduced by Congress in the Prescription Drug User Fee Act of 1992 (PDUFA) and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), were an attempt to remedy FDA's chronic shortage of resources and accelerate product approval times by authorizing companies to pay fees to the FDA for products in review. Since user fees were introduced, FDA reports that it has been able to increase staff by approximately 600 reviewers and significantly decrease approval times. But approximately one-third (32 percent) of life sciences companies surveyed, and nearly half (48 percent) of all responding medical device companies, reported that user fees have not decreased product approval times.

This finding could prove significant as Congress debates renewal of the Prescription Drug User Fee Act, which expires in September 2007. Some industry critics believe that a complete overhaul of the Act is in order. Staffing issues are likely to continue to be a problem given that federal appropriations to FDA have been flat at a time when life sciences discovery has quickened at a feverish pace.

Furthermore, and perhaps most troubling, is industry's perception that the FDA reviewers still cannot keep pace with review queues. Notably, approximately half of all companies that responded indicated that goal time-frames have caused FDA to reject products simply because reviewers ran out of time to resolve issues. The overwhelming majority (85 percent) of life sciences companies said that if FDA cannot reduce approval times, it should modify the process to make programs more effective. The types of goals that can be modified include increasing staffing specifically for reviews and changing hiring goals for reviewers.

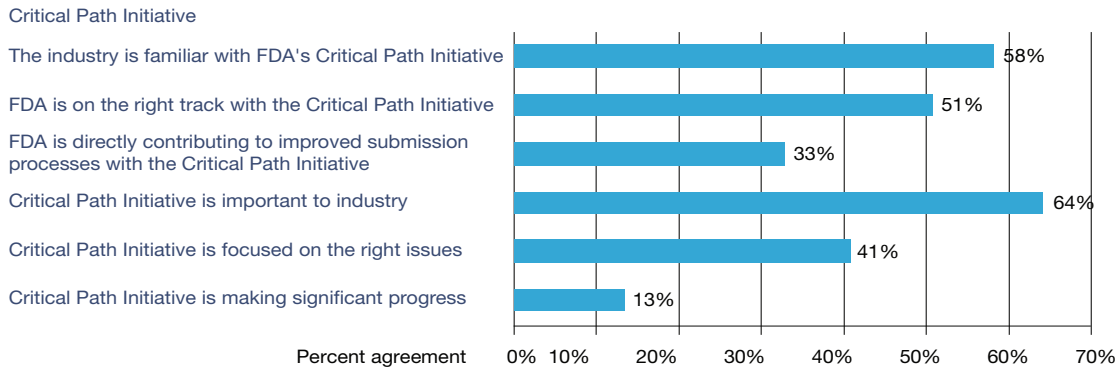


On its own, FDA introduced the Critical Path Initiative to facilitate a national effort to modernize the scientific process through which a potential drug, biologic or medical device product is developed and brought to market. FDA took the lead in the development of

a Critical Path Opportunities List, providing specific examples of how new scientific discoveries—in fields such as genomics and proteomics, imaging and bioinformatics—could be applied to improve the accuracy of the tests used to predict the safety and efficacy of investigational medical products.

While a majority (58 percent) of life sciences companies surveyed said they are familiar with the FDA Critical Path Initiative and agree with its importance (64 percent), responding biologic (38 percent) and medical device (48 percent) companies are less informed on the initiative than their counterparts on the drug side (73 percent).

Approximately half of the respondents indicated that FDA is on the right track with the Critical Path Initiative, but only 41 percent agreed it is focused on the right issues.

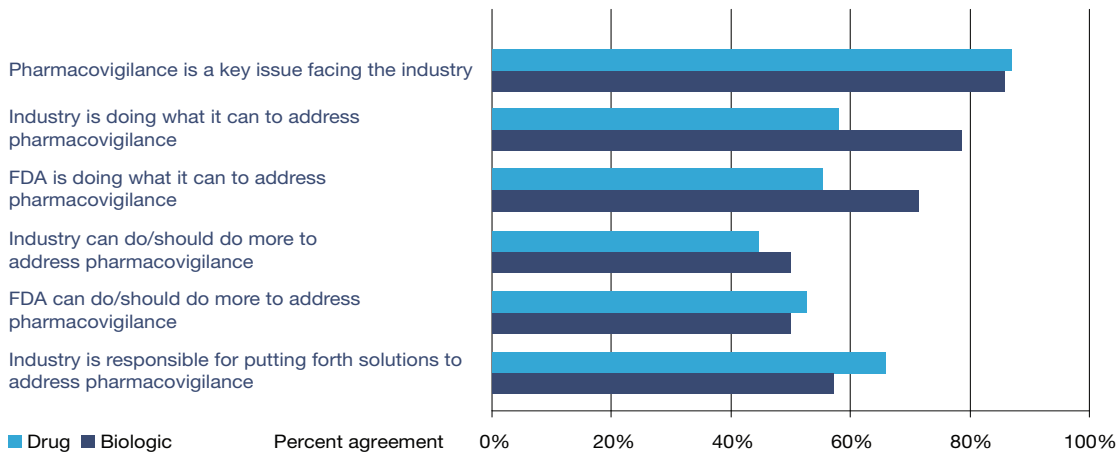


On common ground over safety reporting and monitoring

Where FDA and life sciences companies see eye to eye is on their commitment to improving safety reporting and pharmacovigilance.

More than three-quarters (78 percent) of biologic companies indicated that both FDA and industry are doing what they can to address pharmacovigilance. However, drug companies weren't quite as confident, with only 58 percent saying that they and FDA were doing all they could on this front. (Medical device companies were not included in the pharmacovigilance portion of the survey.)

With regard to pharmacovigilance, please indicate the extent to which you agree or disagree with the statements below.



Both biologic and drug companies identified an opportunity to expand their efforts with respect to technology, data quality and scientific tools, and methodology related to pharmacovigilance. While companies indicated they wanted to become leaders in developing pharmacovigilance solutions, they claim to lack best practices, especially in risk management and reporting and submission processes.

The majority of biologic (79 percent), drug (84 percent) and medical device (72 percent) companies surveyed agreed that a universal adverse event database would improve both patient safety and the analysis of safety data.

Conclusions

The results of the 2006 FDA Survey highlight significant improvements that have been made in the working relationship between FDA and industry since the last report in 1999.

The relationship between FDA and industry is of such vital importance because it has a direct impact on the efficiency and likelihood that new and innovative products become available to physicians and their patients. Despite the vast improvements made thus far, there is still much work to do. Both FDA and industry should strive to optimize the product approval process and adapt to external changes in the regulatory environment. This sentiment was reflected in the survey results: An overwhelming majority (92 percent) of responding companies agreed that changes could still be made to streamline the product approval process without jeopardizing patient safety. A number of considerations for FDA's and industry's continuing efforts to increase the efficiency and effectiveness of the product approval process are outlined below.

Opportunities for consideration

- The vast majority of responding life sciences companies indicated that the currently available FDA guidance documents are useful and would like to have additional FDA guidance. The Agency should continue developing guidance in areas for which it currently does not exist, providing further assistance to industry in advancing products through the product approval process.
- Life sciences companies should be more diligent about incorporating FDA feedback obtained during stage review meetings and throughout the product approval process into their development programs.
- Responding life sciences companies indicated that FDA guidance documents and meetings are very helpful in understanding submission requirements and the quality of the submissions themselves, but indicated the documents and meetings do not expedite the submission process and that FDA turnaround time needs further improvement. The industry and FDA should collaborate to streamline submission requirements and the review process in ways that are not burdensome.
- FDA and life sciences companies should focus on identifying and mitigating potential risks as early in the product approval process as possible so mitigation strategies can be built into the development programs.
- In general, responding companies indicated communication with CDRH was less effective than with CBER or CDER. FDA and industry should consider collaborating to assess the reasons for this disparity, including evaluating which position is designated the primary contact at CDRH for medical device companies. Communications between the industry and CDRH may be more effective if these constituents have reviewers or project managers empowered as decision-makers.
- The Agency should investigate the drivers behind changes in FDA position during the product approval process. Additionally, FDA should consider creating an internal monitoring program and a reasonable Sponsor appeal process to ensure consistency, while maintaining the highest level of patient safety. In the cases when a change in FDA position is required, regardless of the positive or negative effect, FDA should provide clear, scientific reasons for changes.
- FDA and industry should make every effort to participate in and encourage each other's participation in stage review meetings, especially later in the product approval process when delays and failures are more costly.
- FDA should make every effort to understand how it can reduce staff changes during a product review and how processes and guidance can be improved to maintain continuity in the event of a staff change.
- To address the issues raised by industry with respect to user fees, the Agency may need to better define the roles and responsibilities of the additional FDA personnel supported by the Prescription Drug User Fee Act of 1992 (PDUFA) and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to explain how staff increases speed up reviews. The Agency should consider a structural review of the product approval process resourcing model to help ensure a proper balance of resources. Greater transparency may be needed about how user fees are being employed, especially by CBER.
- FDA should consider forming a task force composed of industry, government and consumer or patient groups focused on improving pharmacovigilance and medical device reporting.
- FDA should more effectively engage the industry on the issues laid out in the Critical Path Initiative to gain stakeholder buy-in. In addition, it should determine which aspects of the Critical Path Initiative will have the most impact on product approval processes and focus on improving those elements.

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About

PricewaterhouseCoopers

PricewaterhouseCoopers (www.pwc.com) provides industry-focused assurance, tax and advisory services to build public trust and enhance value for its clients and their stakeholders. More than 140,000 people in 149 countries across our network share their thinking, experiences and solutions to develop fresh perspectives and practical advice.

PricewaterhouseCoopers is the global leader in providing audit, tax and advisory services for the life sciences, medical device and pharmaceutical industries. The firm works with clients to address a broad range of strategic, financial and operational issues. Clients benefit from the firm's global network and extensive portfolio of performance improvement and compliance capabilities specifically designed to support key operating needs in research and development, manufacturing, sales and marketing and in corporate functions such as finance, information technology and human resources. For more information, go to www.pwc.com/lifesciences.

About BIOCOM

BIOCOM is the largest regional life sciences association in the world, representing 550 member companies and firms in Southern California. The association focuses on initiatives that position the region's life sciences industry competitively on the world stage and on the development and delivery of innovative products that improve health and quality of life. This includes initiatives in capital formation, public policy, workforce development and member services. For more information on BIOCOM or the Southern California life sciences community, please visit the organization's Web site at www.biocom.org or call (858) 455-0300.

Improving America's Health IV

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Details

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Introduction

Some of the most important developments in human health have been the discovery of new medicines and man's ability to prevent, cure or eliminate disease. By its very nature, there is urgency for scientific discovery, especially that which can save a life, reduce pain or restore health. This urgency is manifested in the tension between the desire to develop new medicine as quickly as possible and the obligation to protect those who use them. It is a tension that has long characterized the relationship between life sciences companies and the United States Food and Drug Administration (FDA).

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Surveys conducted in 1995, 1997, 1999 and now 2006 show the evolution of the relationship between life sciences companies and FDA, pointing out a stark contrast between their relationship today and 15 years ago. In the early 1990s, product submissions were backlogged in lengthy review queues; the relationship between the industry and the agency was strained; expectations were unclear; and communications were poor.

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In the past, the survey results have been shared with senior FDA officials and Congress after the report's completion. Because of the new directions in this year's survey, BIOCOM representatives and PricewaterhouseCoopers staff met with FDA officials and members of Congress and their staffs to receive their input prior to the development of the survey questions.

The survey covered life sciences companies that had submitted or completed an investigational or product application to FDA between July 1, 1999, and July 31, 2005, for a pharmaceutical, combination, biologic, or diagnostic or medical device product. A total of 66 life sciences companies responded to the survey. (Note that some companies with products in different categories responded separately for the appropriate category, but companies were limited to one response in each category.)

Product type	Number of responding life sciences companies
Drug	37
Biologic	13
Medical device	21

Respondents represent a cross-section of the industry that ranges from companies with fewer than 50 employees to those with more than 5,000, and with annual revenue from zero to greater than US\$1 billion annually. The majority of respondents had 200 or fewer employees; US\$10 million or less in annual revenue; fewer than 10 products currently marketed; and fewer than 20 products in pre clinical and clinical development. Approximately half of the responding companies have operations outside the United States, including manufacturing, preclinical development and/or clinical development. These figures mirror the demographics of the industry, and we consider these to be a representative sample.

Findings

The majority of responding life sciences companies indicated that their working relationship with the Agency has improved during the six years covered by the survey. A strong majority (81 percent) of companies that responded—four in five—across all product types, believed that the Agency itself has made significant improvements in the regulatory review process since the 1997 enactment of FDAMA.

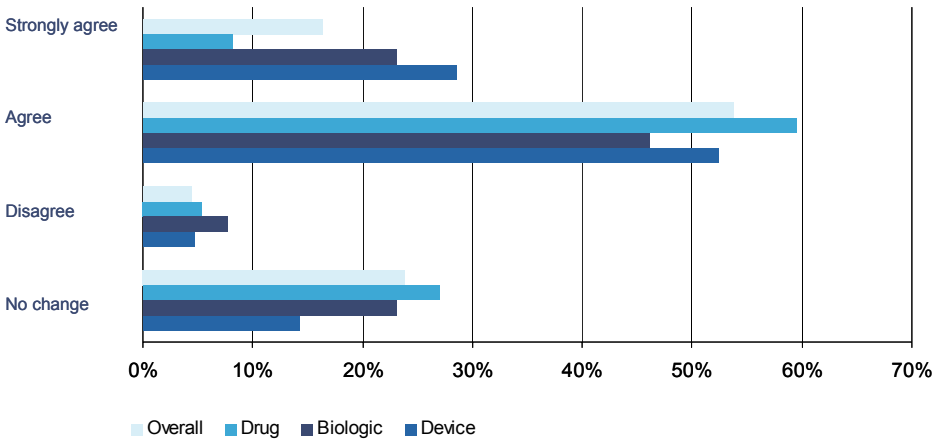
Based on your company’s experience, FDA has made significant improvements since FDAMA enactment. (agree/disagree)

	Overall	Drug	Biologic	Device
Strongly agree	6%	5%	8%	5%
Agree	75%	78%	69%	81%
Disagree	6%	3%	0%	10%
Strongly disagree	1%	3%	8%	0%
No change	10%	11%	15%	5%

Over the past six years, has your working relationship with FDA improved?

As the following chart shows, a majority (70 percent) of life sciences companies that responded, across all product types, believed their working relationship with FDA has improved during the past half-dozen years.

Over the past six years, our overall working relationship with FDA has improved.



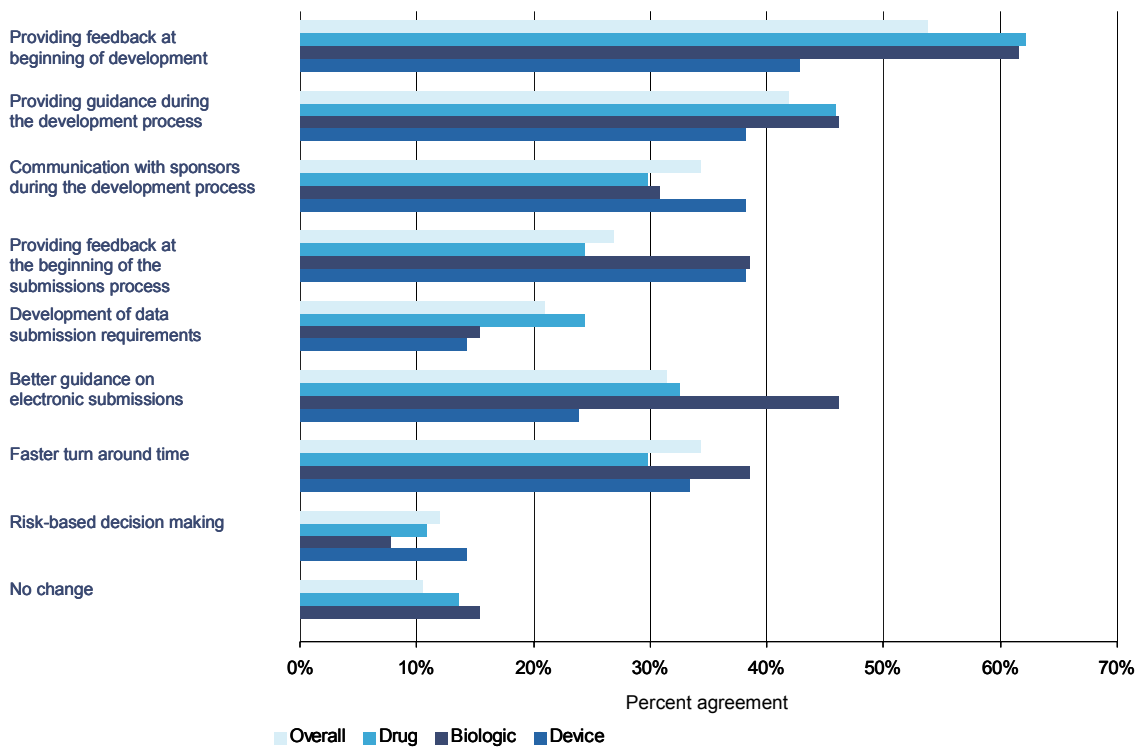
Most improved areas at FDA

The responding companies indicated that FDA has made the most improvement in providing feedback at the beginning of the development process and in providing guidance during the development process itself.

Nearly half (46 percent) of reporting biologic companies indicated the Agency made the most improvement in better guidance on electronic data submissions, compared to 32 percent of drug companies and 24 percent of medical device companies that responded.

These improvements are attributed to the combination of increased or clearer Agency guidance, the accessibility and use of guidance documents by the industry, and the willingness of Agency staff to meet with industry representatives to provide guidance during development. The following chart shows the areas in which respondents believed the Agency has made the greatest improvement.

Over the last six years, in which of the following do you think FDA has most improved?



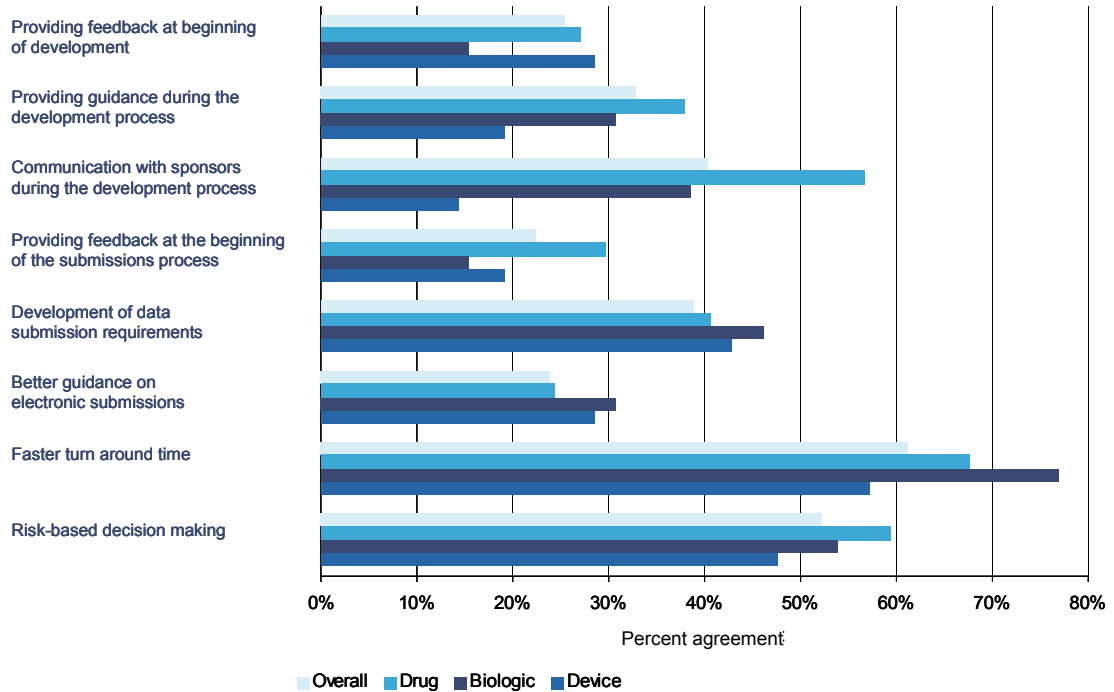
Areas at the FDA needing the most improvement

Life sciences companies that responded indicated that the Agency still needs the most improvement in product review turn around time and risk-based decision-making. Other areas in which a significant number of responding life sciences companies indicated the Agency could improve include communication with the sponsors during the development process and the development of data submission requirements.

Nearly three in five responding drug companies (57 percent) agreed that FDA needs to improve communications with sponsors during the development process. However, 38 percent of the responding biologics companies and only 14 percent of responding medical device companies shared that opinion.

The following chart shows in detail respondents' views of which areas at the Agency need the most improvement.

Over the last six years, in which of the following do you think FDA still needs the most improvement?



Life sciences company contributions to improving the relationship with FDA

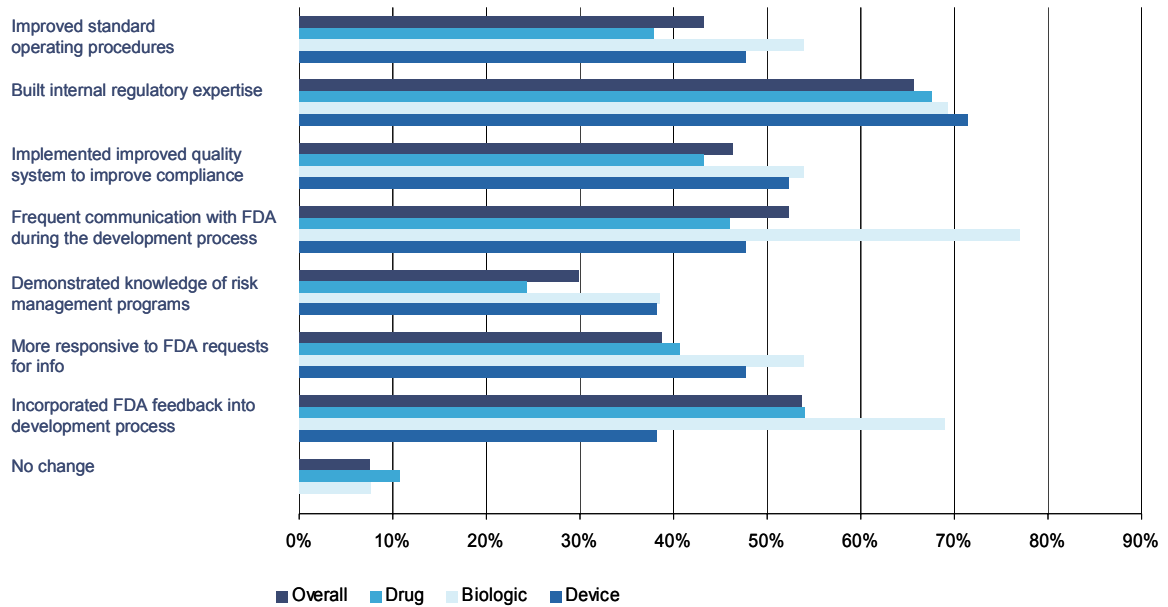
Life sciences companies that responded indicated they have helped improve the overall working relationship with FDA primarily by building internal regulatory expertise.

Nearly four in five (77 percent) biologic companies that responded indicated frequent communication with the Agency during the development process was one of the factors they improved the most, compared to 46 percent of drug and 48 percent of medical device companies that responded.

Approximately half of the life sciences companies surveyed indicated they are incorporating FDA feedback into their own product development process. This percentage is surprisingly low, especially among responding medical device companies (38 percent), because ignoring FDA recommendations could increase the likelihood of delays later in the approval process, a point at which mistakes become more costly from the standpoint of time and resources.

The following chart summarizes the contributions responding life sciences companies indicated they have made toward improving their relationship with the Agency.

Over the past six years, what do you think your company has done to improve the overall working relationship with FDA?



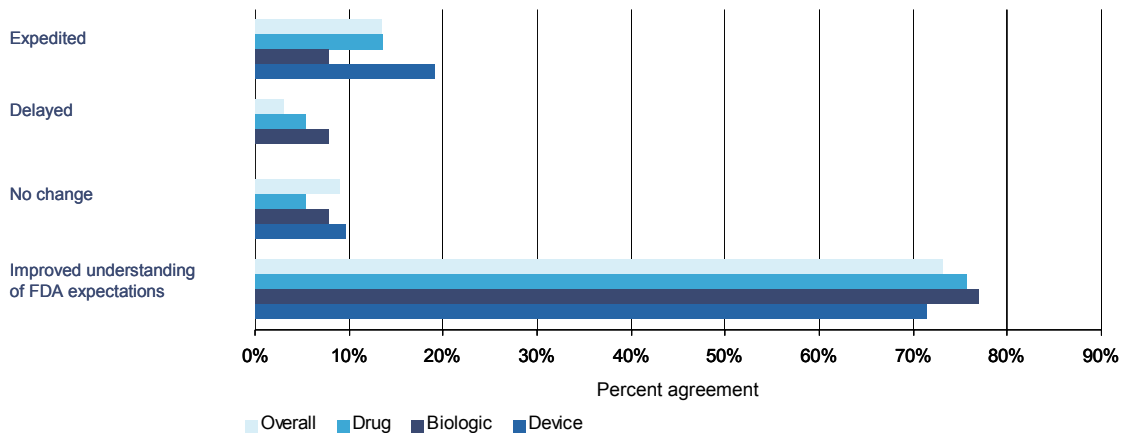
FDA guidance documentation

Overall impact of FDA guidance documentation

The majority of responding life sciences companies, from all sectors of industry, employ FDA guidance documents and other Agency resources to organize development programs, draft submissions and prepare for meetings with regulators.

Life sciences companies that responded strongly agreed that FDA guidance documents have improved their understanding of the Agency’s expectations and, as a result, improved the quality of their submissions. Although the responding companies recognize that these documents have been effective, they also indicated that they have not necessarily expedited the review process.

What do you think has been the overall impact of FDA guidance documents on the product development process?



FDA web site

As the following tables show, the majority of life sciences companies that responded indicated they use the FDA web site as a resource, especially when preparing their product development programs.

How often do you access the FDA web site?

	Drug	Biologic	Device
Daily	35%	38%	38%
1-2x week	22%	8%	43%
1-2x month	27%	38%	19%
Never or seldom	16%	15%	0%

Have you contacted FDA or its web site to obtain documents when preparing your development program?

	Yes
Drug	97%
Biologic	93%
Device	95%

IND or IDE module

As the following tables show, the vast majority of responding life sciences companies indicated they contact the FDA web site and review the relevant guidance documents when preparing their submissions and find the resources helpful in preparing their submissions.

Have you contacted FDA or its web site for relevant documents when preparing your IND/IDE?

	Yes
Drug	97%
Biologic	92%
Device	100%

The FDA web site was helpful in preparing our IND/IDE submission. (agree/disagree)

	Drug	Biologic	Device
Strongly agree	12%	18%	0%
Agree	82%	82%	86%
Disagree	6%	0%	14%

The IND/IDE guidance documents were very helpful in preparing our IND/IDE submission. (agree/disagree)

	Drug	Biologic	Device
Strongly agree	15%	18%	0%
Agree	79%	73%	93%
Disagree	6%	9%	7%

NDA/ANDA or 510(k)/PMA module

As the following tables show, all of the responding drug and medical device companies used the available guidance tools when preparing their NDA, ANDA or 510(k)/PMA submissions. Medical device companies that responded disagreed at a higher rate than the drug companies that the FDA web site was helpful in preparing their IDE and 510(k)/PMA submissions.

Have you contacted FDA or its web site for guidance documents when preparing your NDA, ANDA or 510(k)/PMA?

	Yes
Drug	100%
Device	100%

Insufficient responses from biologic companies to report results

The FDA web site was helpful in preparing our NDA and ANDA or 510(k)/PMA submission. (agree/disagree)

	Drug	Device
Strongly agree	8%	11%
Agree	85%	67%
Disagree	8%	22%

NDA or 510(k)/PMA guidance documents were very helpful in preparing our NDA and ANDA or 510(k)/PMA submission. (agree/disagree)

	Drug	Device
Strongly agree	8%	22%
Agree	77%	67%
Disagree	15%	11%

International Conference on Harmonization Guidelines

A strong majority of drug (78 percent) and biologic (69 percent) companies that responded reported that the International Conference on Harmonization (ICH) Guidelines have had a positive impact on the development process, compared to 38 percent of responding medical device companies.

International Conference on Harmonization Guidelines resulted in a positive impact on the development process. (agree/disagree)

	Percent agreement
Overall	66%
Drug	78%
Biologic	69%
Device	38%

Data management and information technology solutions

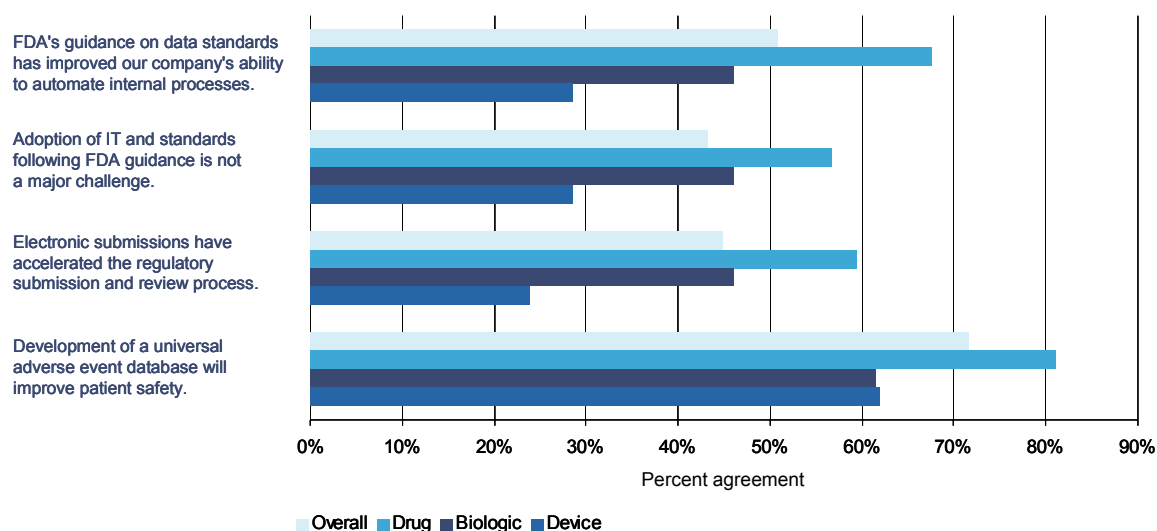
Half (51 percent) of responding life sciences companies, including a majority (68 percent) of drug companies, agreed that FDA guidance on data standards improved their ability to automate internal processes. In contrast, only 29 percent of medical device companies that responded agreed, indicating a need for the Agency to improve guidance on data standards for this sector.

Only 43 percent of respondents agreed that adoption of the information technology and standards is not a major change, which indicates a need to work to improve the guidance and its implementation.

Nearly three-quarters (72 percent) of responding companies indicated an adverse event database will improve patient safety, including substantial majorities of biologic (79 percent), drug (84 percent) and medical device (72 percent) companies that responded.

Throughout this topic, responding drug companies had a significantly more positive view of FDA guidance on data management and information technology solutions than did either biologic or (especially) medical device companies.

Opinion of FDA guidance on data management and IT solutions



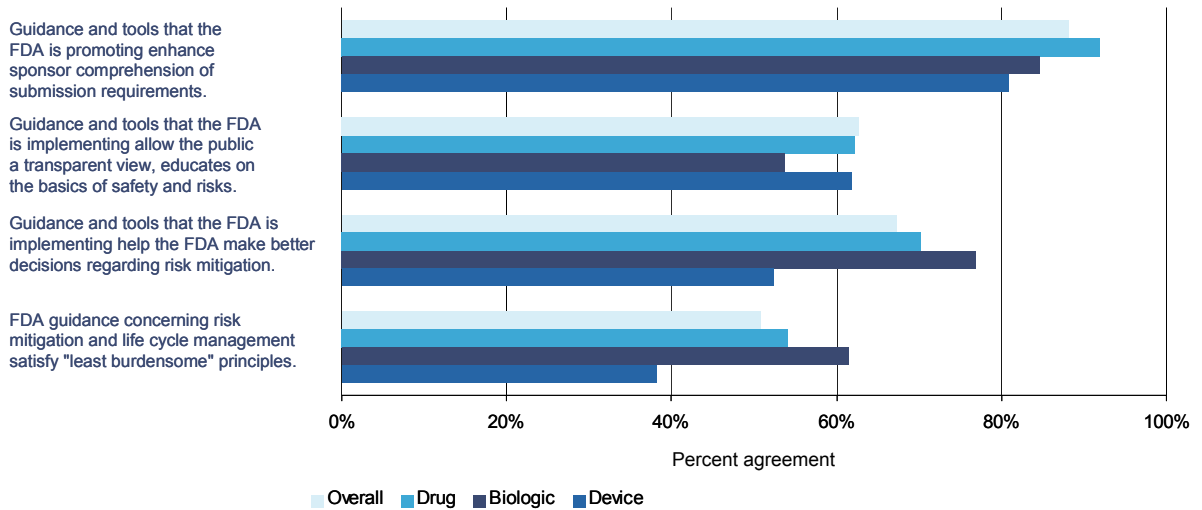
Risk management and mitigation guidance

While a large majority (88 percent) of responding life sciences companies indicated FDA guidance and tools related to risk mitigation and management of product life cycles have improved their grasp of submission requirements, the guidance is considered to be burdensome. Only half (51 percent) of the responding companies agreed that the guidance satisfies "least burdensome" principles.

Almost two-thirds (63 percent) of life sciences companies that responded indicated the guidance tools FDA is implementing allow the public a transparent view and educate it on the basics of safety and risks. By implication, one-third of responding companies believed the Agency needs to do more to educate the public about the inherent risks associated with using any drug, biologic or medical device product.

As the following chart shows, two-thirds (67 percent) of responding companies agreed that guidance tools are helping the Agency make better decisions regarding risk mitigation, including strong majorities of biologic (77 percent) and drug (70 percent) companies that responded. However, barely more than half (52 percent) of medical device companies that responded agreed.

FDA guidance on risk and lifecycle management

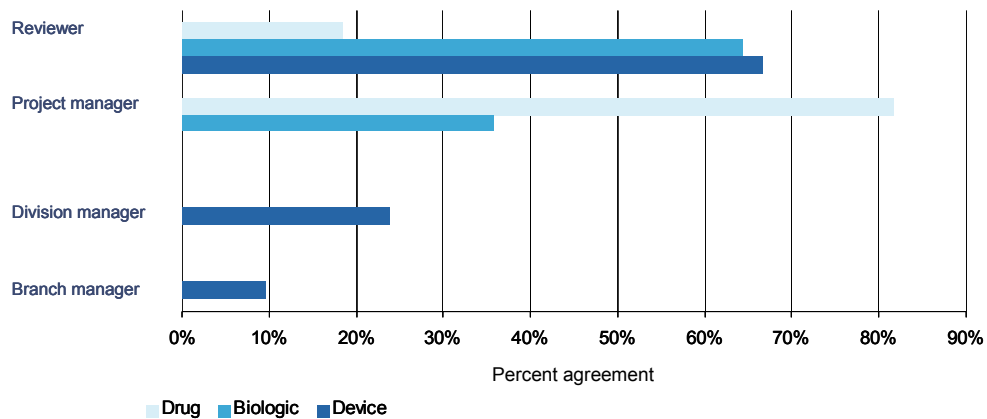


FDA—industry interaction

Whom do you interact with at the FDA?

While the primary contact for the majority of the life sciences companies that responded was an FDA reviewer or project manager, one-third (34 percent) of responding medical device companies indicated that their primary FDA contact was a division or branch manager at CDRH.

In general, do you interact directly with FDA reviewers, project managers, division managers or branch managers?



Are your FDA reviewers easy to contact?

Two in three (66 percent) drug companies that responded agreed or strongly agreed that the appropriate FDA contact was easy to reach compared to nearly nine in ten biologic and medical device companies (86 percent for both). Compared to results from the previous surveys, the results for responding drug companies have remained steady, while the results for biologic and medical device companies have increased significantly.

	1995	1997	1999
Drug			
Very easy/easy	39%	76%	70%
Neither	45%	12%	4%
Difficult/very difficult	16%	12%	26%
Biologic			
Very easy/easy	86%	50%	58%
Neither	14%	25%	37%
Difficult/very difficult	0%	25%	5%
Device			
Very easy/easy	32%	55%	63%
Neither	28%	31%	23%
Difficult/very difficult	40%	14%	14%

A large majority of the life sciences companies that responded agreed that FDA promptly facilitated requests for clarification from the reviewers; the contact was extremely knowledgeable about their submission status; and the reviewer promptly responded to requests. In each of the categories, the level of agreement was less for responding drug companies, especially when compared to medical device companies.

It is easy to reach the appropriate FDA contact for clarification of data or labeling requests. (agree/disagree)

	Drug	Biologic	Device
Strongly agree	11%	36%	19%
Agree	55%	50%	67%
Disagree	26%	14%	10%
Strongly disagree	8%	0%	5%

How is the quality of the interaction with FDA?

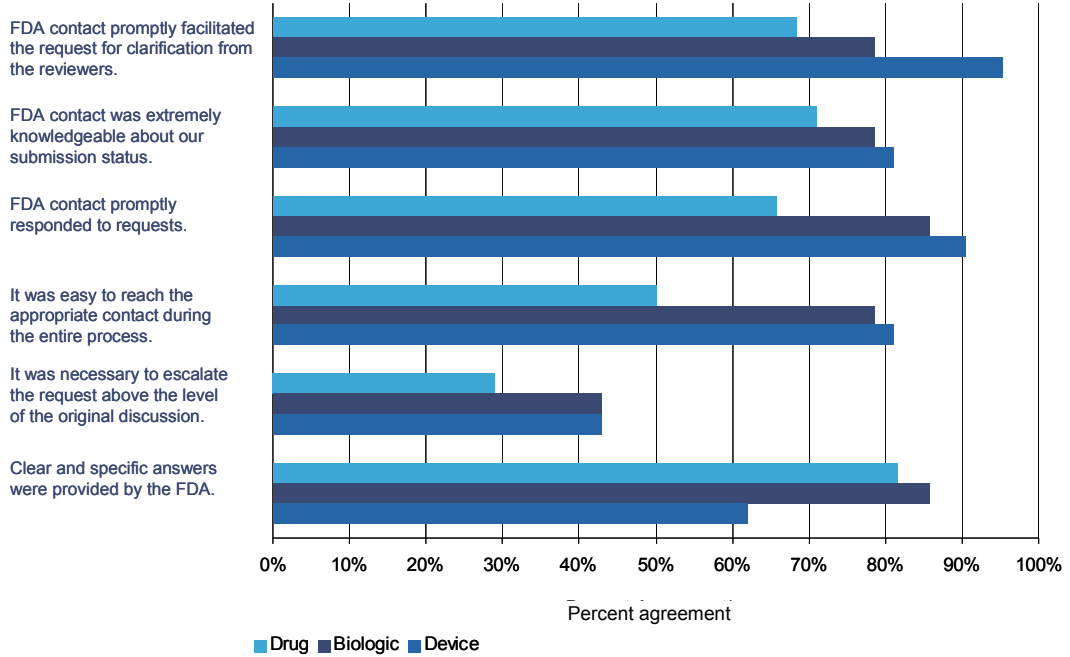
Only half (50 percent) of responding drug companies indicated the appropriate contact was easy to reach during the entire process, compared to eight in ten biologic (79 percent) and medical device (81 percent) companies.

Three in ten (29 percent) drug companies that responded agreed that it was necessary to escalate the request above the level of the original discussion compared to four in ten (43 percent) biologic and medical device companies. In addition, eight in ten drug (82 percent) and biologic (86 percent) companies agreed that FDA provided clear and specific answers, compared to just 62 percent of responding medical device companies.

While CDER project managers and reviewers are more difficult to contact, they are better able to deal with issues without escalation when compared to the other two centers.

However, solid majorities in all sectors, including drug companies, indicated that their FDA contact promptly facilitated the request for clarification from the reviewers, was extremely knowledgeable about their submission status and responded promptly to requests.

Responder's opinions of the quality of their communications with the FDA



Changes in personnel

In previous surveys, a significant number of respondents indicated that changing reviewers in mid-review impeded or stopped the process.

Because the elapsed time between the current and previous survey is longer than any previous pair of surveys, truly valid conclusions cannot be drawn about how FDA is performing now relative to previous years.

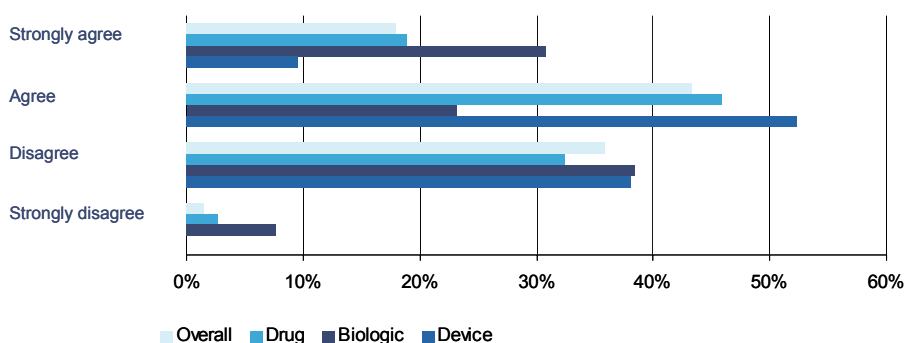
Changes in personnel at FDA

	1995	1997	1999
Drug			
Expedited/facilitated	6%	4%	5%
No impact	55%	75%	38%
Impeded/stopped	39%	21%	57%
Biologic			
Expedited/facilitated	4%	0%	0%
No impact	65%	59%	64%
Impeded/stopped	31%	41%	36%
Device			
Expedited/facilitated	1%	2%	2%
No impact	72%	79%	63%
Impeded/stopped	27%	19%	35%

Six in ten (61 percent) of responding life sciences companies agreed or strongly agreed that FDA personnel changes resulted in a break of continuity in at least one of their reviews.

A change in reviewer may greatly influence the progress of products through development, which can be costly from the perspective of both time and resources.

FDA staff changes resulted in break of continuity of at least one of our reviews.



Meetings between FDA and life sciences companies

IND or IDE module

Only one in six biologic companies (17 percent) that responded were unable to explore all issues with FDA by phone or letter prior to IND/IDE submission, reflective of biologic companies' ability to address these issues effectively through the process. By comparison, 29 percent of drug companies and 43 percent of medical device companies that responded were unable to explore all issues, indicating room for improvement.

Able to explore all issues with FDA by phone or letter prior to IND/IDE submission (agree/disagree)

	Drug	Biologic	Device
Strongly agree	6%	33%	0%
Agree	65%	50%	57%
Disagree	26%	17%	36%
Strongly disagree	3%	0%	7%

Participation in Pre-IND/IDE meetings

Responding life sciences companies overwhelmingly indicated they hold Pre-IND/IDE meetings, regardless of the type of product, as the following table reflects.

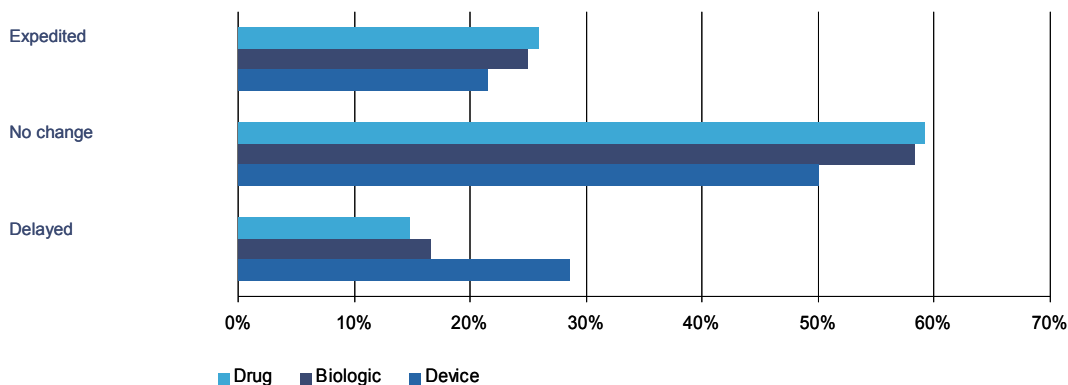
Did you have a Pre-IND/IDE meeting?

	Yes
Drug	79%
Biologic	100%
Device	100%

Quality of the Pre-IND/IDE meeting

Fewer than three in ten responding life sciences companies indicated the Pre-IND/IDE meeting expedited their submission.

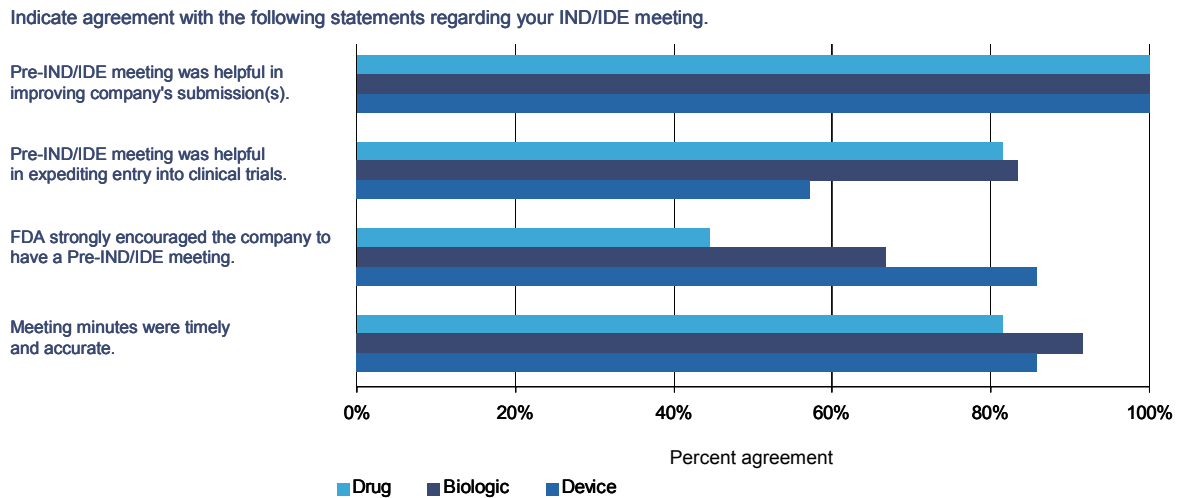
How did the Pre-IND/IDE meeting(s) affect the submission of the IND/IDE?



While eight in ten drug (81 percent) and biologic (83 percent) companies that responded agreed that the Pre-IND/IDE meeting was helpful in expediting entry into clinical trials, just six in ten (57 percent) of responding medical device companies agreed.

While 100 percent of responding life sciences companies indicated the Pre-IND/IDE meeting improved the submission and 57 percent or greater indicated it expedited entry into the clinical trials, fewer than three in ten indicated it expedited the submission. This data implies that the Pre-IND/IDE meeting improved the life sciences companies understanding of FDA’s expectations, which enabled them to improve the submission and reduce approval time, but the FDA’s expectations or requirements for the submission were burdensome so the time required to prepare the submission was not reduced.

As the following chart indicates, eight in ten (86 percent) responding medical device companies agreed that FDA strongly encouraged the company to have a Pre-IND/IDE meeting, compared to 44 percent of drug companies and 67 percent of biologic companies.



End-of-Phase 2 module

Participation in End-of-Phase 2 meetings

A significantly smaller percentage of responding life sciences companies participated in an End-of-Phase 2 meeting with FDA compared to Pre-IND/IDE meetings.

The most common reasons given for not having an End-of-Phase 2 meeting were “sponsor declined” and “insufficient time,” but there were some responding companies that indicated the Agency itself declined to participate in an End-of-Phase 2 meeting.

Did you have an End-of-Phase 2 meeting with the FDA?

	Yes
Drug	42%
Biologic	36%

(Device companies do not have Phase 2)

Quality of End-of-Phase 2 meetings

Three in ten (31 percent) drug companies that responded indicated the End-of-Phase 2 meeting expedited their development program.

How did the End-of-Phase 2 meeting affect your development program(s)?

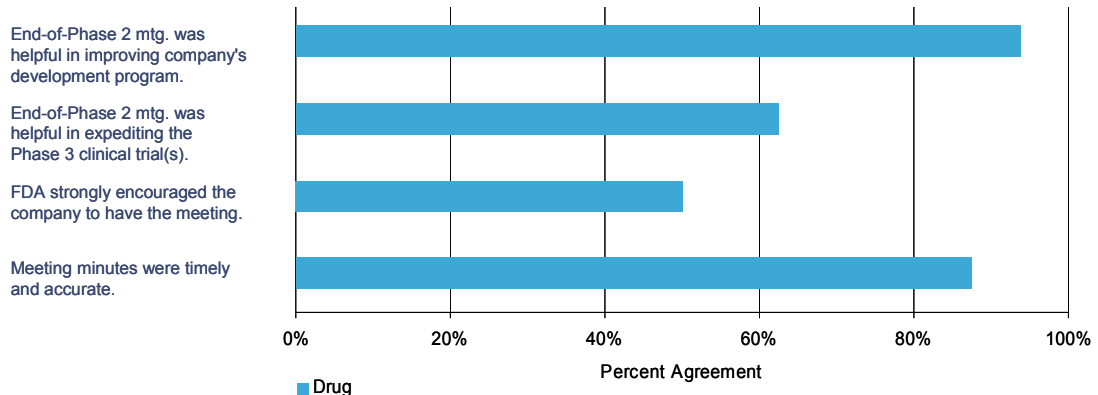
Agree	
Expedited	31%
No change	38%
Delayed	31%

Insufficient responses from biologic companies

Nine in ten (94 percent) responding drug companies indicated the End-of-Phase 2 meeting was helpful in improving their development program, while two-thirds (63 percent) indicated it was helpful in expediting Phase 3 clinical trials. Because the vast majority indicated the meeting was helpful in improving the companies' development programs, even though it didn't expedite their programs, the meeting most likely identified problems with their programs up to that point or changes to the Phase 3 trial design that would not expedite the development programs (e.g., increased patient enrollment requirements). While discovering these issues or changes prior to Phase 3 would ultimately improve a company's development program, it would not expedite the program.

Only half of responding companies indicated the Agency strongly encouraged their company to have an End-of-Phase 2 meeting. This result is similar to those found for the Pre-IND/IDE meetings.

End-of-Phase 2 meeting



NDA/ANDA or 510(k)/PMA module

Participation in Pre-NDA/ANDA or Pre-510(k)/PMA meetings with FDA

A significant majority of responding life sciences companies indicated they participated in Pre-NDA/ANDA or Pre-510(k)/PMA meetings.

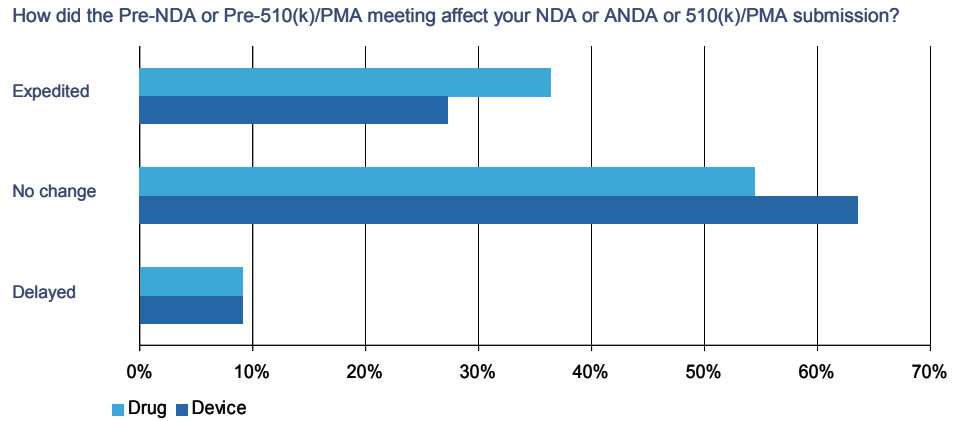
Did you have Pre-NDA/ANDA or Pre-510(k)/PMA meeting(s) with FDA?

Yes	
Drug	85%
Device	61%

Not enough responses from biologic companies to report results

Quality of the Pre-NDA or Pre-510(k)/PMA meeting

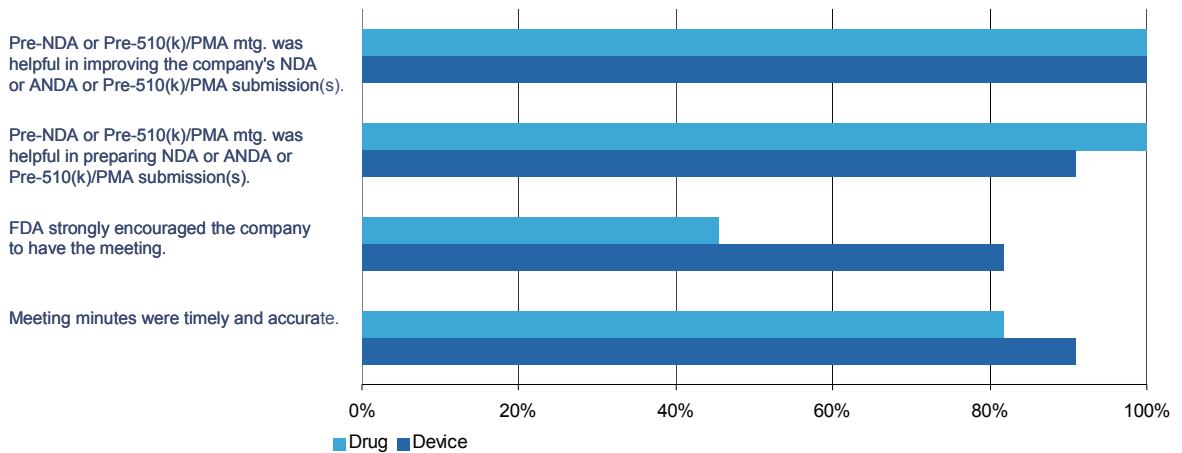
Similar to results reported for Pre-IND/IDE and End-of-Phase 2 meetings, approximately 30 percent of responding companies indicated the premarket filing meeting expedited their submission.



While only approximately 30 percent of responding companies indicated the Pre-NDA/ANDA or Pre-510(k)/PMA meeting expedited their submission, it did improve the submission and was helpful in its preparation, which indicates the NDA/ANDA or 510(k)/PMA submission requirements and/or the process may need to be streamlined.

Similar to results discussed with regard to other types of meetings, 82 percent of responding device companies indicated FDA strongly encouraged the company to have the prefilng meeting compared to only 45 percent of drug companies that responded.

Quality of Pre-NDA or Pre-510(k)/PMA meeting



Changes in FDA position

A significant number of responding life sciences companies, although not a majority in any category, indicated that the FDA position changed during the review of their product submissions.

During the development of the product(s), there were changes to FDA's position.

	Percent agreement
Drug	31%
Biologic	46%
Device	48%

Drug and biologic companies that responded identified changes to FDA position primarily in clinical endpoints and toxicology. Responding medical device companies also identified changes to FDA position in clinical endpoints; in addition, they identified position changes in manufacturing requirements, safety and effectiveness, and labeling/claims.

The impact on sponsors of Agency changes during the review of product could be very costly and early guidance could help prevent recurrences.

New and ongoing improvement efforts

Orphan or Fast-Track status

A significant number of responding drug and biologic companies sought Orphan Drug or Fast-Track designation for their products.

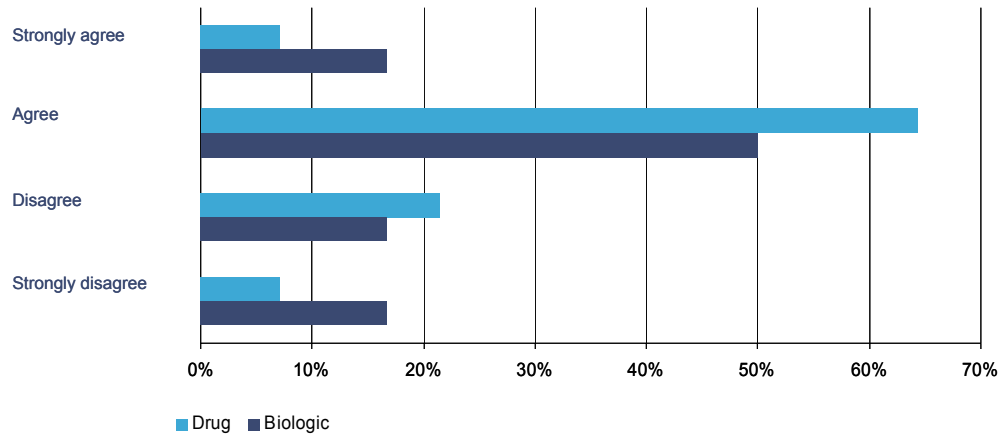
Did your company request or obtain Orphan Drug or Fast-Track designation for any of the products covered by this survey?

	Yes
Drug	34%
Biologic	43%

Device developers were not asked this question.

As the following chart shows, more than two-thirds of biologic (67 percent) and drug (71 percent) companies that responded indicated the Orphan Drug or Fast-Track designation facilitated communications with the Agency and the review process more generally, which demonstrates the Fast-Track program is working.

Orphan Drug/Fast Track designation speeded/facilitated communications with FDA and the review process.



User fees

A significant number of biologic (33 percent), drug (33 percent) and, especially, medical device (50 percent) companies that responded indicated that user fees have not resulted in decreased approval times. Because the industry is not seeing the benefit of user fees, many sponsors believe that these fees are not being used effectively for their intended purpose of improving the review process.

Furthermore, responding biologic (93 percent), drug (89 percent) and medical device (85 percent) companies overwhelmingly indicated that FDA should modify goals to make programs more effective if approval times cannot be reduced. The types of goals that can be modified to make programs more effective include increasing staffing specifically for reviews and changing hiring goals for reviews.

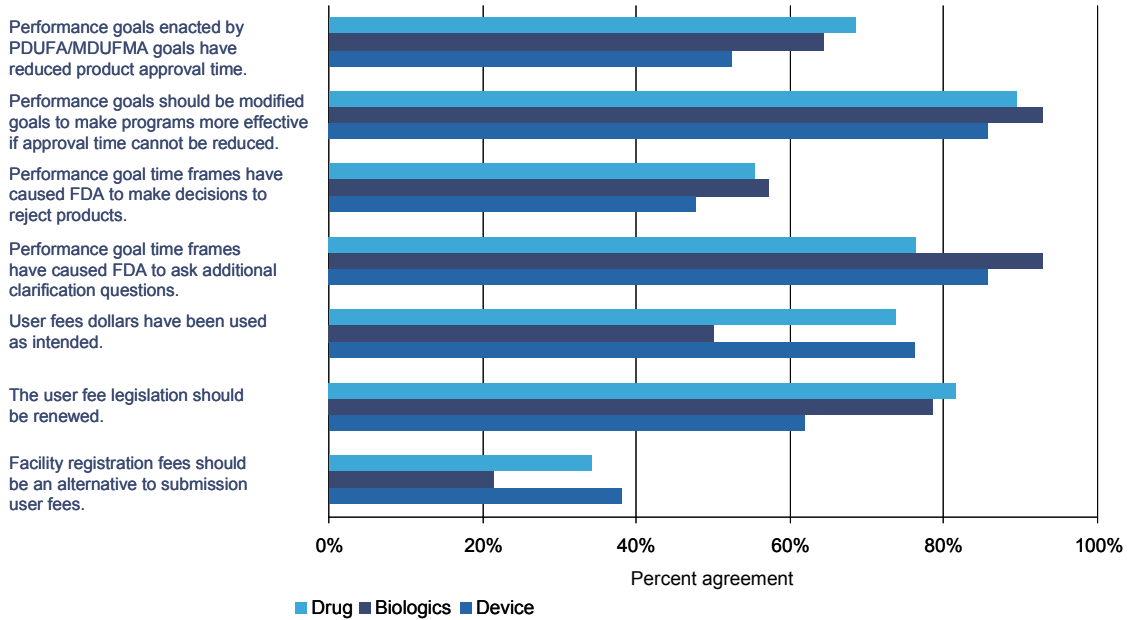
Among the survey's most worrisome findings is that approximately half of responding biologic (57 percent), drug (56 percent) and medical device (48 percent) companies indicated that goal time frames have caused FDA to reject products. In essence, timing goals sometimes can derail the approval of products with potentially important benefits for patient health.

User fees were intended to increase the number of primary reviewers so questions and issues could be raised and addressed in a timely manner. However, companies that responded indicated FDA is rejecting products because the reviewers are not given enough time to resolve questions and issues within a given timeframe. If additional primary reviewers are available, they might be able to address this earlier in the process and complete reviews on time, rather than submitting questions with a rejection letter.

The majority of responding drug, biologic and medical device companies do not agree with facility registration fees as an alternative to submission user fees.

Although the majority of responding drug (74 percent) and medical device (76 percent) companies agreed that user fees have been used as intended, half of biologic companies that responded believed that user fees have not been used as intended.

With regard to user fees, please indicate the extent to which you agree or disagree with the statements below.



Pharmacovigilance

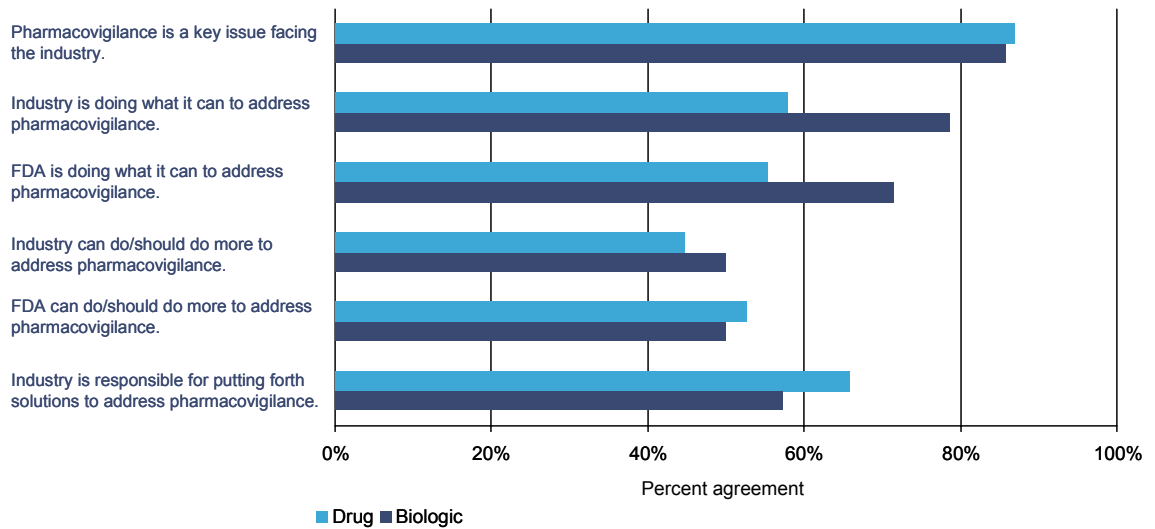
Product safety surveillance (i.e., pharmacovigilance) topics were included in the survey only for biologic and drug companies. In future surveys, product safety surveillance questions also will be included for medical device companies as well.

Nearly nine in ten drug (87 percent) and biologic (86 percent) companies that responded indicated pharmacovigilance is a key issue facing the industry.

While a majority of biologic (78 percent) and drug (58 percent) companies that responded indicated that both FDA and industry are doing what they can to address pharmacovigilance, a significant percentage did not agree, indicating there is more work to be done.

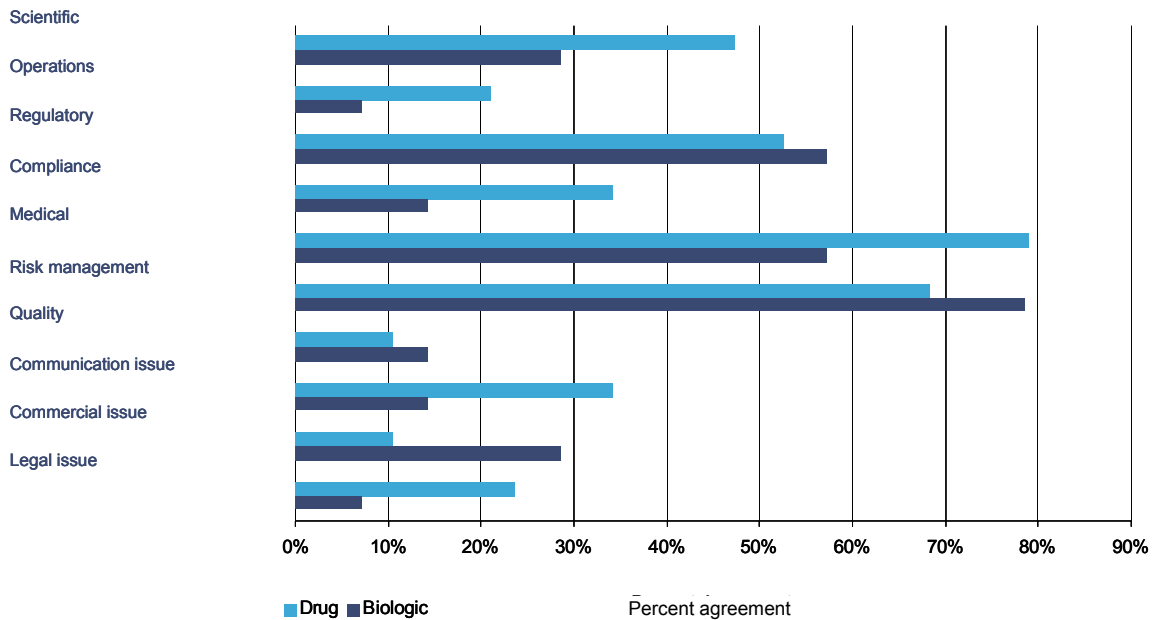
The following chart identifies industry respondents' broader views on pharmacovigilance-related issues.

With regard to pharmacovigilance, please indicate the extent to which you agree or disagree with the statements below.



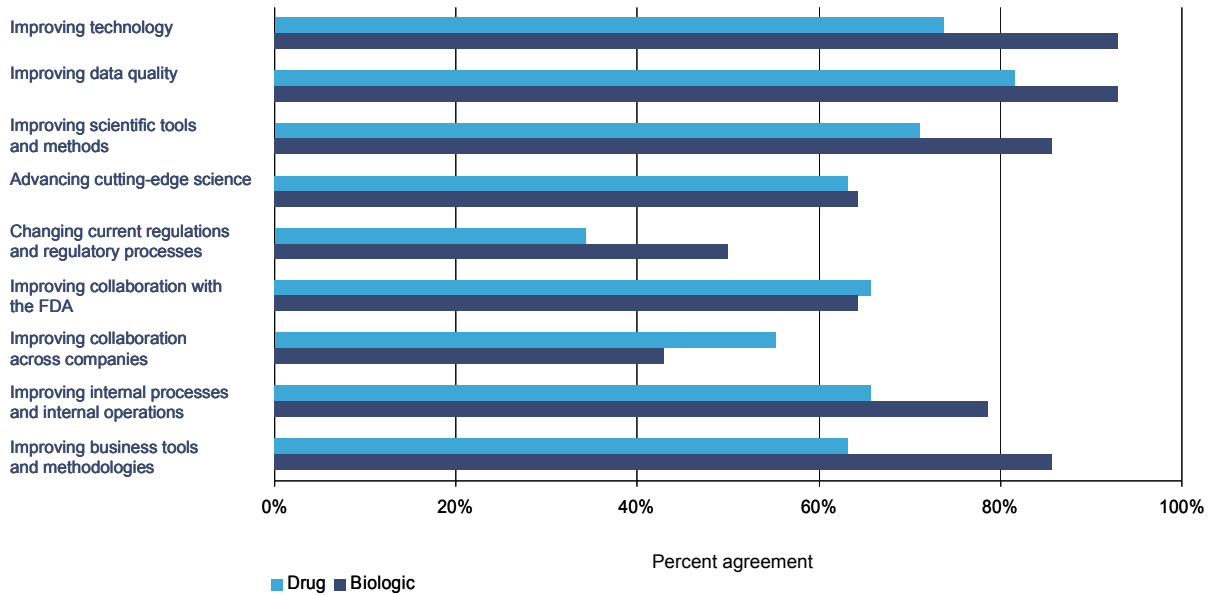
As the following chart indicates, life science companies that responded identified pharmacovigilance as primarily a risk management, regulatory and medical issue. A significant number of responding drug companies also indicated that pharmacovigilance is a scientific issue.

What type of issue is pharmacovigilance?



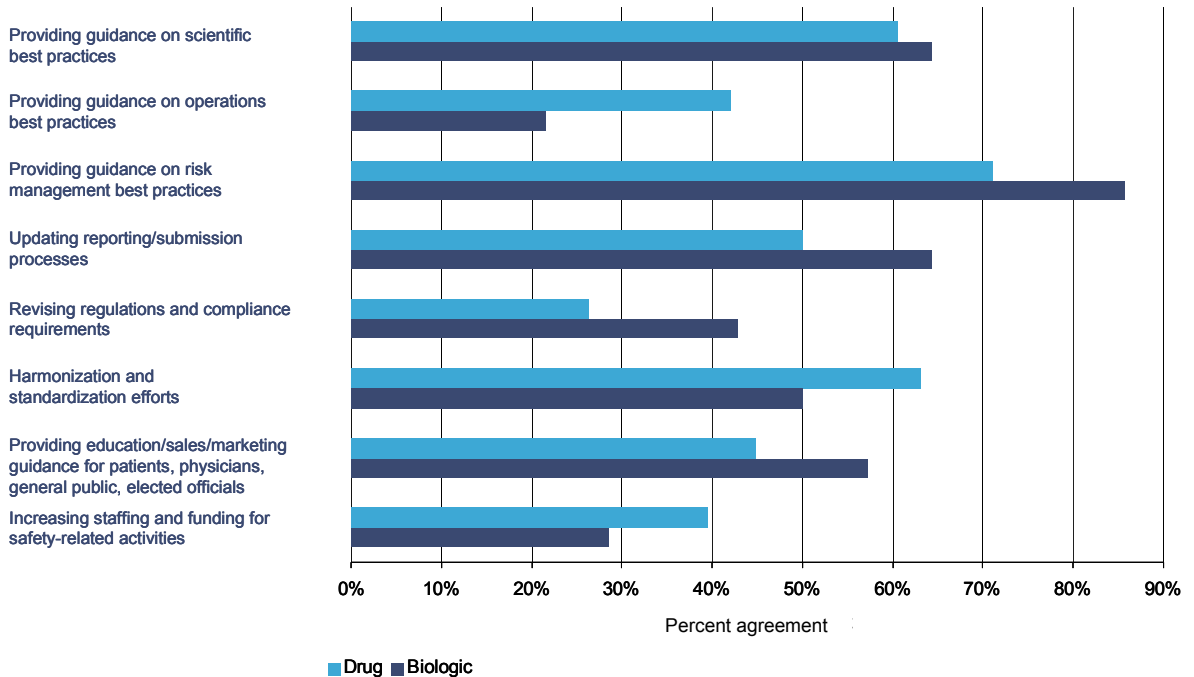
Greater than 60 percent of responding drug and biologic companies indicated that there are a number of areas where efforts could be expanded to improve pharmacovigilance, including improving technology, data quality, improving scientific tools and methods, collaborating with FDA, enhancing internal processes and internal operations business tools and methodologies, and advancing cutting-edge science.

To what extent do you agree or disagree with the statements below in regard to the factors important to improving pharmacovigilance?



Approximately 60 percent of companies that responded indicated that the industry is responsible for putting forth solutions to address pharmacovigilance. However, as the following chart shows, responding drug and biologic companies indicated the need for FDA guidance on best practices, especially in risk management, to assist them in improving their pharmacovigilance efforts.

FDA can improve pharmacovigilance by:



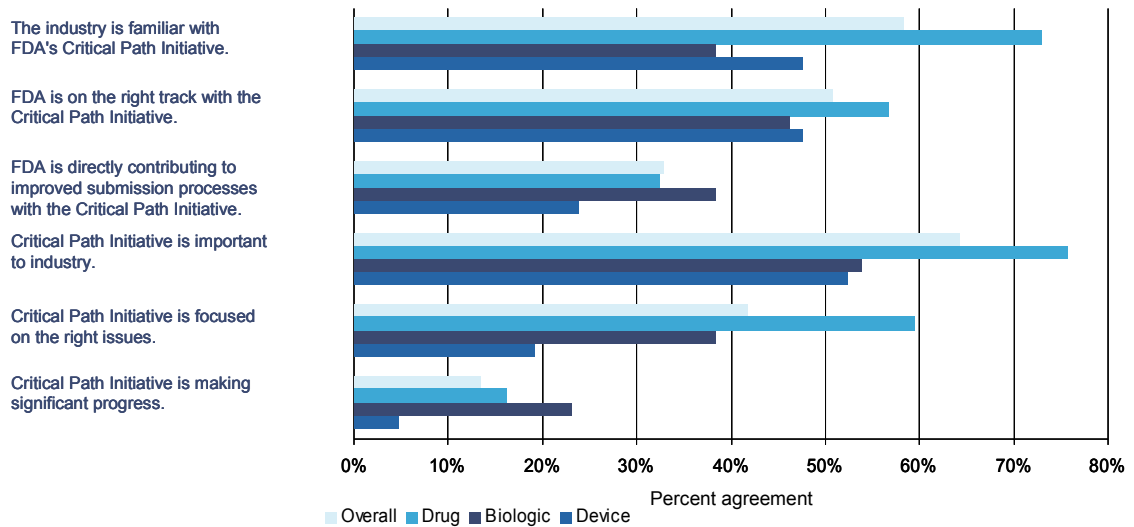
Critical Path Initiative

As the following chart shows, a majority of the responding life sciences companies indicated they are familiar with the Critical Path Initiative and agreed that it is important. While more than seven in ten drug development companies (70 percent) are familiar with the initiative, fewer than half of the companies that develop biologics and devices are aware of it.

Additionally, about half of the companies that responded agreed that FDA is on the right track with the Critical Path Initiative and fewer than half believed it is focused on the right issues.

Fewer than three in ten companies that responded agreed that FDA is making significant progress on the items laid out in the Critical Path Initiative.

Critical Path Initiative

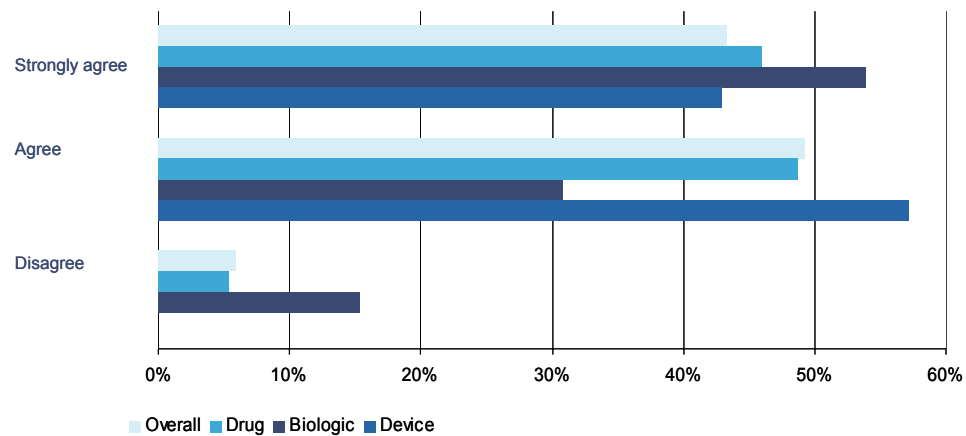


Conclusion

The results of the 2006 FDA Survey, which are detailed in this report, show the vast improvements that have been made in the working relationship between FDA and industry over the six years covered by the survey. This renewal of the survey has successfully created a conduit for providing constructive feedback to FDA and offers a foundation for an ongoing dialogue between industry and the Agency.

The relationship between FDA and industry is of such vital importance because it has a direct impact on the efficiency and likelihood that new and innovative products become available to physicians and their patients. Despite the vast improvements made thus far, FDA and industry should continually strive to adapt to external changes in the regulatory environment and optimize the product approval process accordingly. This sentiment was reflected in the survey results: An overwhelming majority (92 percent) of responding companies agreed that changes could still be made to streamline the product approval process without jeopardizing patient safety.

The FDA approval processes can be streamlined without jeopardizing patient safety.



A number of considerations for FDA and industry continuing efforts to increase the efficiency and effectiveness of the product approval process are outlined on the following pages.

Opportunities for consideration

- The vast majority of responding life sciences companies indicated that the currently available FDA guidance documents are useful and would like to have additional FDA guidance. The Agency should continue developing guidance in areas for which it currently does not exist, providing further assistance to industry in advancing products through the product approval process.
- Life sciences companies should be more diligent about incorporating FDA feedback obtained during stage review meetings and throughout the product approval process into their development programs. Ignoring FDA feedback could increase the likelihood of delays later in the approval process, a point at which delays and mistakes become more costly from the standpoint of both time and resources.
- Drug and medical device companies should make a greater effort to frequently communicate with FDA during the development process because less than 50 percent of responding drug and medical device companies indicated they are currently doing this. Expanded interaction with the Agency should decrease the risk of delays and failures during the product approval process.
- Responding life sciences companies indicated that FDA guidance documents and meetings are very helpful in understanding submission requirements and the quality of the submission themselves, but indicated the documents and meetings do not expedite the submission process and that FDA turnaround time needs further improvement. The industry and FDA should collaborate to streamline submission requirements and the review process in ways that are not burdensome.
- A strong majority of drug (78 percent) and biologic (69 percent) companies that responded indicated the ICH Guidelines have had a positive impact on the development process, compared to 38 percent of medical device companies. FDA should continue to develop, implement and accept guidance with the ICH, but CDRH should work to understand why medical device companies have a less positive opinion of the ICH Guidelines and ensure they are fully accepted and followed when they are approved.
- Only 46 percent of biologic and 29 percent of medical device companies that responded indicated FDA guidance on data management and IT solutions improved their ability to automate internal processes, which indicates CBER and CDRH should consider acting to ensure the guidance documents meet the needs of all of the companies whose submissions they review. Solutions and guidance regarding data management and IT must make significant improvements while ensuring implementation is efficient and cost-effective.
- A strong majority of responding companies, across all product types, indicated the creation of an adverse event database is an important initiative that would improve patient safety. FDA industry and patient advocate groups should collaborate to develop the solutions and relevant guidance required to execute this initiative.
- Because only about half of responding medical device companies indicated guidance tools are improving FDA's ability to make better decisions regarding risk mitigation compared to greater than 70 percent of drug and biologic companies, CDRH should investigate this disparity and ensure that guidance tools are successfully enabling decision making that mitigates risk to development programs.
- FDA and life sciences companies should focus on identifying and mitigating potential risks as early in the product approval process as possible so mitigation strategies can be built into the development program.
- CDER should work to improve availability of its reviewers and project managers since its center performed below CBER and CDRH with regard to its ability to provide prompt responses to industry throughout the development process.
- In general, responding companies indicated communication with CDRH was less effective than with CBER or CDER. FDA and industry should consider collaborating to assess the reasons for this disparity, including evaluating which position is designated the primary contact at CDRH for medical device companies. Communications between the industry and CDRH may be more effective if these constituents have reviewers or project managers empowered as decision makers.

- 61 percent of responding life sciences companies indicated a change in FDA personnel resulted in a break in continuity of one of their reviews, which indicates there is room to improve the transfer of ownership in the event of FDA personnel change. FDA should make every effort to understand how it can reduce staff changes during a product review and how processes and guidance can be improved to maintain continuity in the event of a staff change.
- While responding life sciences companies indicated that the guidance documents and stage review meetings are very helpful in understanding submission requirements and improving the quality of the submissions themselves, they also indicated that the documents and meetings do not expedite the submission process and that FDA turnaround time still needs further improvement. This indicates that industry better understands the requirements, but they remain burdensome. Nine in ten companies agreed the process can be streamlined without affecting patient safety, and so the industry and FDA should collaborate to streamline submission requirements and the review process in ways that will increase efficiency.
- Better communication and encouragement are required for holding Pre-IND/IDE, End-of-Phase 2 and Pre-NDA/ANDA or Pre-510(k)/PMA meetings, especially from CDER. FDA and industry should make every effort to participate in and encourage each other's participation in stage review meetings, especially later in the product approval process when delays and failures are more costly. It is especially important to mitigate potential risks during the approval process before reaching the NDA/ANDA or PMA submission stage.
- Due to the cost associated with Phase 3 trials and their potential impact on filing status, these meetings are critically important. Both FDA and life sciences companies should make every effort to participate in meetings to review Phase 1 and Phase 2 results, as well as the design of Phase 3 trials, to minimize risks prior to investing in Phase 3 trials.
- The Agency should investigate the drivers behind changes in FDA position during the product approval process. Additionally, FDA should consider creating an internal monitoring program and a reasonable Sponsor appeal process to ensure consistency, while maintaining the highest level of patient safety. In the cases when a change in FDA position is required, regardless of the positive or negative effect of a change in position, FDA should provide a clear, scientific reason for changes during trials and submission review.
- To address the issues raised by industry with respect to user fees, the Agency may need to better define the roles and responsibilities of the additional FDA personnel supported by the Prescription Drug User Fee Act of 1992 (PDUFA) and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to explain how staff increases speed up reviews. The Agency should consider a structural review of the product approval process resourcing model to help ensure a proper balance of resources. Greater transparency may be needed about how the user fees are being employed, especially by CBER.
- FDA should consider forming a task force composed of industry, government and consumer or patient groups focused on improving pharmacovigilance and medical device reporting. Industry could develop the technology, processes and systems to collect, analyze and report data regarding adverse events, but would require the help of FDA to develop the guidance which will drive how the process is carried out consistently, efficiently and effectively across the industry.
- FDA should ensure that information about the Critical Path Initiative is disseminated more broadly, especially with regard to expectations and how it affects all sectors of industry.
- FDA should more effectively engage the industry on the issues laid out in the Critical Path Initiative to gain stakeholder buy-in. In addition, it should determine which aspects of the Critical Path Initiative will have the most impact on product approval processes and focus on improving those elements.

“Go Forward” plan

This survey serves to foster open dialogue between FDA and the life sciences industry to better understand what is working in the product approval process and what ought to be considered for improvement.

BIOCOM and PricewaterhouseCoopers will use the results from this survey to improve and expand future surveys, planned to begin in 2007 with results released in 2009. BIOCOM and PricewaterhouseCoopers will strive to make continued improvements to the survey and its methodology, including increasing response numbers across all industry sectors.

Feedback for future surveys will continue to be solicited from FDA and congressional officials to ensure the most relevant information is being captured. Comments on the survey and suggestions for future consideration in the next survey may be addressed to Katie Hansen, BIOCOM Associate Director of Public Policy, at khansen@biocom.org.

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Interviewees

List of interviewees (Congress/FDA)

FDA	Congressional meetings
<ul style="list-style-type: none">• Commissioner von Eschenbach• Dr. Janet Woodcock• Dr. Rachel Behrman• Laurie Lenkel, FDA Ombudsman• Jesse Goodman, CBER Director• Daniel Schultz, CDRH Director• Les Weinstein, CDRH Ombudsman• John Jenkins, Office of New Drugs• Mark Kramer, Office of Combination Products• Dr. Karen Weiss, Office of Oncology Products	<ul style="list-style-type: none">• Lisa German Foster, Senator Jack Reed's Office• Vicki Ball, Senator James Inouye's Office• Greg Pauly, Senator Richard Shelby's Office• Brittney Espy, Senator Johnny Isakson's Office• Page Kranbuhl, Senator Lamar Alexander's Office• David Dorsey, Senator Edward Kennedy's Office• Amy Muhlberg, Senator Michael Enzi's Office• Jennie Quick, Senator Barbara Boxer's Office• Representative, Senator Larry Craig's Office

Glossary

CBER—Center for Biologics Evaluation and Research

CDER—Center for Drug Evaluation and Research

CDRH—Center for Devices and Radiological Health

FDAMA—Federal Drug Administration Modernization Act of 1997

ICH—International Conference on Harmonization—Organization where regulatory authorities of Europe, Japan and United States and experts from the pharmaceutical industry discuss scientific and technical aspects of harmonizing activities across the lifecycle of pharmaceutical products. International harmonization efforts around Medical Terminology (MedDRA), the Common Technical Document (CTD) and Electronic Standards for Transmission of Regulatory Information (ESTRI) have been coordinated under the sponsorship of the ICH. (see also MedDRA) (www.ich.org)

Critical Path Initiative—FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated and manufactured

Pharmacovigilance—Scientific and data gathering activities relating to the detection, assessment, understanding and prevention of adverse events—including, to the extent possible, understanding the nature, frequency and potential risk factors of the adverse events

PDUFA—Prescription Drug User Fee Act of 1992

MDUFMA—Medical Device User Fee and Modernization Act of 2002

BLA—Biological License Application

IND—Investigational New Drug Application

IDE—Investigational Device Exemptions

NDA—New Drug Application

ANDA—Abbreviated New Drug Application

PMA—Premarket Approval

510(k)—Premarket Notification 510(k)—Application required when the new device is substantially equivalent to a previously approved device

Orphan/Fast Track—The Food and Drug Administration Modernization Act of 1997 (FDAMA) includes Section 112, "Expediting study and approval of fast track drugs." This section mandates the Agency to facilitate the development and expedite review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast track adds to existing programs, such as accelerated approval, the possibility of a "rolling submission" for a marketing application. An important feature of fast track is that it emphasizes the critical nature of close early communication between the FDA and sponsor to improve the efficiency of product development.

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