Regulatory Submissions Trends Survey 2002

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Abstract

This Regulatory Submissions Trends Survey, conducted by CDC Solutions in December 2002, takes the first steps to gauge how regulatory departments of US and European life sciences companies are using technology today and how they plan to harness technology in the future. The results specifically present a baseline measure on how pharmaceutical, biotechnology and medical device companies (a) view future increased demand for e-Submissions technology usage, (b) anticipate people, process and technology changes as related to the dynamic regulatory environment and (c) supplement current capabilities with outsourcing vendors. As with any baseline survey, many of the results are important and warrant continued tracking to begin to uncover the best practices in regulatory submissions software.

INTRODUCTION

CDC Solutions[1] conducted this global survey on regulatory submissions trends, the first of its kind, in December 2002 to gauge how regulatory departments are using technology today and how they plan to harness technology in the future. Slightly over half of the respondents came from the USA with the remainder coming from various European countries, including 11 per cent from Germany, 8 per cent from the UK and 7 per cent from Ireland. Over three-quarters of respondents were from large pharmaceutical, medium/small pharmaceutical, biotechnology and medical device sectors. This survey concentrates on three key areas: technology usage trends, outsourcing trends and regulatory trends.

According to the survey respondents, 70 per cent currently make regulatory submissions. When asked what kind of system they use for submissions:

- 37 per cent use a paper-based system;
- 34 per cent use a combination of paper and electronic;
- 7 per cent say they use an electronic system.

Within the next 12 months, 19 per cent of respondents say they plan to move to a full electronic system while an additional 34 per cent say they plan to make the change in more than 12 months. More than half of respondents (58 per cent) anticipate their use of regulatory submissions software will increase and respondents identified process improvement and compliance with 21 CFR Part 11 as the greatest benefits to using regulatory publishing software.

Nearly 50 per cent of respondents anticipate their use of outsource vendors as a whole will increase or stay the same. The majority of respondents indicate they are either compliant with 21 CFR Part 11 or are planning to become compliant. But to become compliant, respondents believe it will affect their company's people, processes and technologies.

SURVEY METHODOLOGY

CDC Solutions distributed over 5,000 surveys to professionals in the regulatory departments of pharmaceutical, biotechnology, medical device and contract research organisations (CROs). The majority of the 105 survey responses were collected electronically. Results were calculated and rounded to the

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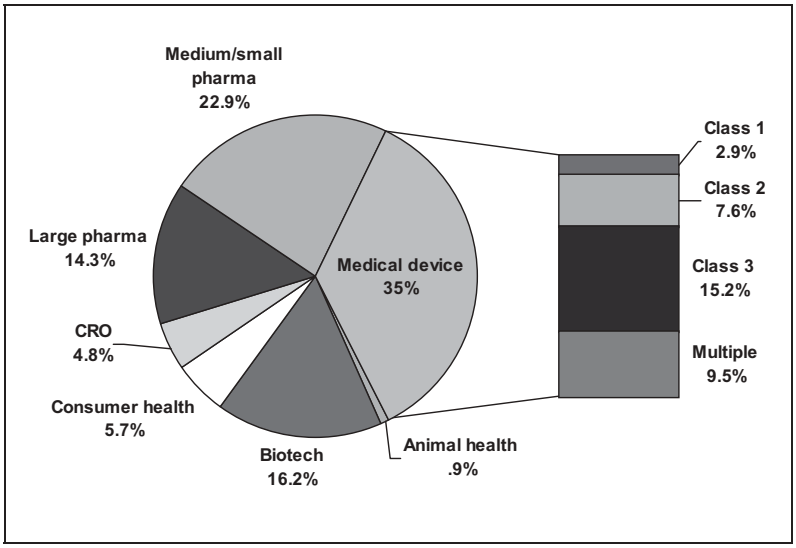

Figure 1: Breakdown by industry sector

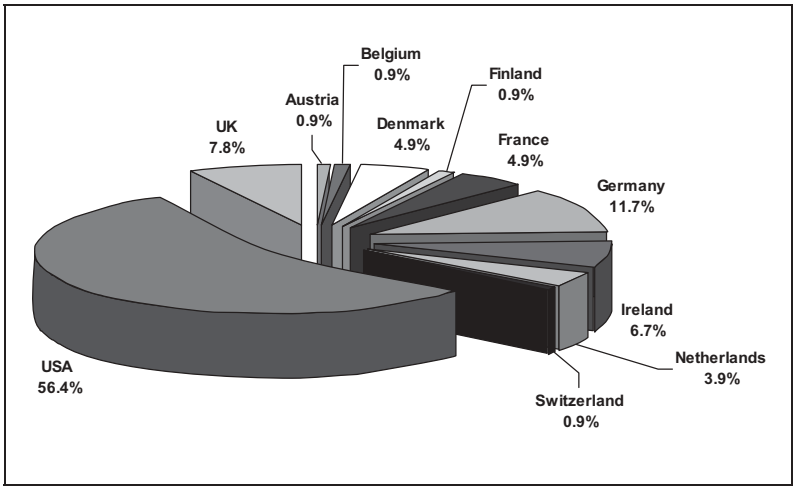

Figure 2: Breakdown by country

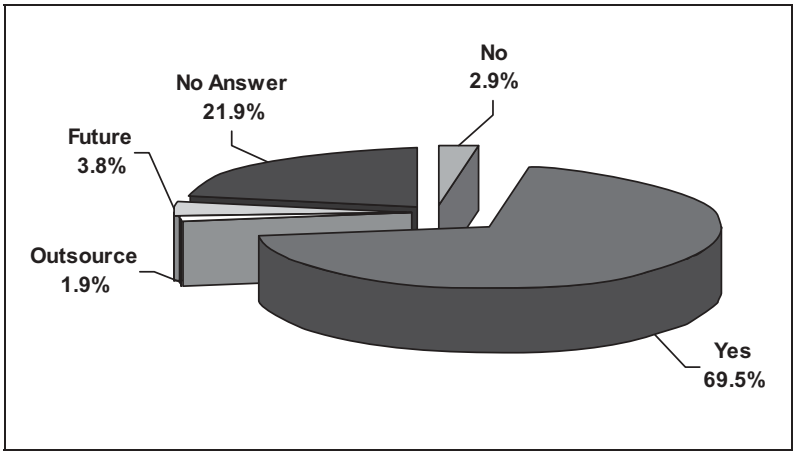

Figure 3: Question 1 Does your department/organisation make regulatory submissions?

nearest tenth of a per cent. All responses were included in the results, and each question depicts answers as they were given by survey respondents.

This survey is not a statistical survey. The results are meant to give a first look at where life sciences companies are in adopting technology for submissions and to provide insight into emerging and future trends in regulatory submissions. CDC Solutions will conduct this survey on an annual basis.

The 2002 Regulatory Submissions Survey is intended to provide a snapshot of industry trends and emerging needs as they relate to three broad categories: e-submissions technology, regulatory trends and outsourcing trends. The survey is not intended to be a statistical or scientific investigation. As the information compiled here is the first endeavour of its kind, it should be viewed purely as a market investigation and comparison of how various sub-segments within life sciences (specifically large pharmaceutical, small/mid-pharmaceutical, biotechnology and medical device) compare and contrast with each other within these three broad categories.

DEMOGRAPHICS OF SURVEY RESPONDENTS

Figure 1 shows that the medical device sector as a whole was the largest group responding to the survey (37 per cent). Medium/small pharmaceutical (defined as turnover up to US$1bn) was next with 23 per cent. Companies defining themselves as biotechnology were third with 16 per cent and large pharmaceutical (companies with turnover over US$1bn) made up 14 per cent of the responses.

Figure 2 shows that the majority of respondents (56 per cent) came from the USA. German respondents were the next largest group (12 per cent). Respondents from the UK made up 8 per cent of responses.

TECHNOLOGY USAGE

Over two-thirds of the respondents indicate that their companies already

make regulatory submissions with more anticipating making submissions – the Food and Drug Administration (FDA) is the regulatory authority to which most respondents are submitting. Technology usage will increase in the next year: 60 per cent of respondents say their use of regulatory submissions software will increase, and 19 per cent believe that they will implement a full electronic submissions system within 12 months.

Respondents place high importance on electronic document management and compliance with 21 CFR Part 11. Less importance, according to respondents, is being placed on regulatory information databases. Figure 3 shows that the majority of the companies responding to the survey make regulatory submissions (70 per cent), and an addition 4 per cent say they will make submissions in the future. Just 3 per cent of respondents say they do not make submissions.

Paper is still the leading system used to make submissions (37 per cent; Figure 4) but 34 per cent of respondents say they use a combination of electronic and paper methods while 7 per cent are using electronic submissions software. When asked about a timeframe to move to a full electronic submissions system (Figure 5), 19 per cent say they will make the move within 12 months. An additional 34 per cent anticipate that they will make the move but it will be more than a year.

In an open-ended question, respondents were asked to list all of the authorities to which they will make regulatory submissions (Figure 6). Over half (53 per cent) listed the FDA and respondents additionally listed the Center for Drug Evaluation and Research (CDER) (19 per cent), Center for Biologics Evaluation and Research (CBER) (20 per cent) and Center for Devices and Radiological Health

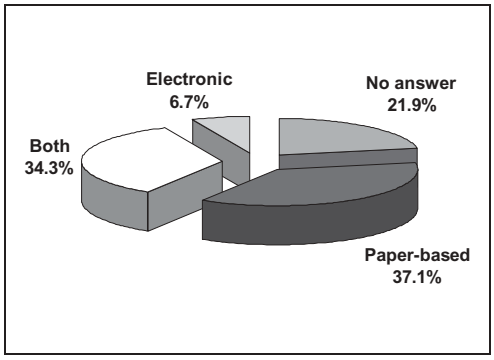

Figure 4: Question 2 What kind of system do you use for submissions?

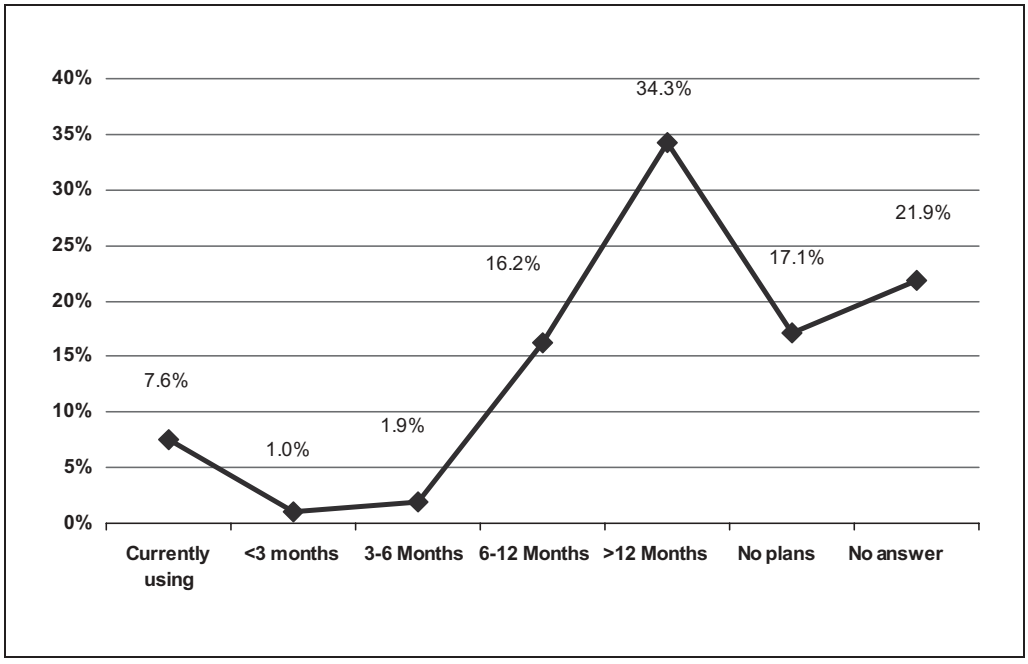

Figure 5: Question 3 In what timeframe do you anticipate moving to a full electronic submissions system?

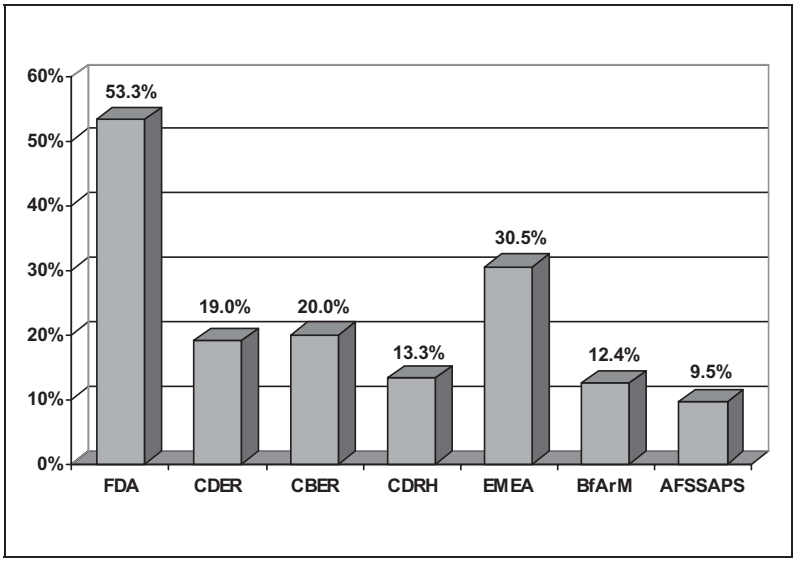

Figure 6: Question 4 To what authority will you submit?

(CDRH) (13 per cent). The European Agency for the Evaluation of Medicinal Products (EMEA) was named by 31 per cent of respondents, 12 per cent listed the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Germany) and 9 per cent listed Agence Française de Securité Sanitaire des Produits de Santé (AFSSAPS) (France).

The companies responding to the survey have multiple products at various stages in the submissions process (63 per cent; Figure 7). Figure 8 shows that just over half (50.5 per cent) believe that it is best to employ electronic submission software during the submissions stage and 27 per cent say it is best during investigational new drug (IND) submissions. Respondents could give more than one answer for this question.

Companies responding to the survey make multiple filings per year (Figure 9): 22 per cent make between 10 and 25 submissions and 15 per cent make more than 50. Figure 10 shows that 42 per cent of the survey respondents use a document management system. Slightly more than a third (34 per cent) say they do not yet use one. Of the companies that say they use a document management system, 60 per cent use Documentum®. Oracle® was the only other system with multiple

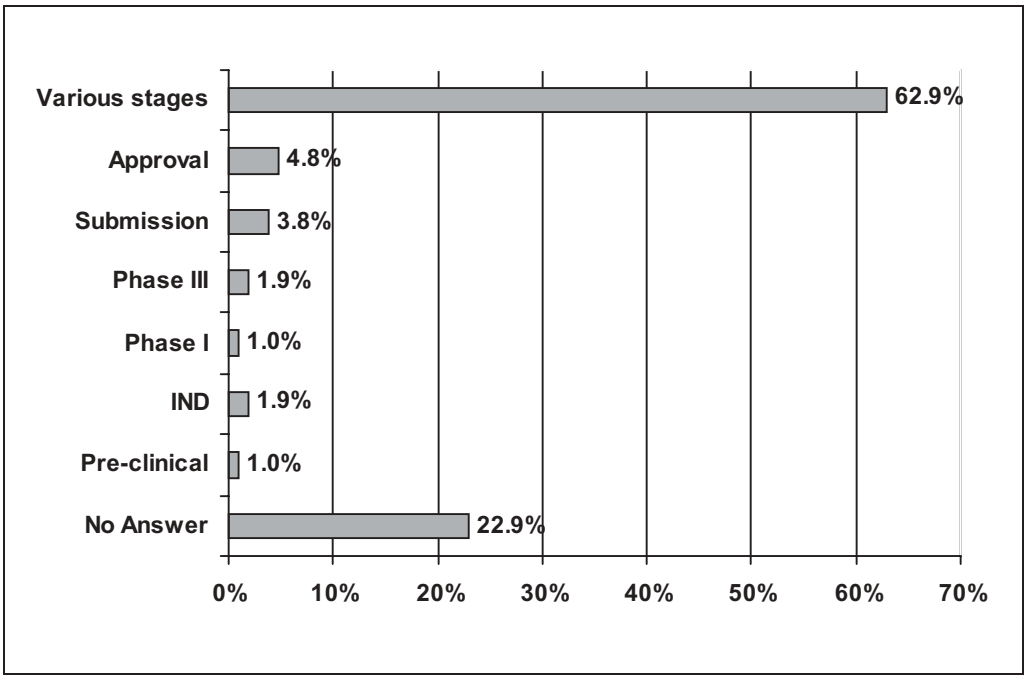

Figure 7: Question 5 At what stage are you in the submissions process?

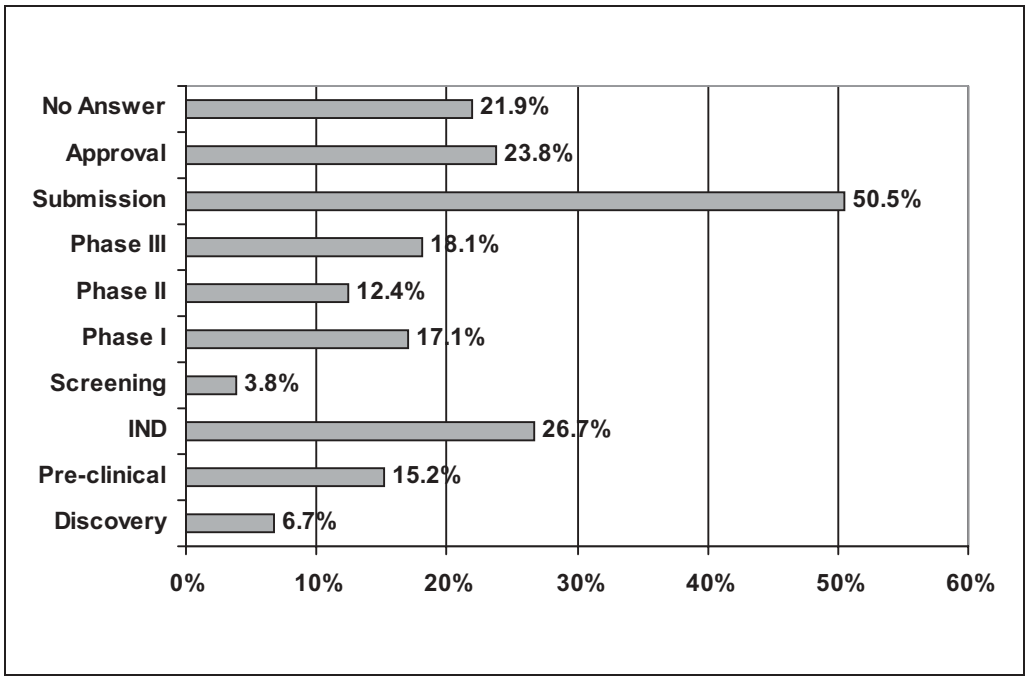

Figure 8: Question 5a At what stage do you believe it is best to employ electronic submissions?

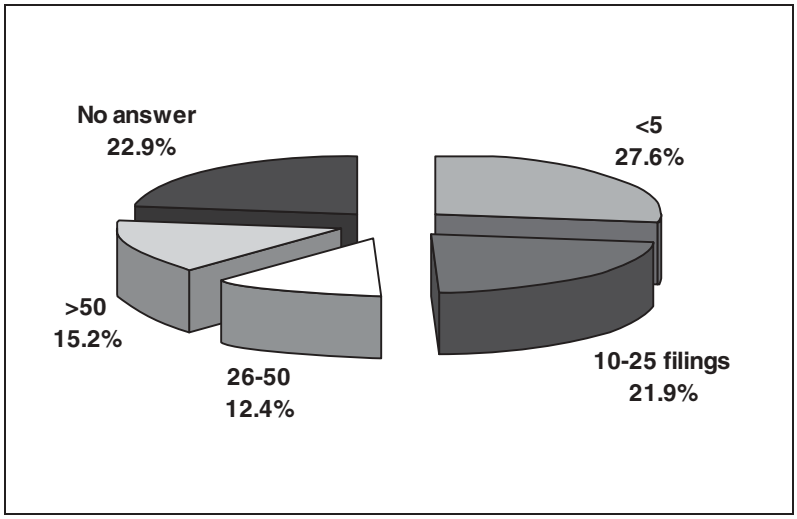

Figure 9: Question 6 How many regulatory filings does your company initiate per year?

mentions by survey respondents (Figure 11).

Respondents were asked to rank in terms of importance electronic document management, software for submissions and compliance with 21 CFR Part 11 (Figure 12). Electronic document management was most often ranked at the highest or medium importance (57 per cent). Compliance with 21 CFR Part 11 was next, with 46 per cent placing this at high or medium importance. Of the respondents, 30 per cent placed software for submissions at high–medium importance. One-third of respondents chose not to answer this question.

For Question 10, respondents were asked in an open-ended question to name what they consider the benefits of electronic document management. Benefits relating to version/document control, information sharing and access were most often noted.

When asked how they rank the importance of electronic document management, regulatory publishing software for submissions, and a regulatory information database (Figure 13), electronic document management was most often listed at a high or medium importance (54 per cent) and regulatory software was second with 40 per cent listing this at high or medium importance. Of the respondents, 33 per cent listed regulatory information database as high or medium importance. Figure 14 shows that overwhelmingly, survey respondents

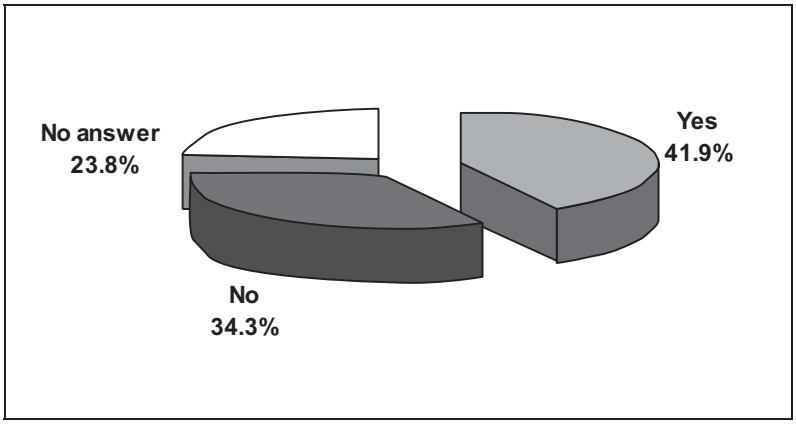

Figure 10: Question 7 Do you use a document management system?

anticipate their use of regulatory submissions software will increase (58 per cent).

For Questions 13 and 14, respondents were asked what they considered the benefits of regulatory publishing software (they were asked to check all that apply) and, of those, what are the two greatest (Figure 15). Process improvement and compliance with 21 CFR Part 11 were most often noted as the benefits of regulatory publishing software and they were the two greatest concerns as well.

SUBMISSION OUTSOURCING TRENDS

While nearly a quarter of respondents say they do not use outsource vendors, most companies responding do outsource some activities, and nearly half expect that their use of outsource vendors will increase or stay the same (Figure 16). Clinical research tops the list of activities that survey respondents outsource (35 per cent). A quarter of respondents (26 per cent) say they do not outsource and 14 per cent say they outsource submissions. Nearly 50 per cent of respondents (49 per cent) believe their use of outsource vendors will increase or stay the same (Figure 17). Just 10 per cent say it will decrease.

REGULATORY TRENDS

The majority of respondents indicate they are either compliant with 21 CFR Part 11

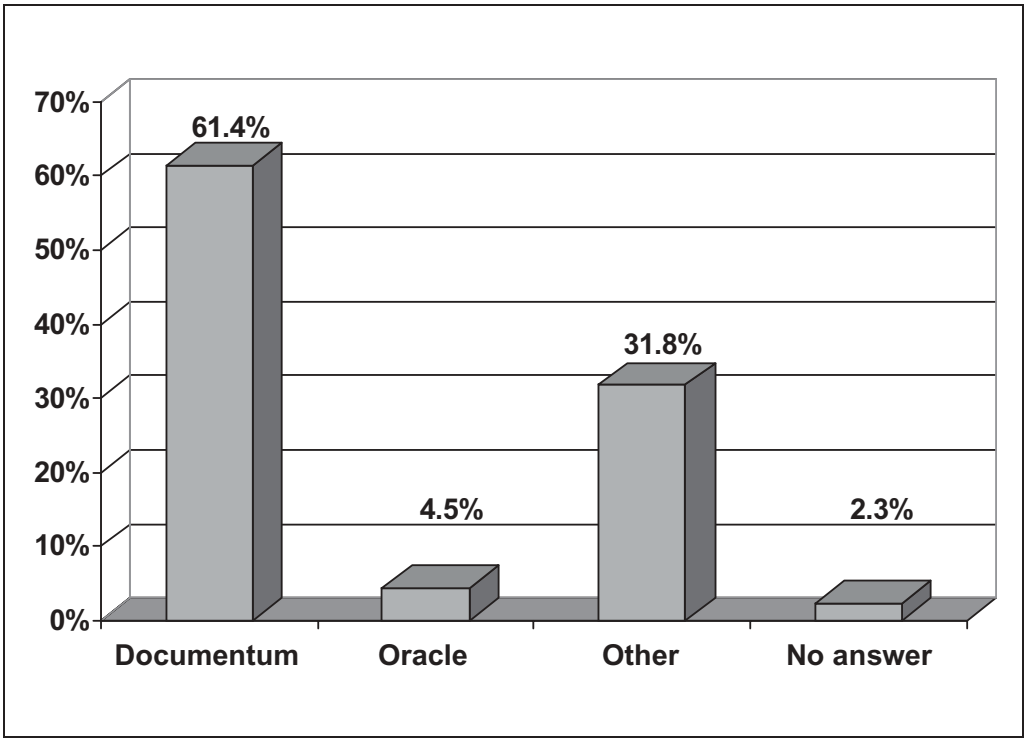

Figure 11: Question 8 If yes, what system?

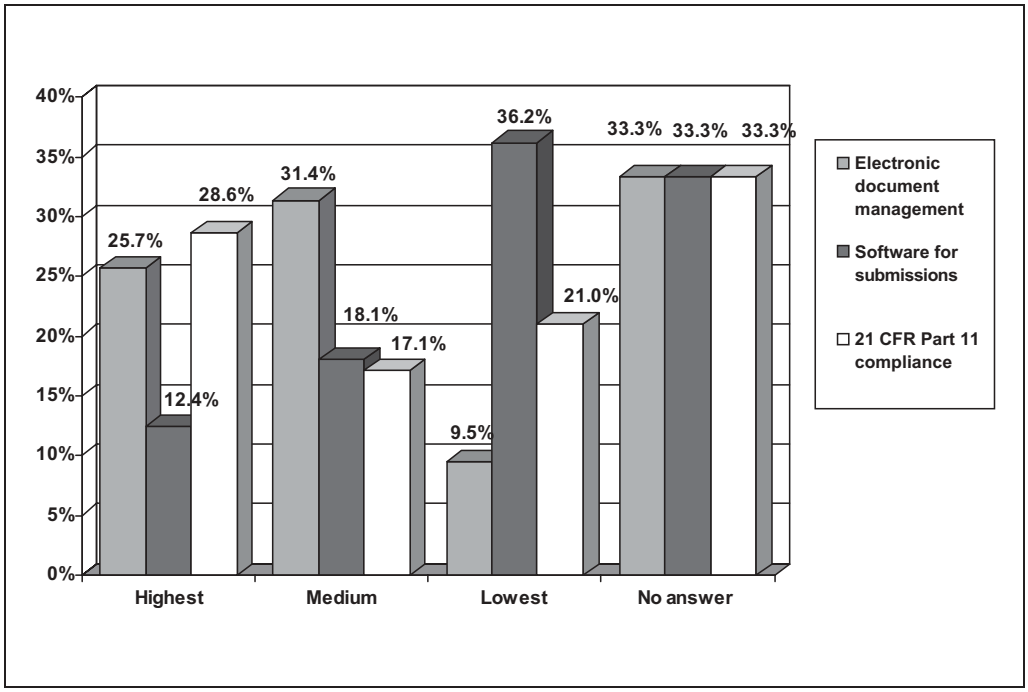

Figure 12: Question 9 How do you rate the importance of electronic document management, software for submissions, and 21 CFR Part 11 compliance?

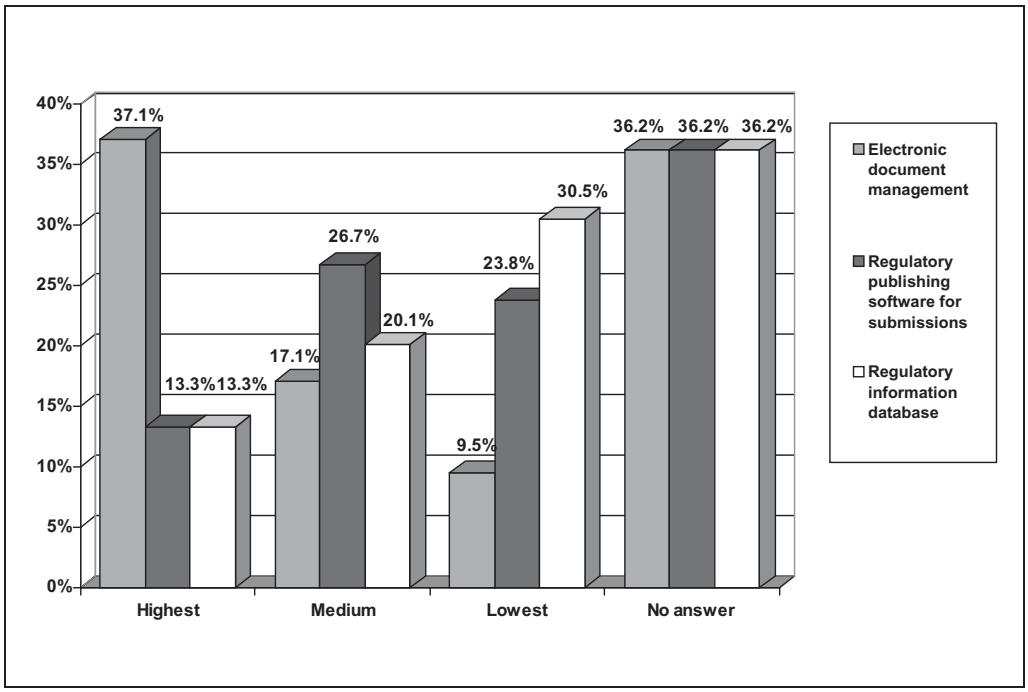

Figure 13: Question 11 How do you rate the importance of electronic document management, regulatory publishing software, and regulatory information database?

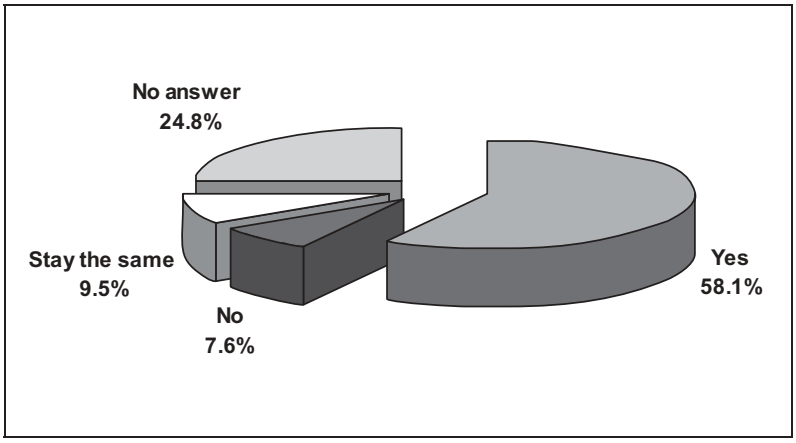

Figure 14: Question 12 Will your use of regulatory submission software increase?

or are planning to become compliant. But to become compliant, respondents believe it will impact their company's people, processes, and technologies.

Regarding their plans to migrate the submission process to the electronic Common Technical Document (eCTD), one-fifth of respondents say they are uncertain while over one-third say they do currently have plans (Figure 18). More than one-third, though, feel the eCTD will require a change in their submissions process within the next 18 months. More than 50 per cent of respondents are either already compliant (11 per cent) or planning to become compliant (42 per cent) with 21 CFR Part 11.

It is clear from the respondents who answered the question 'If you are planning to become compliant, how will it impact your company's people, processes, and technology' that they believe becoming compliant with 21 CFR Part 11 will affect their people (37 per cent), company processes (43 per

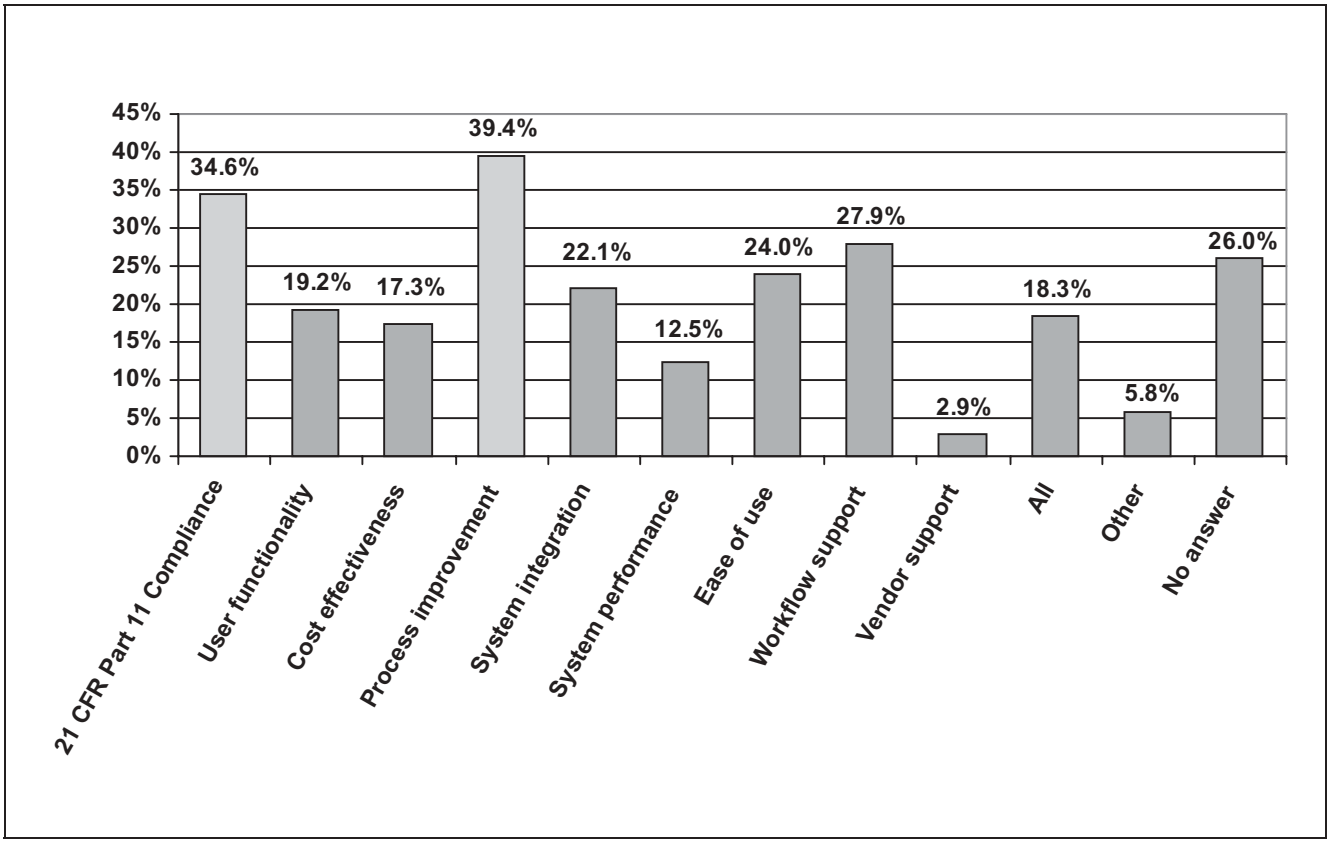

Figure 15: Questions 13 and 14 Benefits of regulatory publishing software

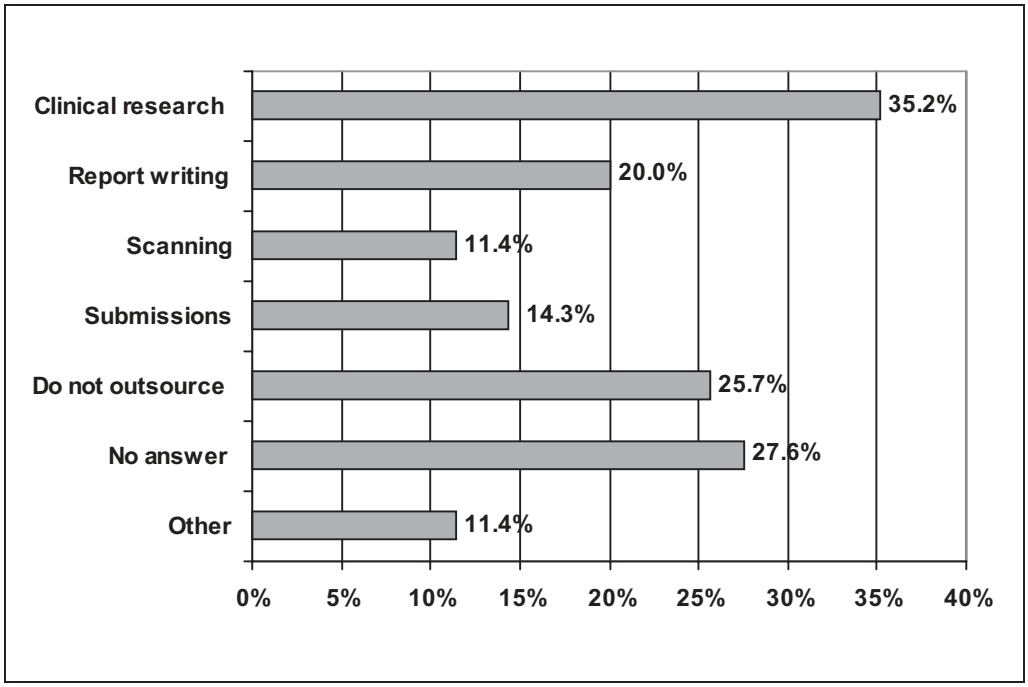

Figure 16: Question 15 For what activities do you use outsource vendors?

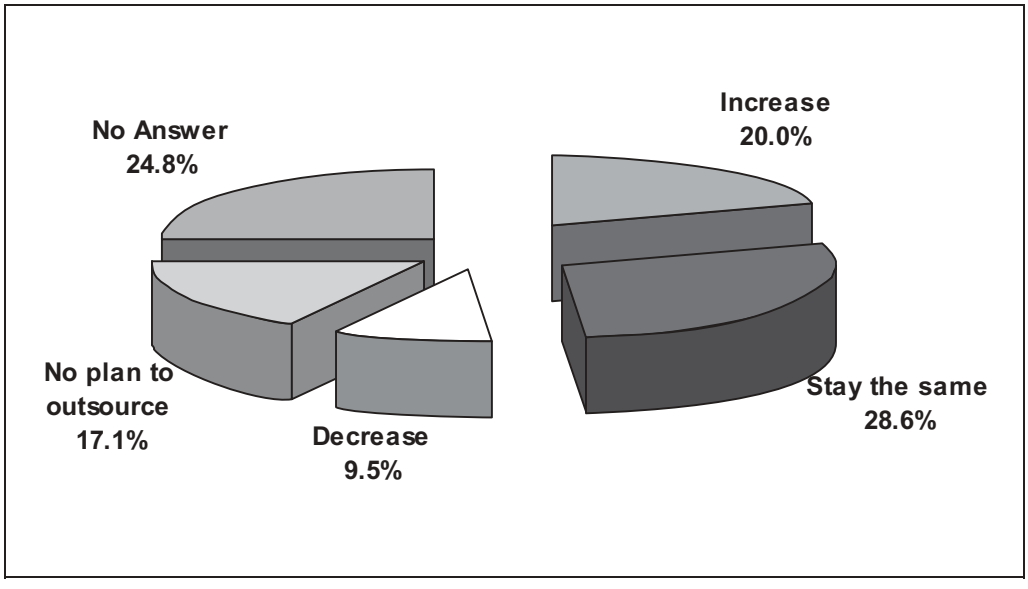

Figure 17: Question 16 How will your use of outsource vendors change?

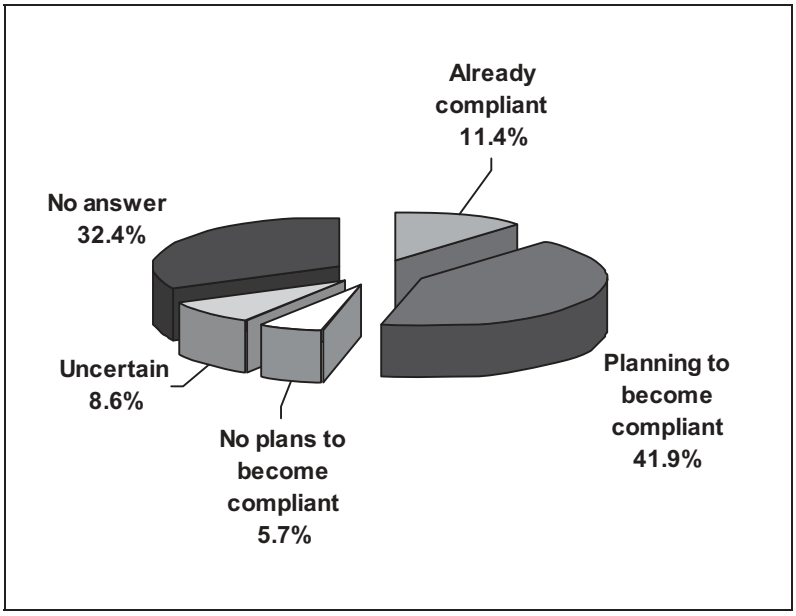

Figure 18: Question 17 Do you have plans to become compliant with 21 CFR Part 11?

cent) and their technologies (42 per cent); Figure 19. Few respondents did not feel that these areas will be affected by 21 CFR Part 11, but 42 per cent did not respond to the question.

Figure 20 shows that the respondents who answered the question 'Will the CTD impact your people, processes, and technologies' most feel that the CTD will affect their company's people (39 per cent), processes (45 per cent) and technologies (40 per cent). Nearly one-third of respondents chose not to answer the question.

Over one-third of respondents (35 per cent) say they have plans to change their submissions process to the eCTD (Figure 21). Another 20 per cent were uncertain about plans, and 12 per cent said they do not currently have plans to change. Figure

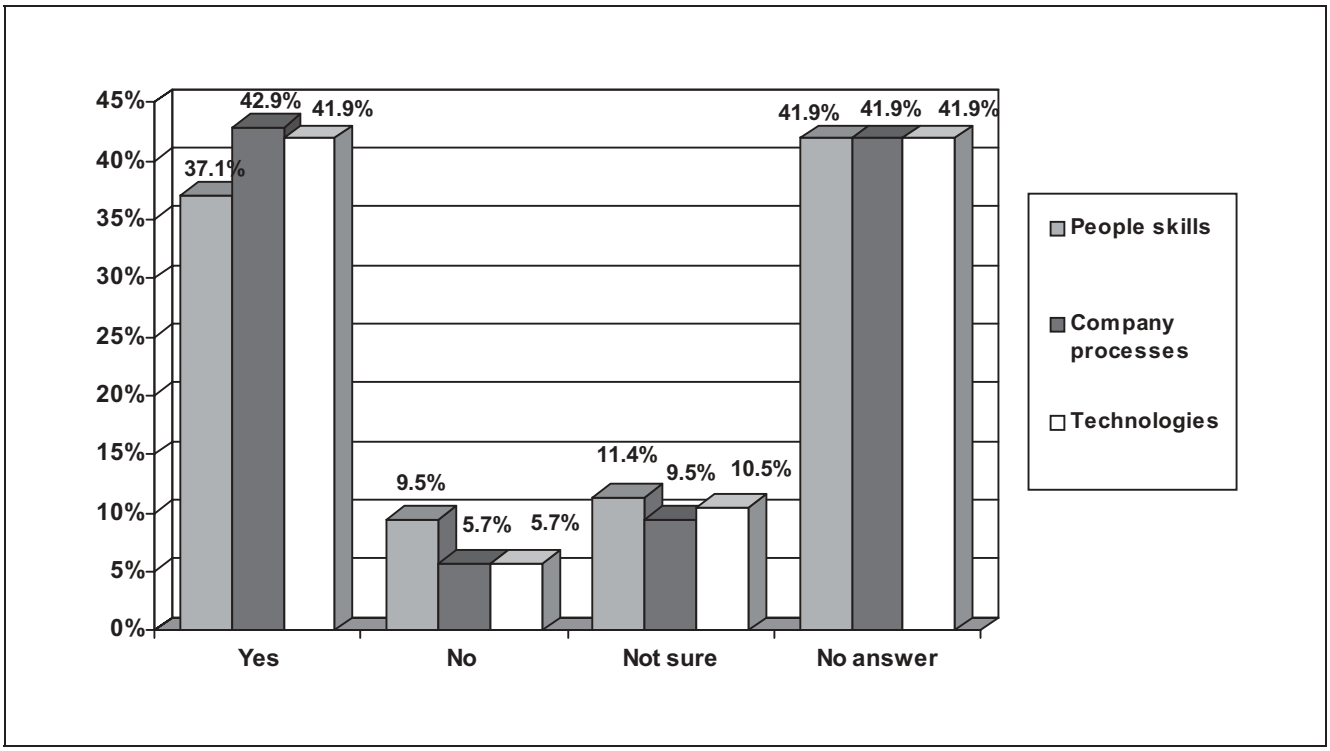

Figure 19: Question 18 If you are planning to become compliant, how will it impact your company's people, processes, and technology?

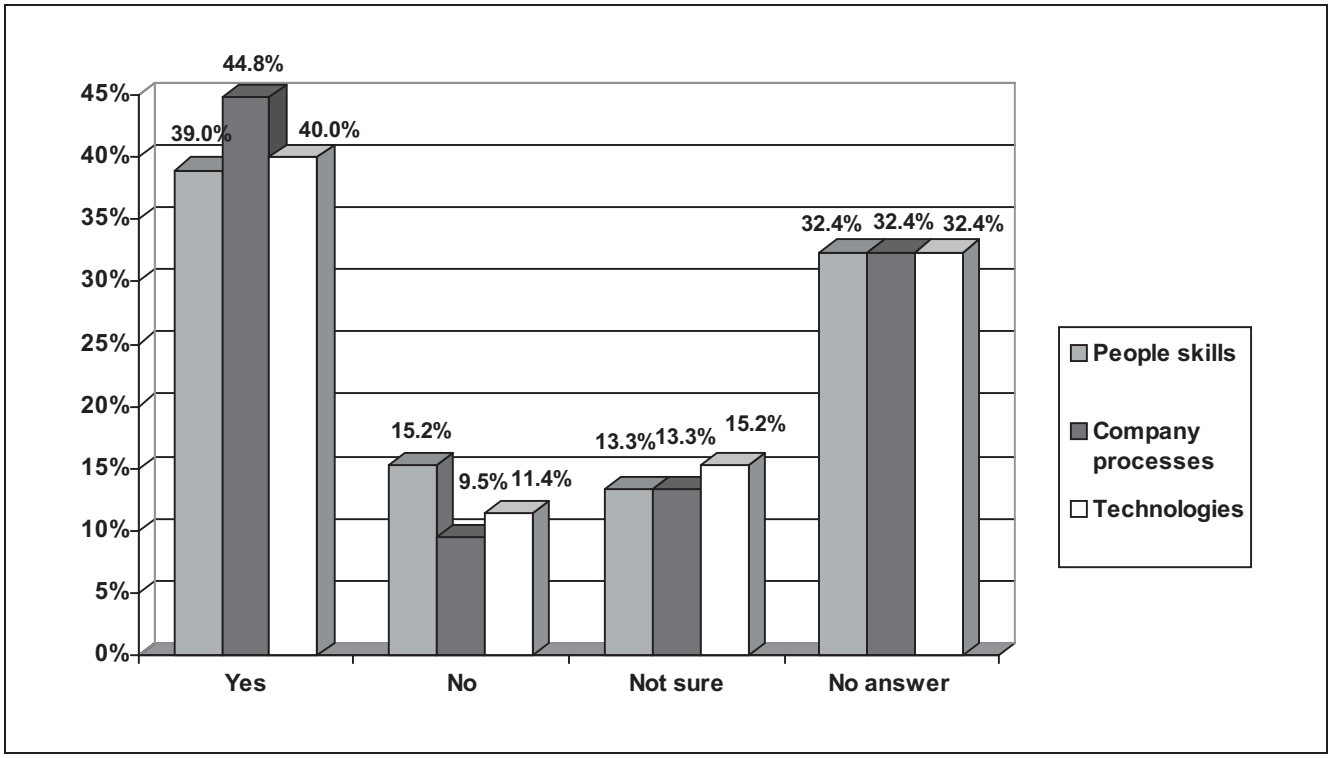

Figure 20: Question 19 Will the CTD impact your people, processes, and technologies?

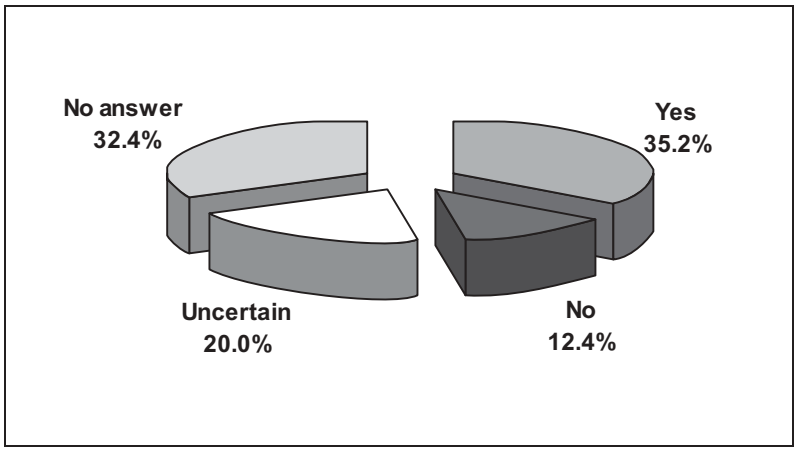

Figure 21: Question 20 Do you have plans to migrate the submission process to the eCTD?

22 shows that while 25 per cent of respondents are not sure when the eCTD will require a change in the submissions process, 34 per cent believe that the change will come within 18 months. About moving to the eCTD, Figure 23 shows that 40 per cent of respondents have no concerns about moving, but 28 per cent do have concerns. Respondents with concerns most often cited training issues and lack of support and guidance by regulatory agencies.

Respondents were asked in an open-ended question to list where they go for information on regulatory submissions and technology (Figure 24). The FDA was the top source with 22 per cent of respondents naming this agency. The Regulatory Affairs Professionals Society (RAPS) was second with 14 per cent and the Drug Information Association (DIA) was third with 11 per cent of respondents listing it.

CONCLUDING SUMMARY

This study takes the first steps to gauge the US/European life sciences community around eSubmissions and

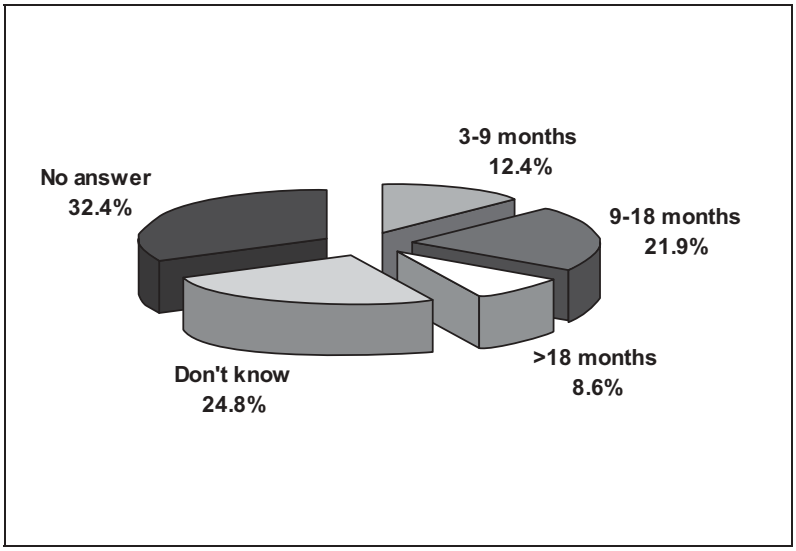

Figure 22: Question 21 When do you feel the eCTD will require a change in your organisation's submission process?

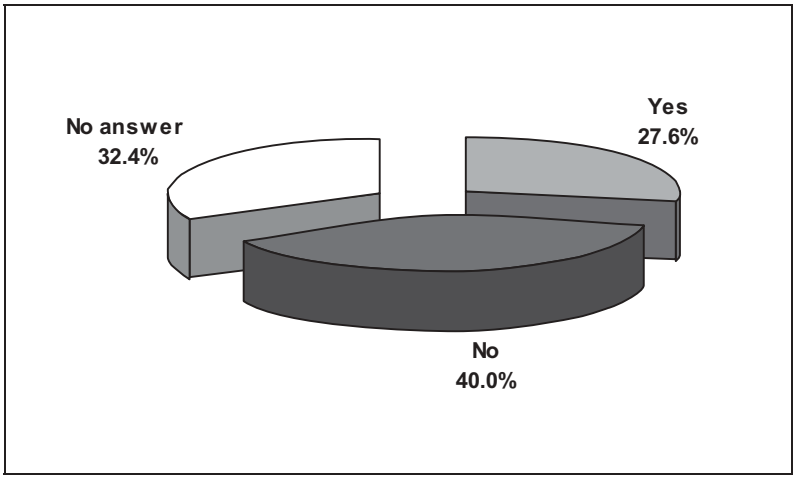

Figure 23: Question 22 Do you have concerns about moving to the eCTD?

specifically it presents a baseline measure on how pharmaceutical, biotechnology and medical device communities:

- view future increased demand for e-submissions technology usage;
- anticipate people, process and technology changes as related to the dynamic regulatory environment; and
- view their need to supplement current capabilities with outsourcing vendors.

As with any baseline survey, many of the results are important and warrant continued tracking to begin to uncover the best practices in regulatory submissions software. For example, as the market stands today:

- While 37 per cent currently use a paper-based (submission) system and 34 per cent use combination (electronic and paper, 19 per cent of respondents say they will make the move to a full electronic system within 12 months (this study was conducted in December 2002).
- Over half (58 per cent) say their use of regulatory software for submissions will increase in some form.
- Findings indicate that the industry is clearly being reshaped by the FDA's 21 CRF Part 11 and the International Conference on Harmonisation's (ICH) introduction of the CTD. Both of these, respondents indicate, will affect their company's people, processes and technologies.
- Some 42 per cent of respondents are planning to be compliant with 21 CFR 11, and many fell that becoming compliant will affect their people (37 per cent), processes (43 per cent) and technologies (42 per cent). Respondents also feel that the CTD will affect the people (39 per cent), processes (45 per cent) and technologies (40 per cent). Even with the knowledge that the CTD will require a change in processes and technologies, 35 per cent of respondents say they have currently plans to move the submissions process to the eCTD.

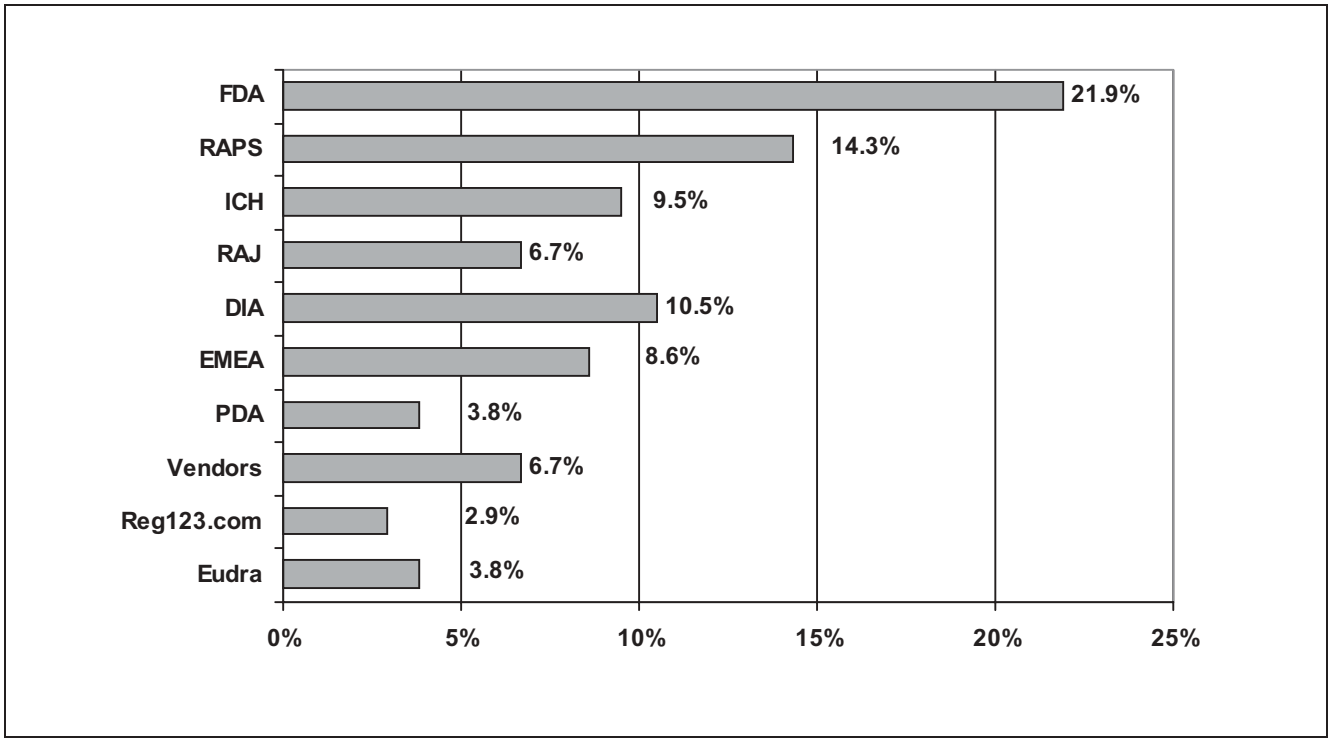

Figure 24: Question 23 Where do you go for information on regulatory submissions and technology?

Finally, it is worth noting that 14 per cent of respondents will outsource submissions, and the trend for future outsourcing needs appears to make this number increase.

Reference

1. URL: http://www.cdcsolutions.com