Qualified Statisticians in the European Pharma Industry: Present and Future Directions

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An EFSPI Qualifications Working Party questionnaire was completed by the boards of 10 EFSPI-affiliated organizations. Questions concerned responsibilities, qualifications, training, continuing professional development (CPD), and professional certification of statisticians in the pharmaceutical industry. A master's degree in statistics was most frequently the minimum requirement for an entry-level statistician, although some companies would accept a qualification where statistics was not the primary discipline. Recent developments in statistics were considered optional for an entry-level statistician, which may suggest that the pharmaceutical statistical community is not in the best position to respond to the current changing environment. Development of statisticians by companies is well supported, although therapeutic area and personal development courses are less well supported. Smaller countries noted there were insufficient statistical courses in their country for training after formal qualification. Interpretation of the ICH E9 term qualified statistician was still inconsistent five years after EFSPI published a common core definition. No EFSPI organization planned to publish a CPD policy or implement a registration scheme.

Key Words
Statistician; Pharmaceutical industry; Qualifications; Training

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INTRODUCTION

At present, statisticians play an acknowledged key role in drug research and development at a global level. They do so in a range of roles, either within the pharmaceutical industry or as regulators, academic researchers, or consultants. In Europe, but not necessarily only in Europe, standards of professional qualifications to meet these roles used to be unclear due to the large diversity of educational and professional career paths that could lead to the profession of statistician in drug research and development.

Triggered by the International Conference on Harmonization (ICH) E6 and E9 guidelines (1,2), a previous working party of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) established a common core definition of a "qualified statistician" (3). Today's environment of drug development is dynamic, with a multitude of technical, political, and societal factors influencing the way new drugs can be developed and marketed for true benefit to human health. These factors have had a large impact on the roles and responsibilities of statisticians. EFSPI therefore initiated a working party to revisit and evaluate the professional standards set previously, and investigate the professional development for statisticians needed to continue to deliver optimal value to the pharmaceutical industry.

This article presents the results of a survey of EFSPI-affiliated organizations that concerned the qualifications and experience of individuals working as statisticians in the European pharmaceutical industry. It provides a snapshot in time of these factors. Many pharmaceutical companies are international; therefore the results are of interest outside of Europe. The results are discussed in the context of the main trends affecting the statistician's role and thus the potential future needs for training and certification programs.

The article starts with introductory sections on the development of the working environment of statisticians in the pharmaceutical industry, accreditation schemes for statisticians, and European higher education. The methods and results of the survey are then presented. The results are discussed and the future considered.

WORKING ENVIRONMENT

The evolution and expanding role of the statistician in the pharmaceutical industry (4,5) and the changing times in pharmaceutical statistics (6,7) have been discussed. The increasing regu-

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latory requirement for statistical input in critical areas and the changing face of the science of drug development have driven the evolution. A change in the statisticians' approach to their role and the correct training and experience were identified as being critical for the profession to optimize its contribution to the drug discovery and development process. As the statistician role continues to develop from a technical to a strategic role, emphasis on experimental design, communication and presentation skills, general science, decision theory, and risk assessment were seen as key aspects of a future statistician's training.

ACCREDITATION SCHEMES

In Europe, three accreditation schemes (in Germany, Netherlands, and the UK) are running whereby statisticians can register and be approved by a statistical organization to show that they have attained a defined level of qualifications and experience. These schemes are broader than for just the pharmaceutical industry.

In Germany, the German Society for Medical Informatics, Biometry and Epidemiology (GMDS) and German Region of the International Biometric Society established criteria for the certificate of Biometry in Medicine in 1981 (8). In 1987, the certificate received official recognition by the German Federal Institute for Drugs and Medical Devices (BfArM) as proof of qualification of the responsible biometrician.

In the Netherlands, the Dutch Society for Statistics and Operational Research (VVS) has had an accreditation scheme for the registration of biostatisticians working in medical, biological, agricultural, and environmental areas of application since 2002 (9). In the UK, the Royal Statistical Society introduced an accreditation scheme in 1993 (10). The award of chartered statistician (CStat) covers all areas of statistics and is not specific to statisticians working in biostatistics or the pharmaceutical industry.

The requirements of each scheme differ in detail. However, in general, to be awarded accreditation, a candidate must have completed a university education in statistics and have 5 years practical experience in applying statistics.

Outside of Europe, similar registration schemes for statisticians also exist in Australia and Canada. The American Statistical Association has also considered a certification scheme (11), but has not implemented one to date.

EUROPEAN HIGHER EDUCATION

In Europe, statistics can be studied at the undergraduate level, but is more commonly studied at the postgraduate level. At the undergraduate level, usually a 3- or 4-year course, study would lead to a qualification such as a bachelor of science (BSc). At the postgraduate level, a further 1 to 3 or more years of study would lead to a master of science/philosophy (MSc/MPhil), licensiate, or doctor of philosophy (PhD).

The availability of courses focusing on biostatistics or medical statistics varies between countries (3). General statistics courses may be available with a varying content of biostatistics. Other courses may be mathematical or in another discipline (eg, social sciences, econometrics) with an option to specialize in statistics. Hence, the statistical qualifications of statisticians working in the pharmaceutical industry are likely to vary both within and between countries.

SURVEY OF EFSPI-AFFILIATED ORGANIZATIONS

In June 2004 a questionnaire was sent to each of the 11 EFSPI-affiliated organizations. The questionnaire was designed to be completed by the board of each organization, rather than the individual members of the organizations. The boards used membership data, board meeting discussions, and local knowledge to provide answers. Some or all of the board members in each organization would have been experienced statisticians from the pharmaceutical industry. The method of obtaining the results was at the discretion of each organization and data available for generating the response is likely to have varied between the organizations. In addition to background information, questions were related to the responsibilities, qualifications, training, continuing professional development (CPD), and certification or registration

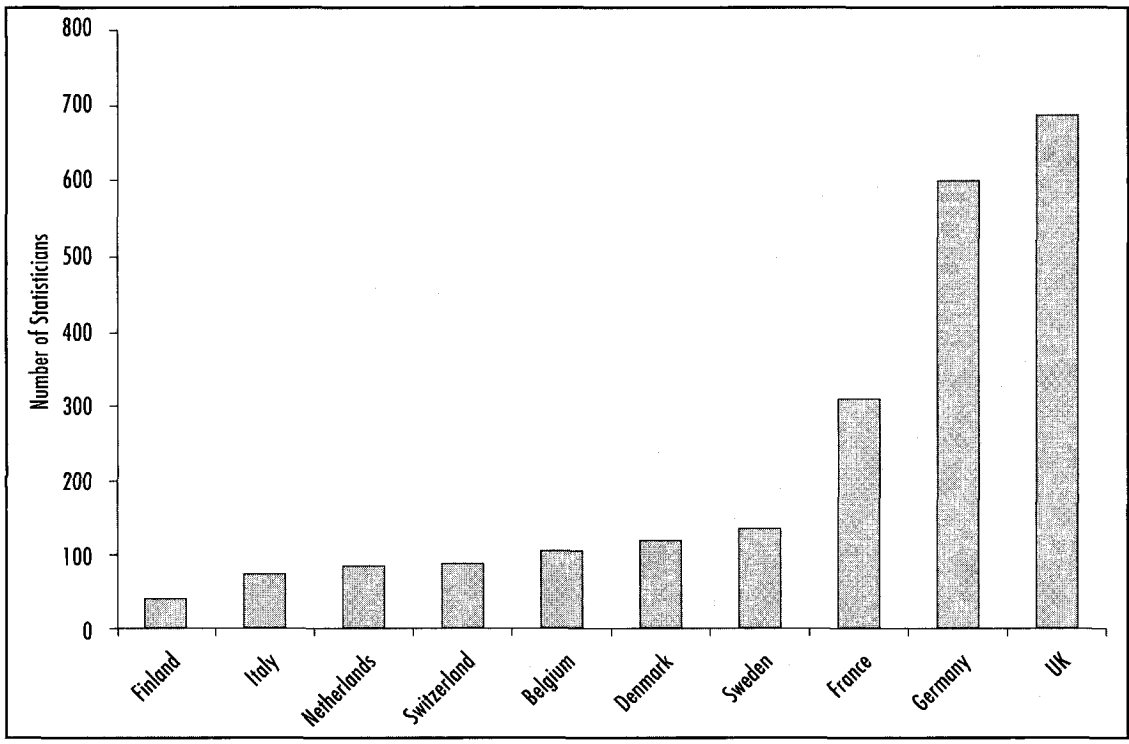

FIGURE 1

Estimate of the number of statisticians employed by the pharmaceutical industry, including contract research organizations and consultants.

of statisticians working in the pharmaceutical industry. Each organization was asked to provide information concerning the statisticians working in the pharmaceutical industry in their country. The pharmaceutical industry was defined to include all statisticians employed by pharmaceutical companies as well as those employed by contract research organizations (CROs) and independent consultants working for the industry. It was also to include all functions (eg, in research, development, operations, marketing).

SURVEY RESULTS

BACKGROUND INFORMATION

Societies from 10 of the 11 countries completed the questionnaire: Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Sweden, Switzerland, and the UK.

An estimate of the number of statisticians in each country is shown in Figure 1. Overall, it is estimated that over 2,200 statisticians are working in the pharmaceutical industry in the 10 countries who participated in the survey. The UK, Germany, and France have the largest number of statisticians and in total account for approximately 75% of statisticians.

In all countries, the large majority of statisticians (70–95%, per country) were employed in the clinical area (Table 1). Between 5% and 30%, per country, were estimated to be employed in the nonclinical area and between 0 and 25% in other areas. Statisticians were employed in both pharmaceutical companies and CROs in all countries.

Many statisticians were in the <5 years and 5 to <10 years experience groups (Table 1): the median percentages over the nine countries were 25% and 35%, respectively. For the 10 to <15 years and the >15 years experience groups, the median was 20% and 15%, respectively.

RESPONSIBILITIES

Table 2 presents the median and range, over countries, of the minimum number of years experience that companies generally require statisticians to have for the main tasks of the statistician role.

At the study level, for statistical input to study design (including the protocol and statistical

TABLE 1

Median and Range, Over Countries, of the Percentage of Statisticians Estimated to Be Working in the Pharmaceutical Industry, by Business Area, Sector, and Experience

	Median (%)	Range (%)
Business area*		
Clinical	84	70–95
Nonclinical	10	5–30
Other	3	0–25
Sector		
Pharmaceutical company	67	40–85
Contract research organization	26	15–50
Other	5	0–15
Experience*		
<5 years	25	10–41
5 to <10 years	35	20–60
10 to <15 years	20	14–35
>15 years	15	3–36

*Data based on nine countries: the UK did not provide a response.

analysis plan), performing statistical analysis, quality control of statistical analysis, and input to the study report, the median of the lowest number of years experience that companies require statisticians to have was 1 year. The median was greater for sign-off, being 3.5 years for the sign-off of study design (including protocol, statistical analysis plan) and 3 years for report sign-off.

The response across countries was similar for statistical analysis and quality control of statistical analysis (range 0–1.5, and 0–3, respectively). For both of these tasks, the Scandinavian countries tended to be lower (Denmark, 0 years; Finland and Sweden, 2 years) compared to other countries.

For input at a project level, the median was greater, being 5 years for input to development plans and high-level regulatory submission documents (eg, summaries and overviews) and 6 years for participation in meetings with regulatory or health authorities.

For input at a project level, the Scandinavian countries were lower (Denmark, 0 years for project development and 2 years for high-level regulatory submission documents or participation in meetings with regulatory or health authorities; Finland and Sweden, 3 years for all these activities). For project development, the range for other countries was 5 to 6 years. Italy was higher (10 years) for high-level regulatory submission documents and participation in meetings with regulatory or health authorities compared to the other remaining countries (range 5–6 years). Italy (10 years), Belgium (10 years), and France (10 years) were higher for participation in meetings with regulatory or health authorities compared to the other remaining countries (range 5–7.5 years).

The individual country responses varied on the interpretation of the ICH E9 statement:

TABLE 2

Median and Range, Over Countries, of the Minimum Number of Years Experience That Companies Generally Require for Statisticians' Main Tasks

Responsibility	Median (Years)	Range (Years)
Study-level responsibilities:		
Statistical input to design/protocol/statistical analysis plan	1	0–5
Statistical sign-off of design/protocol/statistical analysis plan	3.5	0–5
Perform statistical analysis	1	0–1.5
Quality control statistical analysis	1	0–3
Statistical input to the (study) report	3	0–6
Report sign-off	3	0–10
Project-level responsibilities:		
Project development plans/teams	5	0–6
High-level regulatory submission documents (eg, overviews/summaries)	5	2–10
Participation in meetings with authorities (eg, regulatory authorities, health authorities)	6	2–10

TABLE 3

Qualification Requirements for an Entry-Level Statistician

	Number of Countries (%)				
Number of Companies	Doctorate in Statistics	Master's in Statistics	Licensiate in Statistics	Graduate in Statistics	Other Graduate
All	0	2 (20)	0	2 (20)	0
Many	0	7 (70)	1 (11)	1 (10)	0
About half	0	0	1 (11)	0	0
Some	2 (20)	1 (10)	0	6 (60)	9 (90)
None	8 (80)	0	8 (80)	1 (10)	1 (10)
Total 0	10	10	10	10	10

> [I]t is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6. . . . Thus, the trial statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance. (2)

Many countries stated that it was dependent on the interpretation by an individual company or head of statistics. In terms of qualifications, six of the countries mentioned that an MSc in statistics is usually a requirement. In terms of experience, estimates were from 3 to 8 years.

QUALIFICATIONS

The responses to the questions related to the minimum requirements for an entry-level statistician are given in Table 3. In 9 of the 10 countries, all or many companies required a master's in statistics as the minimum requirement. This compared with three countries for which all or many companies required a graduate qualification in statistics as the minimum requirement. In Belgium many companies required a licensiate degree, a qualification that is at a similar level to a master's.

In 9 of the 10 countries there were some companies that would accept a graduate, postgraduate, or other qualification where statistics was not the primary discipline. Such a qualification was unacceptable in Switzerland. Subjects such as psychology, mathematics, and computer science were given as examples of disciplines considered as being acceptable. It was also noted that some companies might allow a graduate qualification in a subject other than statistics, provided that an individual studied for a qualification (eg, master's) while working.

Table 4 shows the categorization, by the countries, of statistical topics to have been completed by a statistician on joining the pharmaceutical industry, as either essential or optional. Statistical inference was the only subject that was identified by all countries as essential. Subjects that at least half of the countries selected as being essential were linear models, sample size, statistical computing, experimental design, medical statistics and clinical trials, logistic regression, and survival analysis. Repeated measurements, multivariate methods, and time series were considered essential by less than half the countries. All countries considered Bayesian statistics, epidemiology, and simulation to be optional.

TRAINING

Source and type of training are given in Table 5. There was a spread across the categories in respect of internal training, with five countries stating that many or all companies used internal training and five countries stating that about half or some companies used internal training.

External training within the country was used

TABLE 4

Categorization of Statistical Topics as Either Essential or Optional to Have Been Completed by a Statistician on Joining the Pharmaceutical Industry

Topic	Number of Countries (%)	
	Essential Topic	Optional Topic
Statistical inference	10 (100)	0
Linear models	9 (90)	1 (10)
Sample size	7* (70)	3 (30)
Statistical computing	6 (60)	4 (40)
Experimental design	5* (50)	5 (50)
Medical statistics/clinical trials	5* (50)	5 (50)
Logistic regression	5 (50)	5 (50)
Survival analysis	5 (50)	5 (50)
Repeated measurements	4* (40)	6 (60)
Multivariate	3 (30)	7 (70)
Time series	1 (10)	9 (90)
Bayesian	0	10 (100)
Epidemiology	0	10 (100)
Simulation	0	10 (100)

*Includes one response of essential/optional 50:50.

by many or all companies in six countries. In the four remaining countries, external training within the country was used by some or about half of the companies. Use of external training outside the country was lower. This source of training was used by many companies in four countries (Belgium, Denmark, Netherlands, and Switzerland). In the remaining six countries, external training outside the country was used by some or about half of the companies.

All countries, with the exception of France, considered that there was sufficient training available for formal statistical qualifications. Considering the availability of training, excluding formal qualifications, four countries stated that there was adequate provision within their country. These were the UK, Germany, France, and Sweden, although Sweden commented that companies may look abroad for specialist courses. Hence the remaining six countries (Belgium, Denmark, Finland, Italy, Netherlands, and Switzerland) felt that insufficient statistical training (excluding formal) was available in their country. Insufficient courses were chosen as a reason in all of these countries. One country selected insufficient funding as an additional reason. Another country stated that most courses focused on sophisticated statistical methods and not on applied statistics.

Attendance at therapeutic area training cours-

TABLE 5

Source and Type of Training

	Number of Countries (%)				
	Statistical Training				
	Internal Training	External Within Own Country	External Outside Country	Therapeutic Training	Personal Development Courses
All	2 (20)	2 (20)	0	1 (10)	2 (20)
Many	3 (30)	4 (40)	4 (40)	3 (30)	4 (40)
About half	2 (20)	3 (30)	5 (50)	3 (30)	1 (10)
Some	3 (30)	1 (10)	1 (10)	3 (30)	3 (30)
None	0	0	0	0	0
Total	10	10	10	10	10

es was encouraged by all or many companies in four countries, by about half of the companies in three countries, and by some companies in three countries. Encouragement of attendance at personal development courses was higher. Attendance at these courses was encouraged by all or many companies in six countries, by about half of the companies in one country, and by some companies in three countries.

CONTINUING PROFESSIONAL DEVELOPMENT AND CERTIFICATION

None of the nine EFSPI-affiliated organizations who completed the questionnaire reported having a published CPD policy or that a policy was in development. Germany and the UK reported that another statistical society within their country had published a CPD policy. For Germany this is linked to the award of a certificate in medical biometry by GMDS (8). In the UK, the Royal Statistical Society encourages members to keep a record of their professional development activities. These can be statistical or technical and personal or nonstatistical. The society also recommends the number of hours to be spent on CPD (10).

A registration scheme is available in Germany, Netherlands, and the UK. In three countries (Denmark, France, Sweden) a scheme had been considered in the past but has not been implemented. In Denmark the reason given was that the statisticians working in the industry have graduated from a small number of universities and are considered to be similar with respect to education; however, the possible need for such a scheme in the future was noted. In Sweden and France, a scheme had been suggested by the affiliate organization in the past but had been turned down by the members and had not been reconsidered. The reasons given for the lack of support were fear that too narrow a profession would be created, an element of subjectiveness in the assessments, administrative burden, and the perception that there was no problem in not having a scheme.

In Belgium, Finland, Italy, and Switzerland a scheme had not been considered or implemented. Belgium commented that many statisticians do not see the need for such a scheme. Finland commented that there had been no urgent need to date.

DISCUSSION

Over 2,200 statisticians are working in the pharmaceutical industry in the 10 countries participating in the survey. The survey showed that the distribution of employment of these statisticians is diverse. The majority are working for pharmaceutical companies, but a significant number are also working for CROs and as independent statisticians. The pharmaceutical industry is highly regulated by government, and statisticians in the industry work to guidelines published by the regulatory authorities. In contrast, the number of statisticians employed by the regulatory authorities is small, and the need for more statisticians in the authorities has been highlighted (12–15).

As would be expected, most statisticians are working in the clinical area and the ICH E9 guideline (2) is particularly relevant to this group. Many have less than 10 years experience and therefore are likely to have entered the industry since the publication of this guideline. ICH E9 requires that an appropriately qualified and experienced statistician be responsible for all statistical work associated with clinical trials. The guideline also requires that "[t]he protocol and subsequent amendments should be approved by the responsible personnel, including the trial statistician" and "[t]he trial statistician should be a member of the team responsible for the clinical study report, and should approve the clinical study report." The lack of definition of qualifications and experience by ICH E9 led EFSPI to publish the "concept" of a qualified statistician (3). In the EFSPI definition, a "qualified and experienced medical statistician" is expected to have "a university degree in statistics or equivalent, plus more than 3 years of experience in medical statistics."

The survey showed that, in the majority of companies, a graduate qualification in statistics is the minimum requirement for an entry-level statistician, with many companies requiring a postgraduate qualification such as an MSc.

However, there are some companies in most countries that will accept a graduate qualification in another subject and examples of mathematics, psychology, and computer science were given. A comment suggested that such personnel would be encouraged to take further studies in statistics while working as statisticians.

The reason for companies to accept a graduate qualification in a subject other than statistics was not collected in the survey. One explanation is likely to be that the supply of statisticians is insufficient. The number of statisticians working in the pharmaceutical industry rose sharply in the last two decades of the 20th century. PSI, the UK pharmaceutical statistical organization, grew from a membership of 47 in 1977 to over 1,100 in 2004 (5). In many countries demand may have been greater than numbers available. There is also a lack of MSc courses (or equivalent) in some countries. The EU higher education system is diverse and lacks consistency, making it difficult to compare the status of some qualifications against an MSc. There is a need to set a clear standard in biostatistical education at the BSc and MSc levels. Working in a global marketplace with management being conducted across countries, it would be advantageous if universities offered similar levels of qualifications across Europe. In the future this may be possible. The EU Bologna Declaration of June 1999 put in motion a series of reforms to make European higher education more compatible and comparable (16). The outcome of the Bologna Process is expected in 2010 (17).

The only topic that all countries identified as essential for a statistician joining the industry was statistical inference. Hence, although the focus of the majority of statisticians working in the industry is on the application of statistics, formal training in statistical theory is considered important. More recent developments in statistics such as Bayesian statistics and simulation were not considered compulsory by any country. Thus it appears that the expectation is for statisticians entering the industry to have been trained in commonly applied statistical methods, but not necessarily in more recent methodology. Companies must therefore expect to take responsibility for training in more recent statistical methodology as part of the CPD of their statisticians.

As pharmaceutical companies strive to deliver new medicines to market more quickly and regulatory authorities impose greater demands, the profession needs to be more innovative and embrace change. The low priority of the inclusion of recent developments in statistics (eg, Bayesian and simulation) suggests that the profession may not be assertive enough to lead the change required. Rockhold (4) has also highlighted the need for statisticians in the industry to question whether the right career development strategies are in place to be able to support the pharmaceutical industry in the future. Time and cost have been highlighted as obstacles to the implementation of a career development program within companies (18). A statistician's time is often at a premium because of greater needs than can be met by the staff available. The requirements for training of the modern pharmaceutical statistician also need to be communicated back to universities to ensure the supply of appropriately trained statisticians in the future.

In terms of experience, the minimum number of years required for sign-off (median across countries) was 3.5 years (range 0–5) for the protocol and 3 years (range 0–10) for report approval. The median is consistent with the EFSPI concept of 3 years; however, the range shows that in some countries a lower level of experience is accepted.

Given that few statistical topics covered by formal qualifications were considered essential and that these are not specific to the pharmaceutical industry, further training of statisticians is important. ICH E6 requires that "each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)" (1). It is therefore surprising that none of the EFSPI-affiliated organizations had or was developing a policy for CPD. Hence training is at the discretion of individual companies.

Statistical training came from different

sources, both internal and external, and within and outside the country. Although most countries considered that adequate formal statistical training was available within their country, many (in particular the countries with fewer statisticians) felt that there was insufficient other statistical training. Thus, in these countries, the training of statisticians new to the industry could prove more difficult, time consuming, and expensive, requiring travel outside the home country.

The role of the statistician in the pharmaceutical industry requires broader skills than statistical expertise alone (19) and this is even more relevant in the current environment. Statisticians work in multidisciplinary teams and need to be able to communicate with nonstatistical personnel at different levels within an organization, depending on their role. Often good knowledge of the scientific or therapeutic area that they are involved in is essential for an effective contribution. Statisticians may also be involved in external meetings, for example, with investigators or regulatory authorities. Many companies supported the attendance of statisticians at therapeutic area and personal development courses. This shows that many statisticians are being given the basis to develop important nonstatistical skills; however, the survey also highlighted that some companies could do more in this area.

The ICH requirements for appropriately qualified and experienced statisticians could provide the basis for development of a registration scheme for statisticians working in the pharmaceutical industry. Keiding (20) concluded that the need to fulfill regulatory agency requirements as part of the pharmaceutical statistician role suited an accreditation concept well. Regulatory authorities do not require registration of statisticians, although the German scheme is recognised by BfArM. The registration schemes present in three European countries are not specific to the pharmaceutical industry.

The majority of countries did not feel the need for a registration scheme and there is mixed opinion concerning the desirability of a formal accreditation scheme for pharmaceutical statisticians in Europe. However, certification does help in setting standards and the survey showed that interpretation of the ICH E9 phrase "appropriately qualified and experienced statistician" varies between countries and companies. A certification system would ensure that the ICH E9 requirements could be met and ensure the quality of statistics produced with the added benefit of improving the general awareness of the profession.

FUTURE DIRECTIONS

In the 1990s, the International Conference on Harmonization provided the framework for drug development to be more international. As a consequence, now, more than ever, statisticians in the pharmaceutical industry throughout Europe are working toward the same goals in terms of providing information to support the drug development process. A consistent approach to the development of statisticians in the industry would be expected and the outcome of the survey broadly supports this. However, this is against the background of diverse education systems in the different European countries. The pharmaceutical statistical community needs to embrace new methodology and thinking to meet the requirements of drug development in the 21st century.

There appears to be a good level of support for the development of statisticians by companies. This has occurred without formal recommendations for CPD or registration of pharmaceutical statisticians. However, there is room for further development and improvement. It is of concern that some companies employ nonstatisticians to perform a statistical role. A formal registration scheme would ensure that such statisticians did not assume a study statistician role until appropriately qualified. However, there is little desire for formal registration schemes within the countries at present. Additionally, although the provision of formal statistical training appears to be nearly adequate, the provision of training courses that may be used as part of the CPD of statisticians is not readily accessible in all countries. Advances in e-learning may help in this regard. The American Statistical Association now

provides webinars and PSI provides e-learning training courses. EFSPI has recently introduced a new website. One of its primary aims is to better advertise training, conferences, and one-day meetings provided by its membership organizations, across Europe, in order to invite a wider audience.

BACKGROUND ON EFSPI

The objectives of EFSPI are:

- To promote professional standards of statistics and the standing of the statistical profession in matters pertinent to the European pharmaceutical industry.
- To offer a collective expert input on statistical matters to national and international authorities and organizations.
- To exchange information on and harmonize attitudes toward the practice of statistics in the European pharmaceutical industry and within the member groups.

EFPSI contributes to the development of statisticians in the European pharmaceutical industry by organizing and supporting professional meetings with academia, industry, and regulatory statisticians. The purpose of these meetings is to exchange state-of-the-art methodology and views, focusing on practical aspects of statistics to address current problems. EFSPI also collates comments from the different countries on new regulatory guidance and provides feedback to the regulatory authorities. EFSPI actively supports its membership organizations in organizing local training courses, facilitating the sharing of best practices across Europe. Through facilitating training in Europe and providing input to emerging regulatory guidance, it supports further education of statisticians and the maintenance of standards.

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