The Professional Background of Statisticians in the European Pharmaceutical Industry

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STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY

The developing role of statisticians in the pharmaceutical industry has resulted in over 2000 statisticians being employed in Europe within companies and Contract Research Organisations, chiefly working on clinical trials. Lewis (1996) and Koepcke et al (1998) point out that national drug regulatory authorities in Europe are employing an increasing number of statisticians in order to facilitate statistical review of marketing authorisation applications.

The International Conference on Harmonisation (1998) emphasises the importance of statistical input to the design and analysis of clinical trials and states that “...the statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance” (Section 1.2). Such an individual could be expected to take responsibility for the design and analysis of a clinical trial and would be recognised as an appropriate signatory of a trial protocol and report.

This statement raises the question of what qualifications and experience make an individual appropriate for such work. The pharmaceutical industry operates on a global basis, with the objective that standards of research work should be harmonised in different parts of the world. One key aim of this harmonisation is that conclusions drawn from clinical trials in one region should be recognised as providing sufficient evidence for regulatory approval of the product worldwide. Hence there needs to be some means of assessing statistical competence on a common basis. However, this is problematic when different countries have such widely differing educational systems and history of applying statistics in the pharmaceutical industry.

In countries such as the USA, Canada and UK, degree programmes in statistics have existed for some time, leading to a clear concept of a statistician’s skills and role. In Germany and the UK some attempt has been made to define the experience necessary to provide professional accreditation for statisticians. However there is no common European-wide understanding of what it means to be “an appropriately qualified and experienced statistician”. There are still striking differences in the number and nature of statisticians working in the industry in different European countries. One source of diversity is the wide variety of university educational systems in Europe.

CURRENT SITUATION

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPi) reviewed the current situation and future developments in the qualifications and
experience of individuals regarded as ‘qualified statisticians’ for the pharmaceutical industry in the major European countries. Their findings are outlined in a recent publication by the EFSPI Working Group (1999).

In the UK, Denmark and Sweden most pharmaceutical statisticians have passed through the well-established MSc or other degree courses in statistics. In Belgium, Germany, the Netherlands and Switzerland, the majority of statisticians have a primary qualification in mathematics, with some subsequent specialisation in statistics. In France, Italy and Spain, many people working in pharmaceutical statistics have a primary qualification in medicine or biology rather than formal qualifications in statistics. In general there is little opportunity for specialisation in medical statistics in the European university systems, though such focussed courses have been appearing in several countries during the 1990s.

In addition there are schemes for the accreditation or certification of statisticians, in several countries in Europe. Around one third of pharmaceutical statisticians in the UK are Chartered Statisticians, which requires a degree in Statistics or equivalent, plus five years practical experience. In Germany some 50 statisticians in the pharmaceutical industry have qualified as “Certified Medical Biometrician”, which generally involves a degree in statistics or mathematics, plus three years practical experience with biometrics in medicine and at least five years of further scientific and medical education after the degree. The qualification is also open to those qualified in medicine, who would then need further mathematical and statistics training: this route of entry weakens this certification in some eyes. In Spain an accreditation scheme for medical statisticians in the pharmaceutical industry was initiated in 1996 for statisticians meeting the criteria outlined in the next section.

OUTLINE DEFINITION OF AN APPROPRIATELY QUALIFIED AND EXPERIENCED STATISTICIAN

The skills and knowledge required by a statistician in the pharmaceutical industry include those defined by Lewis (1994). He suggests that effective statistical professionals need a strong technical foundation, knowledge of the pharmaceutical context, plus skills in communication and project management. These attributes would clearly be gained through a mixture of education, other technical training and relevant experience.

Following extensive consultation within the industry EFSPI have proposed the definition that a "qualified medical statistician" is expected to have a university degree in statistics or equivalent, plus more than 3 years experience in medical statistics.

An example of an equivalent qualification would be a degree in mathematics or related subject, involving more than one year’s (full time equivalent) courses in statistics, i.e. where statistical content formed at least one third of a three year course or one quarter of a four year programme. The definition requires experience in Medical Statistics, involving clinical trials and associated regulatory requirements, but not necessarily experience in the pharmaceutical industry itself.

While inevitably being somewhat vague and lacking detail on what might be included in university courses, this definition does make certain things clear. First, it is not necessary for an individual’s degree to be in statistics, provided that it has a suitable
statistical content. Second, a degree in medicine, with only a small number of courses in statistics, would not entitle someone to be regarded as a qualified medical statistician.

In addition the generality of this definition gives the advantage that it is not restricted in application to Europe, or to the clinical arena. Its principles could easily be adapted to use in North America or Asia, or to non-clinical statisticians.

**ISSUES NOT ADDRESSED BY THIS DEFINITION**

In striving for simplicity, the definition above does not address the content of statistics courses, which may differ considerably in their coverage. However it is felt that if the mathematical background and basic principles are well covered at an appropriate level, additional material in a specialised area should be readily acquired by personal study.

In developing this guideline it was recognised that in the short term many good pharmaceutical industry statisticians would not meet the definition adopted, due to lack of formal statistical qualifications. In addition, it should not be taken to imply that statisticians rely purely on material covered in their degree programme. It is important to keep up to date with developments in their area of statistics by attendance at training courses, conferences and other forms of continuing professional development. In addition pharmaceutical statisticians need to broaden their capabilities, for example in terms of communication, management and consultancy skills, in addition to gaining knowledge in the areas of other sciences relevant to their work.

The definition is given to provide guidance for those who may find it useful. It is not intended to be the basis of a formal accreditation scheme. However it has been designed to be broadly consistent with requirements already in place. For example, the Chartered Statistician certification awarded by the Royal Statistical Society in the UK requires an appropriate degree in statistics “or in a subject containing a substantial coverage of statistical method and theory”, plus five years practical experience in applying statistics, “of which three years should involve the candidate taking responsibility for the statistical content of their work”. The requirements are also largely consistent with those for the German “Certified Biometrician” award, though they would not embrace the minority whose qualifications are in medicine.

The definition also does not address the difficult issue of when an appropriately qualified and experienced statistician should no longer be regarded as such, i.e. when should someone be ‘de-certified’.

It must be recognised also that the quality of statistical work cannot be guaranteed purely by someone satisfying the criteria given here – the work itself must be open to scrutiny. However these criteria may provide a useful screening step for those making this type of assessment.

**THE WAY FORWARD**

It is hoped that the outline definition presented here will give guidance to pharmaceutical companies in a variety of situations, for example when selecting
candidates for statistical roles with unfamiliar qualifications, or when assessing the competence of Contract Research Organisations. In addition it may be helpful to regulatory authorities and to universities in terms of defining an appropriate background to provide statistical expertise to support clinical trial and other pharmaceutical development activities and may provide a foundation for the future of the statistical profession in the global pharmaceutical industry.

REFERENCES


