Accreditation Pharmaceutical Statisticians

Proposal to introduce an accreditation on European level

- Background
- Why
- EFSPIs draft Proposal
- Questions
- Discussion
Accreditation is a process in which certification of competency, authority, or credibility is presented.

Professional certifications are earned from a professional society. In general, must be renewed periodically, or may be valid for a specific period of time. As a part of a complete renewal of an individual's certification, it is common for the individual to show evidence of continued learning. Most certification programs are created, sponsored, or affiliated with professional associations … interested in raising standards. The growth of certification programs is also a reaction to the changing employment market.
Accreditation - Why

- Voluntary accreditation exists within several professions (especially skill based trades)
- Accreditation of statisticians has been much discussed over last 15 years
- Variety of national European statistical associations have accreditation for statisticians
- ASA has currently implemented an accreditation for Professional Statisticians
- No European wide accreditation system exist and no system focuses exclusively on pharmaceutical statisticians
Accreditation - Why

- Pharmaceutical statistics becomes more technical and innovative, therefore it becomes more important to ensure that statisticians are appropriately qualified

- Statisticians are moving across countries more often

- Desire to demonstrate skill sets and professional development in consistent and measured way to

  Employers, Peers, Regulatory authorities, …
EFSPI is developing a proposal to introduce an accreditation system on European level:

- Target group
- Level of accreditation
- Criteria for registration
- Fee
- Renewal process
- European Registration board
Proposal – Target Group

Target group: Pharmaceutical Statistician

Who to cover?

- It should cover the ‘qualified statistician’ mentioned in GCP and requested in regulatory settings

Other options:

- Statisticians in general – See e.g. RSS, ASA and discussion in Sweden
- Biostatistician / Biometrician – See Dutch system and German certification “Biometrics in Medicine”

Question:
Do you agree with the proposed target group of Pharmaceutical Statisticians?
Proposal – Level of Accreditation

One level: Professional level (PSTAT)

• Relevant education and minimum number of years with professional experience

Consideration:
• Some systems with a wider scope recognize a second level to cover those who satisfy only the academic requirements
  – See Graduate Statistician (GradStat, RSS and GS, ASA)
Proposal – Criteria

• Combination of adequate education and relevant practical experience (on discretion of registration board):
  1. MSc (or PhD) in statistics or equivalent (to be defined) and \( \geq 5\) yrs relevant experience with 2 yrs of personal responsibility
  Or*
  2. Relevant BSc or MSc and \( \geq 10\) yrs of experience with 2 yrs of personal responsibility

Both: Training in GCP and ICH guidance, in particular ICH E9

• Two registered statisticians to confirm relevant practical experience and professional competence

* to cope with current situation: review after 5 years whether still needed

Question:
Do you agree with the proposed level and proposed registration criteria?
Proposal – Fee

Fee around 100 Euro

• Registration fee should be low and valid until renewal
• Should at least cover administrational costs
• No objective to make excessive profit, could degrade credibility

Considerations:
• Annual fee would imply administrative burden
• No related membership is required
• Final fee depends on assessment of administration costs

Question:
Do you agree with the proposed structure behind the registration fee?
Proposal – Renewal Process

- Accreditation is for 5 years
- Verify work location and position of applicant
- Keep administration as low as possible
- Same fee for renewal (to cover administrative costs)

Considerations:
- Individual should show evidence of continued learning?
- Keep it simple:
  - no verification of basic education is needed
  - Ongoing experience will cover the required continued learning
- Fee should not discourage people to renew

Question:
Do you agree with the proposed renewal process?
Proposal – European Registration Board

Role of European registration board:

• Define rules of acceptability
• Establish and maintain overview of acceptable educations across Europe
• Verify registration criteria and make decisions
• In charge of verification at renewal status
• To maintain list of registered people
Proposal – European Registration Board

Who should be on the board:

• Members should be selected across Europe to represent main countries and education systems.

• EFSPi should be represented, preferably by a (dedicated) council member responsible for it.

Question:

Do you agree with the proposed registration board?
Proposal – How should it work?

- Install European registration board
- Align with existing systems and define rules how to accept current national levels within Europe
- Promote, explain and discuss this initiative
- Finally, discuss possibilities to be recognized by health authorities
Questions

Are you in favor of EFSPI’s proposal to introduce a European accreditation system?

Do you agree with the proposed:
- target group of Pharmaceutical Statisticians?
- level and registration criteria?
- structure behind the registration fee?
- renewal process?
- registration board?