

Proposal to introduce an accreditation on European level

- Background
- Why
- EFSPi 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.



- 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



- 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



Target group: Pharmaceutical Statistician

Who to cover?

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

Other o

- Stati
- S
- Bios

Question:

Do you agree with the proposed target group of Pharmaceutical Statisticians?

- See Dutch system and German certification “Biometrics in Medicine”

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)



- **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 ≥ 5 yrs relevant experience with 2 yrs of personal responsibility

Or*

2.

Bo

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

yrs of

E9

- **Two registered statisticians to confirm relevant practical experience and professional competence**

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



Fee around 100 Euro

- Registration fee should be low and valid until renewal
- Should at least cover administrative costs
- No objective to make excessive profit

Question:
Do you agree with the proposed structure behind the registration fee?

Consider

- Annual
- No related membership is required
- Final fee depends on assessment of administration costs



- **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)**

Question:

Do you agree with the proposed renewal process?

Consider

- Individual
- Keep
 - no verification of basic education is needed
 - Ongoing experience will cover the required continued learning
- Fee should not discourage people to renew

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**



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?**