REGISTERED QUALITY ASSURANCE PROFESSIONAL

History, Accomplishments, Future

2002 SQA Annual Meeting
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SQA President

October 2002
Background to Certification

- Changes in US Agency Emphasis
  - Reports from the Office of the Inspector General
  - Diminishing Resources
  - Requests for Input from Regulated Community
  - New Administration
- Increased International Interest in Certification and Accreditation Programs
- Increased Need for Professional Standards
SQA Initiatives

- Create Two Committees
  - Laboratory Accreditation Committee
  - Professional Certification Committee
- Investigate the Issues Surrounding Lab Accreditation
- Investigate Utility & Feasibility of Professional Certification
Review of PCC Activities
First meeting - April 1993

- Identified Pros and Cons
- Reviewed Existing Certification Programs
- Determined “Utility” and “Feasibility”
- Held Discussions with Testing Organizations
- Surveyed SQA Membership
Survey Design Assumptions

- Use of Professional Testing Organization
- Testing for Minimum Competence-US GLP
- Multiple Choice Test
- Test Cost: $300 or Less
- Administration at Annual SQA Meeting
Survey Results

- Do you support, in principle, the concept of a QA certification program?
  - 78% YES  16% NO  6% No Answer

- Do you think this program will enhance the value and acceptance of QA?
  - 62% YES  29% NO  9% No Answer

- Do you think this program will enhance the image of the QA profession?
  - 66% YES  26% NO  8% No Answer

- Is the projected cost acceptable?
  - 49% YES  42% NO  9% No Answer
Survey Results

- Would you take the test within the first or second year of its introduction?
  - 65% YES  23% NO  12% No Answer

- Would you encourage your colleagues, staff, or clients to take the test within the first or second year?
  - 62% YES  25% NO  13% No Answer

- If you are a sponsor, would you more readily contract with a lab or consultant if their staff included certified QA personnel?
  - 44% YES  22% NO  34% No Answer

- If you are a sponsor, would you require your lab or consultant to employ certified QA personnel?
  - 22% YES  44% NO  37% No Answer
Survey Results

- Do you think there should be a minimum QA experience level to take the test?
  - 57% YES  34% NO  9% No Answer

- Should there be a provision for ‘grandfathering’ those with extensive QA experience?
  - 48% YES  49% NO  3% No Answer

- Do you think there should be a minimum formal educational level to take the test?
  - 34% YES  54% NO  3% No Answer

- Should formal education levels reduce any QA experience requirements?
  - 14% YES  80% NO  6% No Answer

- Should the test be limited to SQA members?
  - 23% YES  70% NO  7% No Answer

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Survey Results

- Do you agree with the anticipated focus?
  - 67% YES  21% NO  12% No Answer

- Do you think the proposed certification program should evolve... by certifying a higher level and/or a broader area of expertise?
  - 44% YES  42% NO  12% No Answer

- Would periodic recertification be appropriate for assuring current expertise?
  - 57% YES  38% NO  5% No Answer

- Should some type of evidence of continuing professional involvement in QA... be a requirement for recertification?
  - 53% YES  42% NO  5% No Answer

- Written comments requested more levels/specialties (13); wider (16) and narrower (32) focus; greater training aids (14)
Development Issues

- Identification of Independent Testing Organization
- Development of Independent SQA Certification ‘Board’
  - Job Analysis
  - Test Specifications
  - Test Design (Objective, Oral, Practical, Essay)
  - Test Questions
  - Standards
  - Administration, Scoring, Reporting
Job Analysis

- Define Scope of Profession
- Job Tasking Methods
  - use of content experts
  - identification of knowledge elements, skills, abilities
  - survey of frequency, importance of testing
Test Specifications

- Consider Cost & Objectivity
- Ensure Job Analysis is met and Allows ‘Equating’
- Ensures ‘Weighting’ is Appropriately Distributed
- QA profession, not merely GLPs
Question Development

- Identify Question Writers
- Train Question Writers
- Identify Test Size and Frequency of Administration
- Develop Multiple Versions
- Determine Frequency of Use
- Perform Question Analysis
Standard Setting

- Minimum Passing Score
- Judgmental Procedures
- Quotas, Arbitrary Standards
- Legally Defensible Process
Test Design

- **Multiple Choice**
  - objective; easily given to large groups, quick turn-around; easily revised; defensible

- **Oral; Practical; Essay**
  - generally not for large groups
  - subjective
  - difficult to design and score
  - costly
Administration

- Scoring
  - scanning, scoring and analysis easily achieved

- Reporting
  - pass/fail vs. numerical score
  - challenges

- Security
  - question writers, question pool integrity
  - ancillary issues; test books, transportation & storage, administration
Criteria to take exam

- 4 Years Full-Time Equivalent Experience Working in Quality Assurance Prior to Exam Date
  
or

- Baccalaureate Degree and 2 Years of Full-Time Equivalent Experience Working in Quality Assurance Prior to Exam Date
  
- with copy of diploma or transcripts
Test Administration

- **First exam 1997**
- **Annually administered**
  - SQA Annual meeting
  - Three additional locations
- **One exam in Japan**
- **Possibility of Europe**
- **Possibility in individual companies if enough people register**

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Professional Registry Examination

- 150 multiple choice questions
  - previously reviewed for relevancy, consistency, accuracy and appropriateness
- Test minimum competency in QA profession
- 3 types of questions
- 3 hours to complete
Test questions

- **Recall**
  - Knowledge of GLPs – only relies on knowledge to answer the questions

- **Application**
  - must look at situation, see where GLPs apply

- **Analysis**
  - Thorough evaluation of situation and implementation of GLPs to the specific case
Test Administration

- Passing rate approx 80%
- Each exam includes equalizers to assure consistency from year to year
- Survey conducted indicated the RQAP exam had a larger percentage of eligible personnel registered than other similar exams
Re-registration

- Every 3 years
- Twelve credits required
- Cost of $75.00
Council on Professional Registration

- Independent from SQA BOD
- Elected from RQAP-GLPs
- Three member council
- Has obtained Board approval for expansion of exam into OECD GLPs
- First exam with OECD GLPs in 2003
- 2001 and 2002 exam process showed a profit for SQA, can be applied to expansion
Benefits

- Valuable Personal Accomplishment
- Basic Competency and Knowledge in US FDA and EPA GLP Regulations
- Cost-effective Certification/Registration
- Accessible Means of Peer-Recognition
- Demonstration of Commitment within Research Quality Assurance Profession
Benefits

- Enhances Credibility with
  - Employers - Sponsors - Peers
  - Regulators - Study personnel

- Enhances Marketability
  - you
  - your company