



# REGISTERED QUALITY ASSURANCE PROFESSIONAL

History, Accomplishments, Future

2002 SQA Annual Meeting  
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SQA President

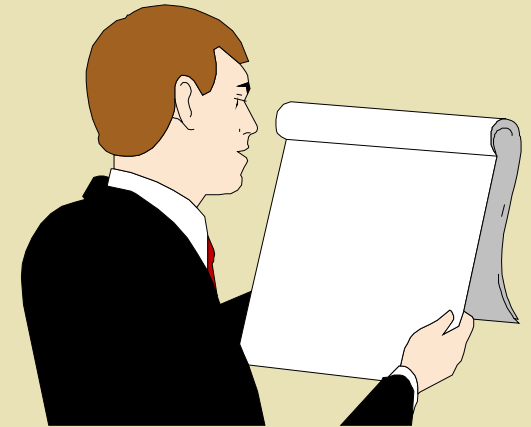
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# Background to Certification

- ◆ **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**



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# SQA Initiatives

- ◆ **Create Two Committees**
  - Laboratory Accreditation Committee
  - Professional Certification Committee
- ◆ **Investigate the Issues Surrounding Lab Accreditation**
- ◆ **Investigate Utility & Feasibility of Professional Certification**



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# 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



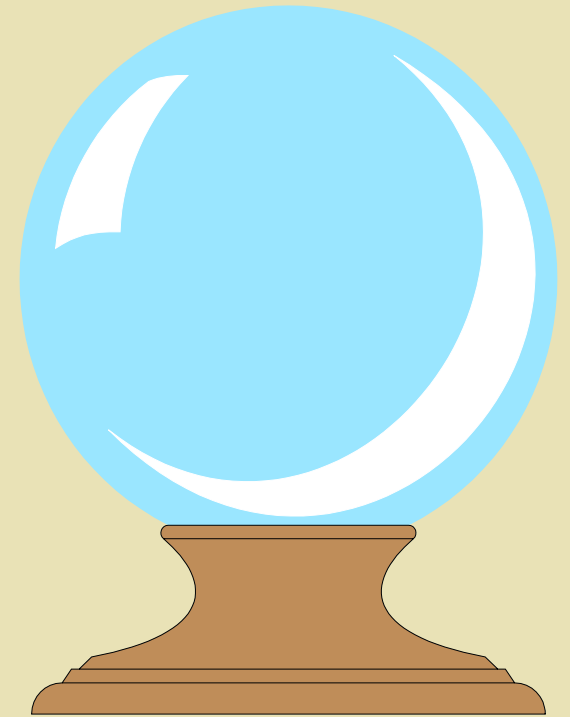
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# Survey Design Assumptions

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



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# 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

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# 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

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# 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)

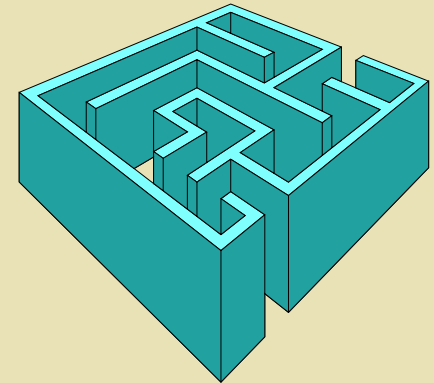
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# Development Issues

- ◆ 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



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# 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



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# Test Specifications

- ◆ Consider Cost & Objectivity
- ◆ Ensure Job Analysis is met and Allows 'Equating'
- ◆ Ensures 'Weighting' is Appropriately Distributed
- ◆ QA profession, not merely GLPs



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# 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



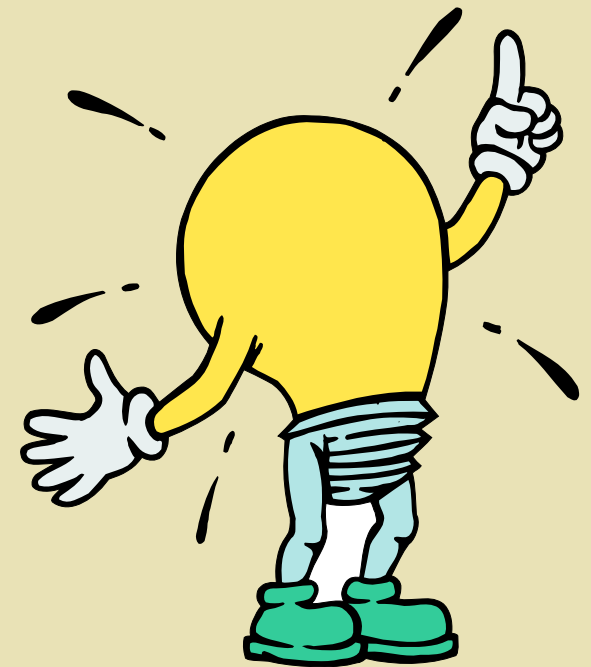
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# Standard Setting

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



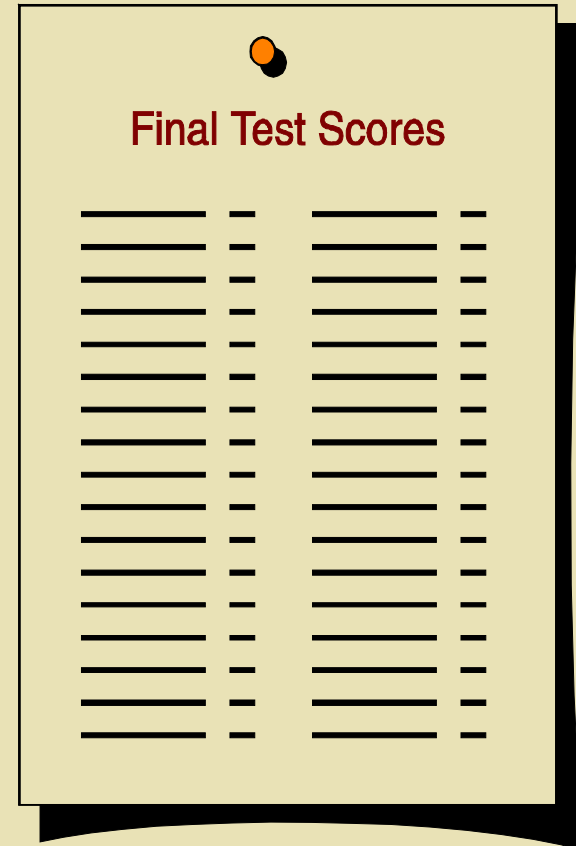
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# Test Design

- ◆ **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

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# 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

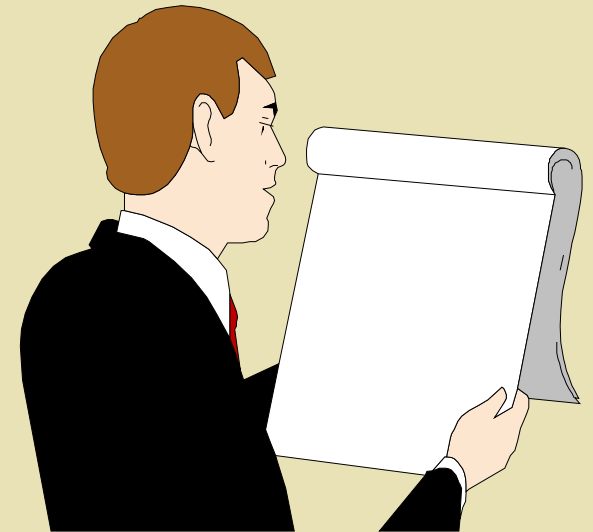
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# Test Administration

- ◆ **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

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# 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

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# 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

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# Re-registration

- ◆ Every 3 years
- ◆ Twelve credits required
- ◆ Cost of \$75.00

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# 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

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# 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

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# Benefits

- ◆ Enhances Credibility with
  - **Employers - Sponsors - Peers**
  - **Regulators- Study personnel**
- ◆ Enhances Marketability
  - you
  - your company

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