

Changes in the QP World

The 9th Joint Symposium on the Qualified Person

‘Study Guide 2006 and Changes to the Process’

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Chair of RPSGB Panel of Assessors

7th November 2006

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QP Assessment process

- Legal basis
- What the process is designed to achieve
- The assessment process
- Study Guide
 - 2006 revision
 - Why
 - Changes
- Statistics

Basis for current process

MHRA have delegated responsibility to assess candidates as **'eligible QPs'** to the three professional bodies :-

RPSGB, RSC and IOB



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Manufacturer's Authorisations

Responsibility to confirm an individual as a **Qualified Person on a Manufacturer's Authorisation** rests with the **MHRA**.

Purpose of QP Assessment process

- Confirm candidate's qualifications and experience are applicable.
- Assure candidate's knowledge of the Study Guide is adequate.
- Test candidate's ability to apply their knowledge and experience.
- Ensure candidate's suitability.

Assessment Process

- ... comprises 3 parts
 - Application form
 - Sponsors report
 - Oral examination

- Each part has a unique and vital contribution

Assessment Process Detail

Completed application form and sponsors report (& £)



Submitted to Professional Body (data review)



QP Assessor 'paper review'



Candidate invited for interview



Viva



Eligibility decision

Experience & Qualification Requirements

- 2 years under full Manufacturer's Authorisation
(1 year for Pharmacists)
- Degree...see directive
- Membership of RPSGB, RSC or IOB

EU Directive

Formal qualification ... in one of the following scientific disciplines; pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.

Directive 2001/83/EC Article 49

EU Directive

The course shall include theoretical and practical study bearing upon at least the following basic subjects:

- Applied physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Physiology
- Microbiology
- Pharmacology
- Pharmaceutical technology
- Toxicology
- Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).

UK Interpretation

No existing single first degree or other qualification awarded in the United Kingdom meets the conditions in full.

Viva

- 60-75 minute oral assessment.
- Panel of 3 assessors ... one from each of the 3 professional bodies.
- Chaired by member of candidates professional body.
- Notes taken.
- Decision at end ... eligible or not.

Role of each part

- Application Form – knowledge and experience described by candidate.
- Sponsor's Report – knowledge, experience and suitability confirmed, (by a practising QP).
- Oral Examination – knowledge and experience verified, and ability to apply it tested.

Why the 2006 Revision?

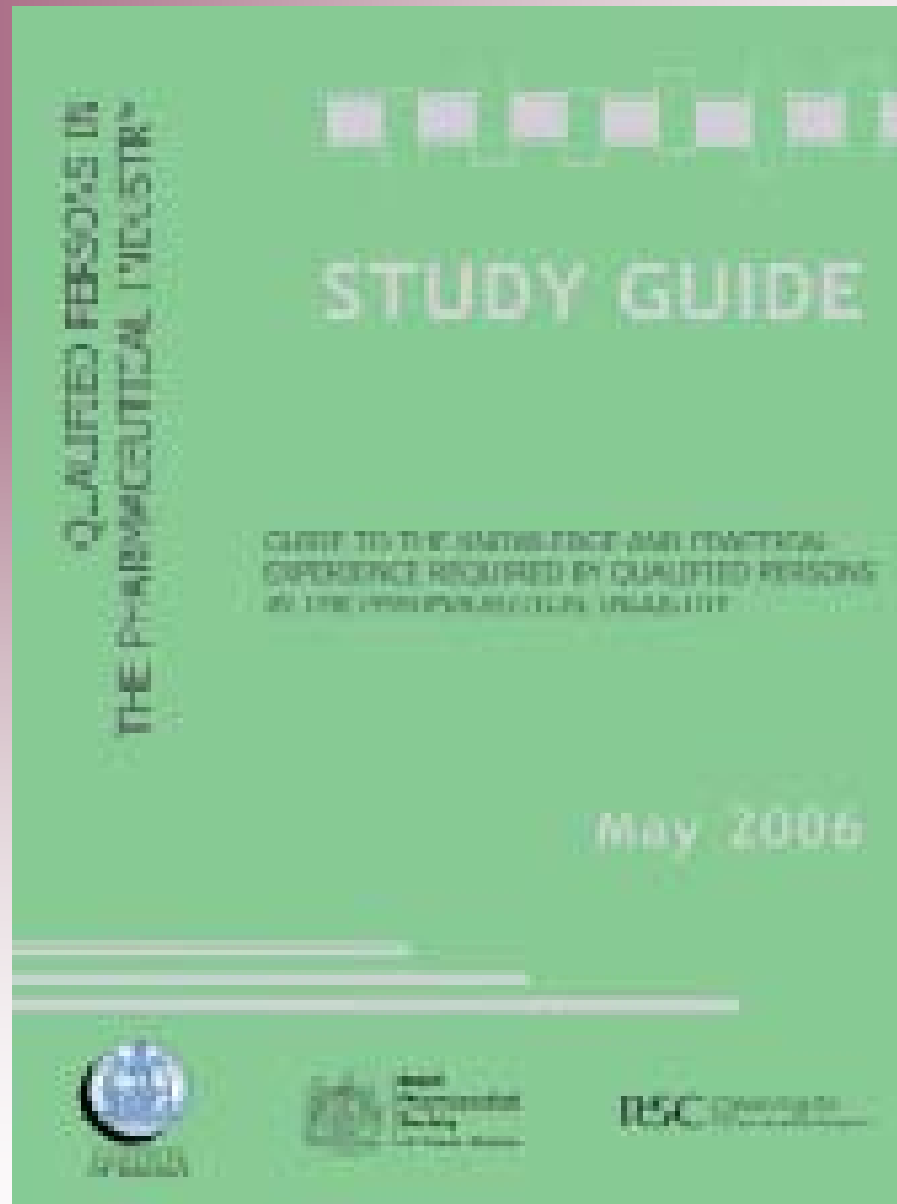
1. Make the process more readily applicable across the range of dosage forms.
2. Promote Consistency
3. Clarity
4. Recognise that new dosage forms and legislation will come forward ... negate the need to expand the Study Guide forever.

Study Guide 2006

... became effective 1st May 2006

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Study Guide 2006

1.0 The QP in the Pharmaceutical Industry

‘... the assessors must be satisfied that an applicant after a suitable induction period, will be able to function as a QP in any licensed undertaking.’

N.B. IMPs licensed

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Study Guide 2006

- Preface:

‘The three professional bodies require an applicant for certification as a QP to demonstrate foundation knowledge and to be able to apply his or her knowledge of QMS principles, they will also be expected to demonstrate understanding of the additional knowledge requirements.’

Study Guide 2006

- The Three Foundation Knowledge Elements
 1. Pharmaceutical Law and Administration
 2. The Role and Professional Duties of a QP
 3. Quality Management Systems

Study Guide 2006

- Additional knowledge requirements
- d. Mathematics and Statistics
- e. Medicinal Chemistry and Therapeutics
- f. Pharmaceutical Formulation and Processing
- g. Pharmaceutical Microbiology
- h. Analysis and Testing
- i. Pharmaceutical Packaging
- j. Active Pharmaceutical Ingredients
- k. Investigational Medicinal Products

Expectations

Candidates to demonstrate -:

- An understanding of Quality Management Systems (QMS) principles.
- Demonstrate an ability to use their knowledge and experience to address new and previously unseen issues and in different situations

Study Guide 2000

What was changed 6 years ago

- Defined foundation knowledge elements
- In-depth experience of one pharmaceutical dosage form.
- Ability to apply their knowledge and experience across **all** dosage forms.

Potential Confusion

- Applicants will be expected to demonstrate a **thorough** understanding of the following.
- Applicants will be expected to demonstrate **an** understanding of the following.
- In addition, applicants **will be expected** to have an awareness of the following.
- In addition, applicants **should have** an awareness of the following.

Changes Introduced in Study Guide 2006

1. All foundation elements to demand ... thorough understanding.
2. All knowledge elements to demand ... an understanding.
3. Awareness statement removed...an understanding

Experience Evolution for QP eligibility

- Pre 2000 Experience of all dosage forms.
- 2000-2006 Detailed knowledge of one dosage form plus ability to extrapolate.
- May 2006 Detailed knowledge of dosage form under which claiming MA experience.

Study Guide 2006

- Preface:

‘The applicant will be required to demonstrate by reference to the products and processes for which he or she is claiming his or her qualifying experience, which will apply wholly or in part to the Manufacturer’s Authorisation(s) detailed on the application.’

Summary of Changes in Study Guide 2006

1. Legislation updated.
2. Knowledge requirement.
 - Foundation ... minor changes
 - Others ... minor changes
3. Knowledge of QMS principles.
4. Dosage form related to MAs.
5. Wording changes re understanding etc

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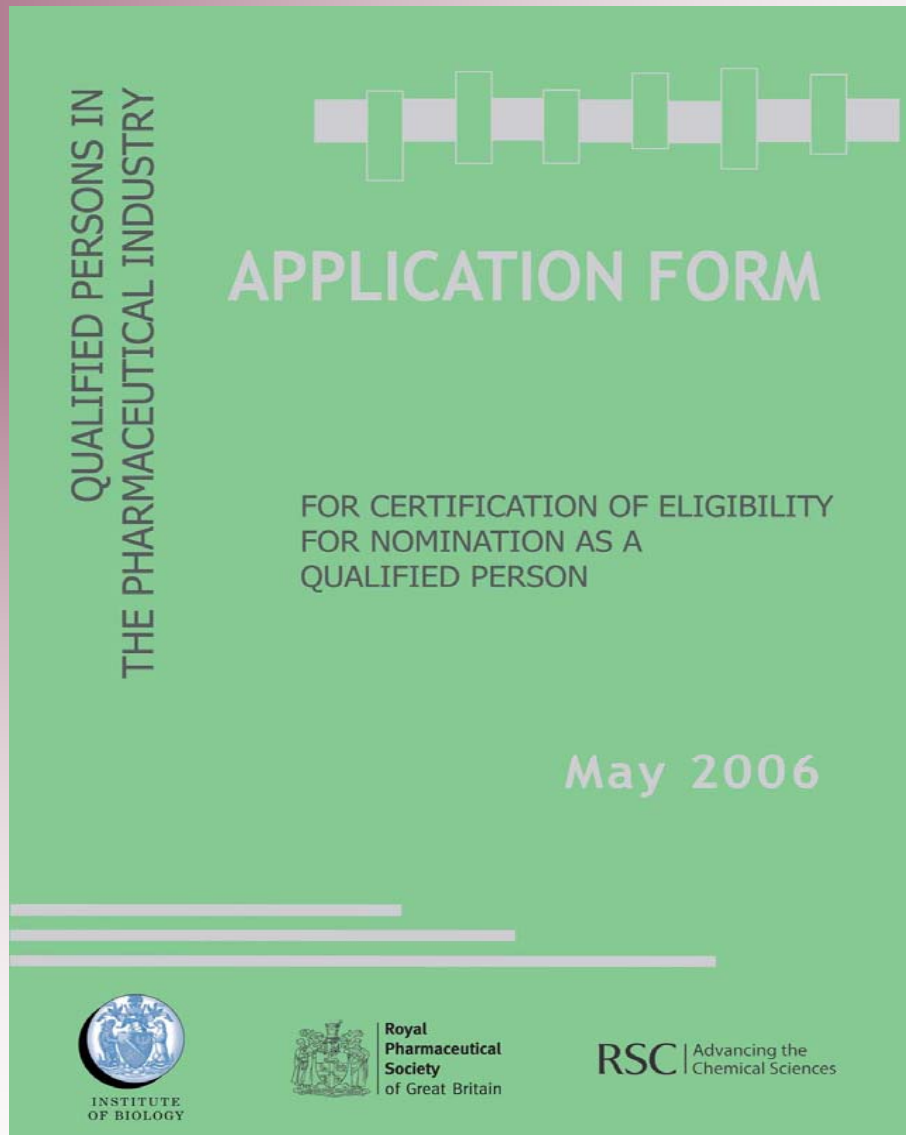
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Assessment Process Changes

Knowledge and experience will be assessed principally via the application form.

Sponsor's form is a key reference document.

Use of scenario questions during the oral examination will allow assessors to verify knowledge and experience plus test a candidate's ability to extrapolate their knowledge.



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Guidance Notes for Applicants & Sponsors

3.1 (c)

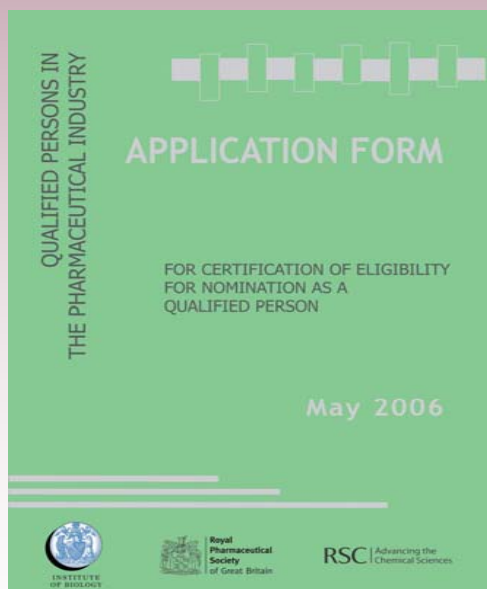
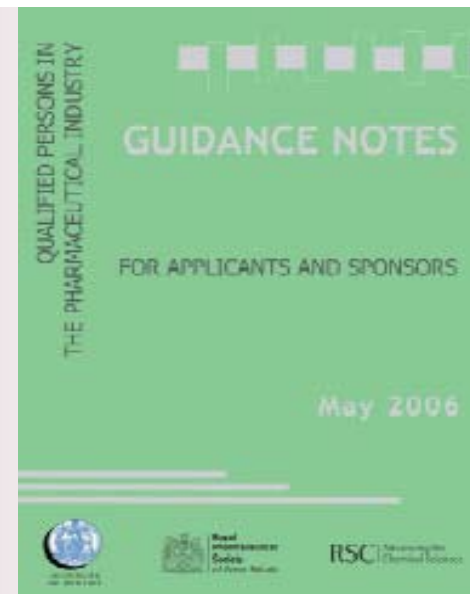
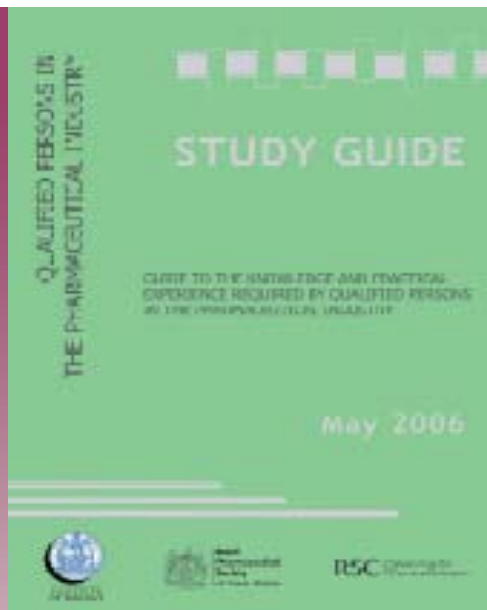
‘The submission of an inaccurate or misleading report will be regarded by the professional bodies as professional misconduct.’

JPB Eligible Qualified Persons 1996 - 2005

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Total 10 yrs
Interview	19	23	28	44	47	44	36	54	42	39	376
Passes	12	18	23	35	35	34	29	41	27	26	280
% Pass	63%	78%	82%	80%	75%	77%	81%	76%	64%	67%	75%

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