

# QP Assessments

2007/2008

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

## **RPSGB, RSC and IOB**

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

# 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.**’

# 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 Knowledge elements

## Foundation

1. Pharmaceutical Law and Administration
2. The Role and Professional Duties of a QP
3. Quality Management Systems

## Additional

- Mathematics and Statistics
- Medicinal Chemistry and Therapeutics
- Pharmaceutical Formulation and Processing
- Pharmaceutical Microbiology
- Analysis and Testing
- Pharmaceutical Packaging
- Active Pharmaceutical Ingredients
- Investigational Medicinal Products

# Experience Evolution for QP eligibility

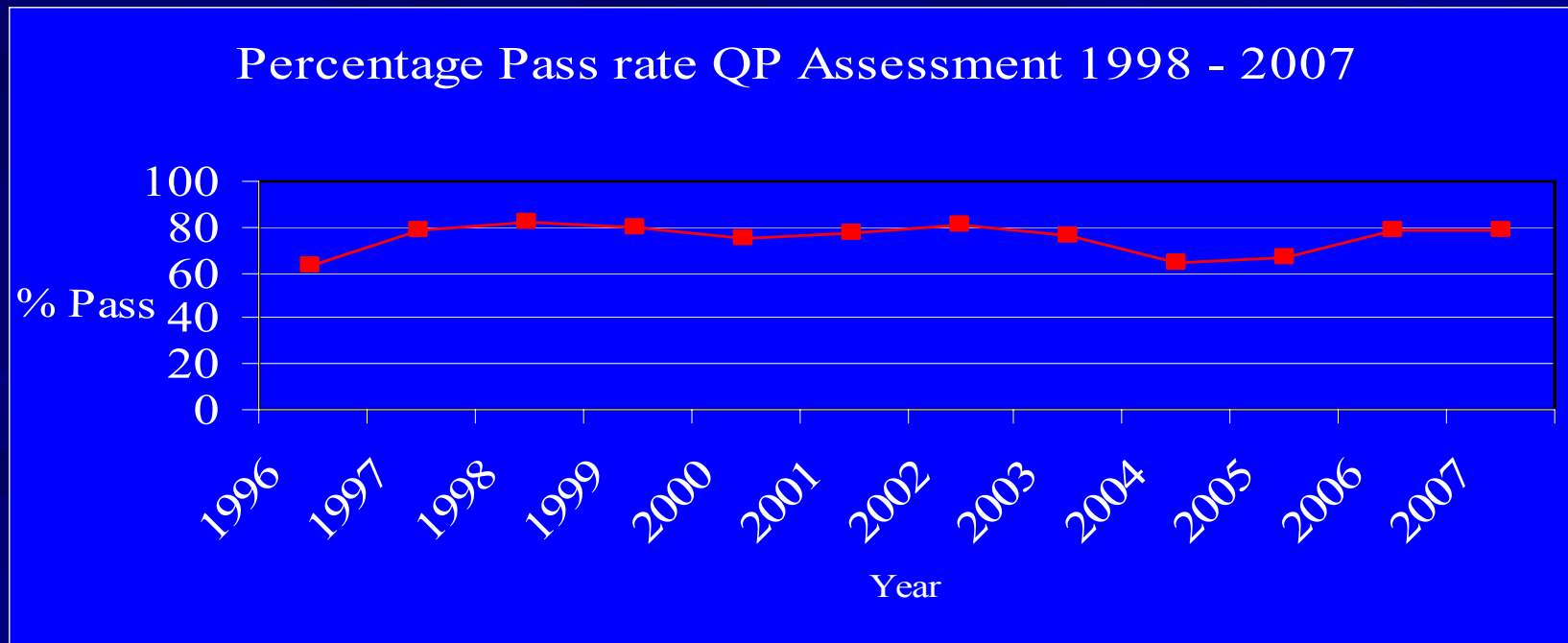
- **Pre 2000** Experience of all dosage forms.
- **2000-2006** Detailed knowledge of one dosage form plus ability to extrapolate.
- **May 2006** Detailed knowledge of dosage form under which claiming MA experience.

# Assessment Process Changes

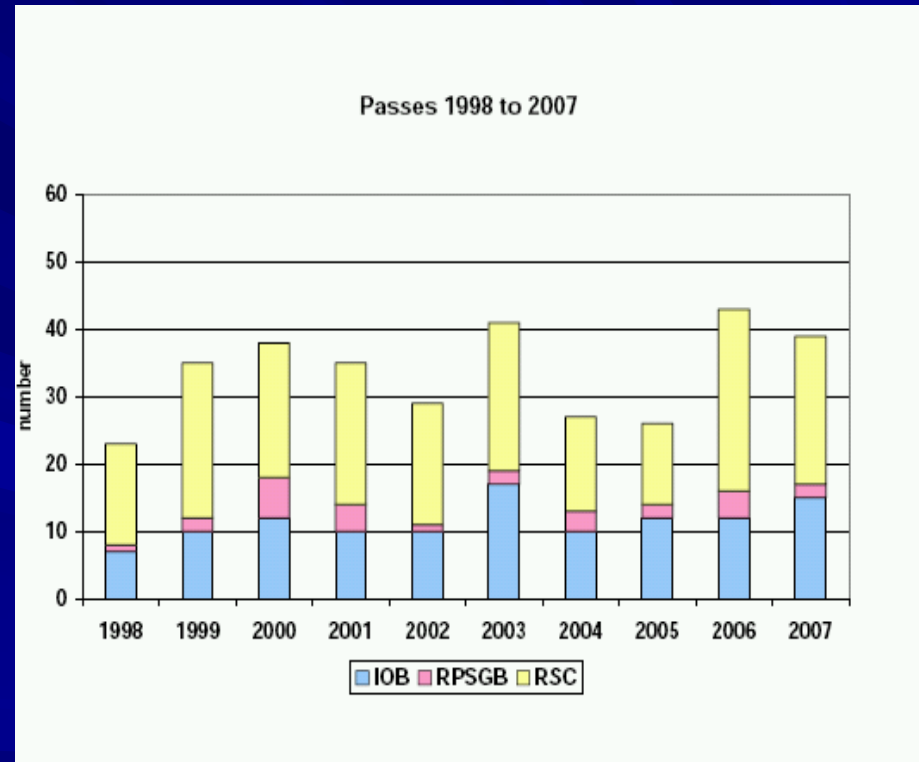
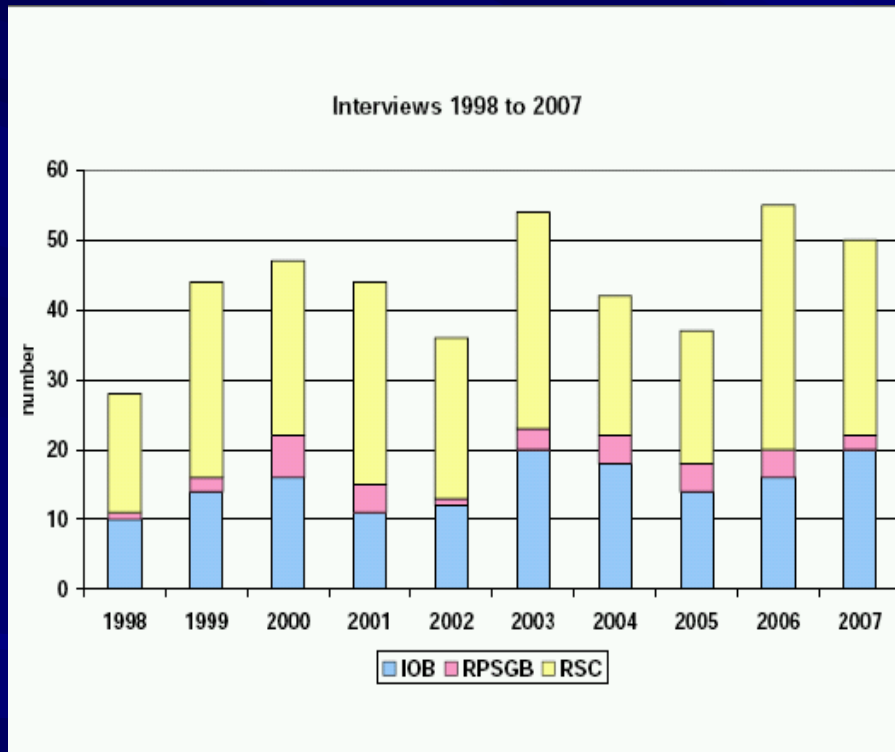
- Knowledge and experience will be assessed principally via the application form.
- Sponsor's form is a key reference document.
- Use of scenario questions during the oral examination will allow assessors to verify knowledge and experience plus test a candidate's ability to extrapolate their knowledge.

# % Pass 1998 to 2007

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
<b>Interviews</b>	28	44	47	44	36	54	42	39	55	50
<b>Passes</b>	23	35	35	34	29	41	27	26	43	39
<b>% Pass</b>	82	80	74	77	81	76	64	67	78	78



# Interviews and passes 1998 – 2007 by Professional Body



*Is there sufficient Supply to meet Demand?*

# Assessment 'Take Aways'

- No statistical difference in Annual pass rate
- Current assessment approach aims to more closely reflect the scenarios experienced by the QP
- Professional bodies constantly reviewing the study guide and assessment process to reflect changes in both the industry and regulatory expectations