QUALIFIED PERSONS IN THE PHARMACEUTICAL INDUSTRY

CODE OF PRACTICE

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INSTITUTE OF BIOLOGY

Royal Pharmaceutical Society of Great Britain

RSC | Advancing the Chemical Sciences

Code of Practice for Qualified Persons

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1.0 INTRODUCTION

1.1 The concept of the Qualified Person (QP), first established in 1975, is a unique regulatory requirement that applies only within the European Union (EU). The only comparable situation exists within Member States of the European Economic Area (EEA) with whom the EU has reciprocal agreements.

1.2 Each holder of an Authorisation to Manufacture products for use in a Clinical Trial or products subject to Marketing Authorisations, within Member States of the EU, must name a person or persons who are eligible to act in the capacity of QP.

1.3 The requirement for QP covers both Human and Veterinary Medicinal Products including those intended for export.

1.4 Particular conditions for formal qualifications and practical experience for eligibility to act as a QP are specified in the relevant EU Council Directives (see 2 below). Ensuring compliance with these conditions is the responsibility of the Competent Authorities of the Member States.

1.5 The primary legal responsibility of the QP is to certify batches of Medicinal Product prior to use in a Clinical Trial (Human Medicinal Products only) or prior to release for sale and placing on the market (Human and Veterinary Medicinal Products). However, the wider technical, ethical and professional obligations in terms of patient Safety, Quality and Efficacy must also be considered. Hence this professional Code of Practice, which is designed to take account of these issues.

2.0 REGULATORY BASIS FOR THE QUALIFIED PERSON

For ease of reference the key regulatory documents concerning the QP are as follows:-

(i) Directive 2003/94/EC - Principles and Guidelines of Good Manufacturing Practice for Medicinal Products for Human Use – **Article 7**.

(ii) Directive 91/412/EEC – Principles and Guidelines of Good Manufacturing Practice for Veterinary Medicinal Products – **Article 7**.

(iii) Directive 2001/20/EC – Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use – **Article 13**.

(iv) Directive 2001/82/EC – Community Code Relating to Veterinary Medicinal Products – **Title IV – Manufacture and Imports** – **Articles 44-57**.

(v) Directive 2001/83/EC – Community Code Relating to Medicinal Products for Human Use – **Title IV – Manufacture and Importation** – **Articles 40-53**.

(vi) Eudralex Volume 4 – Good Manufacturing Practices

Annex 13 – Manufacture of Investigational Medicinal Products

Annex 16 – Certification by a Qualified Person and Batch Release

3.0 PURPOSE OF THE CODE

3.1 The legal functions of the Qualified Person (QP) are stated in Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC. and reproduced in the preface to the UK Joint Professional Bodies' Study Guide 2000.

3.2 The aims and objectives of the Code of Practice are to provide operational guidelines for carrying out the functions of the Qualified Person within a professional code of conduct in accordance with Article 56 of Council Directive 2001/82/EC and/or Article 52 of Council Directive 2001/83/EC.

3.3 The Code is in the interests of Qualified Persons, their employers, patients and the Competent Authorities of the Member States.

4.0 APPLICATION OF THE CODE

4.1 The Code is equally applicable to Qualified Persons who have achieved that status under the transitional arrangements, and under the permanent provisions.

4.2 Qualified Persons have a professional duty to decline to act as Qualified Persons in the release of product types for which they do not possess the relevant experience and knowledge.

4.3 It should be noted that Qualified Persons are eligible to certify batches of medicinal product as follows:

i) those who have achieved Qualified Person status under the permanent provisions are eligible to certify batches of human or veterinary medicinal products in any member state within the European Union (EU);

ii) those who have achieved Qualified Person status under the transitional arrangements for human medicines are eligible to certify batches of human or veterinary medicinal products, and such certification is restricted to acting in the United Kingdom (UK) although such products, once certified, can legally be sold or supplied throughout the EU;

iii) those who have achieved Qualified Person status under the transitional arrangements for veterinary medicines are only eligible to certify batches of veterinary medicinal products, and such certification is restricted to acting in the UK although such products, once certified, can legally be sold or supplied throughout the EU.

4.4 The Code applies equally to Qualified Persons involved in human and/or veterinary medicines.

4.5 The Licensing Authority may refer to this Code in connection with disciplinary proceedings against a Qualified Person under Article 52 of Directive 2001/83/EC or Article 56 of Directive 2001/82/EC.

5.0 TERMINOLOGY

5.1 The terminology used in this Code of Practice corresponds with that used in the current versions of the EC directives on Good Pharmaceutical Manufacturing Practice (GMP) and the Guide to Good Pharmaceutical Manufacturing Practice.

5.2 Within the EU the terms Marketing Authorisation, Manufacturing Authorisation and Investigational Medicinal Products Authorisation are generally used and shall henceforth be referred to throughout this Code.

The UK licensing system currently uses the equivalent terms Product Licence (= Marketing Authorisation) and Manufacturer's Licence (= Manufacturing Authorisation) or Wholesale Dealer's (Import) Licence.

6.0 GENERAL PRINCIPLES

6.1 Pharmaceutical Manufacturers and the Competent Authorities of the Member States have a duty to ensure that patients are properly protected and that medicinal products meet appropriate requirements for safety, quality and efficacy.

6.2 The legal framework is provided by the European Directives and "The Rules Governing Medicinal Products in the European Union", which are implemented by individual Member States' national legislation.

6.3 An operational framework is provided in the current Volume 4 of the Rules Governing Medical Products in the European Union 'Good Manufacturing Practices'. In Chapter 1 of the Guidelines, Quality Management, it states that:-

> *"The holder of a Manufacturing Authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, the company's suppliers and the distributors.*
>
> *To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice and thus Quality Control. It should be fully documented and its effectiveness monitored. All parts of the Quality Assurance system should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. There are additional legal responsibilities for the holder of the Manufacturing Authorisation and for the Qualified Person(s).*
>
> *The basic concepts of Quality Assurance, Good Manufacturing Practice and Quality Control are inter-related. They are described here in order to emphasise their relationships and their fundamental importance to the production and control of medicinal products".*

6.4 Qualified Persons should be aware that whilst Quality Management applies to full-scale manufacture, it also extends to original product design, development, formulation and preparation of medicinal products for use in clinical trials. This includes the establishment of well-defined manufacturing processes, sampling programmes and analytical tests methods and

appropriate specifications for ingredients, printed and unprinted packaging components and finished dosage forms.

7.0 ROUTINE DUTIES OF A QUALIFIED PERSON

Qualified Persons have routine duties, some of which may be delegated (see later), in line with the above general principles. Before certifying a batch prior to release the Qualified Person doing so should always **ensure** that the following requirements have been met:

*The meaning of the word **ensure** in this context is that the Qualified Person must be confident that various actions, which may not be under his/her direct control, have in fact been taken. See also Section 8.*

7.1 The Marketing Authorisation and Manufacturing Authorisation or Investigational Medicinal Products Authorisation requirements for the Medicinal Products have been met for the batch concerned.

7.2 The principles and guidelines of GMP as stated in Directive 2003/94/EC (Human) or Directive 91/412/EEC (Veterinary) and as interpreted in the EU Guide to GMP have been followed.

7.3 The principal manufacturing and testing processes have been validated.

7.4 All the necessary quality control checks and tests have been performed, and account taken of the manufacturing and packaging conditions including a review of batch records.

The EU Guide to GMP suggests that the Head of Production and the Head of Quality Control assume line management responsibilities for these activities.

7.5 Any changes or deviations in manufacturing, packaging or quality control have been notified in accordance with a well-defined reporting system before any product batch is released. Such changes may need notification to and approval by the Competent Authorities of the Member States.

7.6 Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover changes or deviations.

7.7 All necessary manufacturing, packaging and associated documentation has been completed and endorsed by suitably authorised staff trained in the concept of Quality Assurance and Good Manufacturing Practices.

7.8 Regular audits, self-inspections and spot checks are being carried out by experienced staff.

7.9 All relevant factors have been considered including any not specifically associated with the output batch directly under review (e.g. calibration and maintenance records, environmental monitoring).

7.10 The legal requirements regarding imported products have been fully met.

For products imported from outside the EU or EEA the Qualified Person should ensure testing within the EU/EEA to the requirements of the Marketing Authorisation and any other tests to assure quality of the products, unless a mutual recognition agreement between the EU and the third country concerned allows the acceptance of manufacturer's batch certification in lieu.

The Qualified Person should also be satisfied that the medicinal products have been manufactured in accordance with GMP standards which are equivalent to those of the EU or EEA.

7.11 The Qualified Person should also recognise the need to consult other company experts in the various areas of the Study Guide to reinforce his/her knowledge on appropriate points when a doubtful situation arises *(e.g. stability, unusual analytical results, process or equipment changes, potential environmental or microbiological risks, re-labelling, abnormal yields, cross contamination risks etc.).*

7.12 To maintain a register (or equivalent document) as a record of product batches certified by the Qualified Person prior to batch release.

7.13 To retain reference samples of each product batch at the site of manufacture for a period of time in compliance with EU regulations and the Licensing Authority's requirements.

7.14 In considering how to perform the above duties, 7.1 to 7.13, the Qualified Person will have to take account of the nature and size of the operations being performed. For example, in a very small company with a limited range of products it may be possible that the Qualified Person can take direct responsibility for some or all of the tasks outlined above. In larger organisations, the Qualified Person will be dependent upon the knowledge and expertise of his/her colleagues in undertaking some or all of the tasks.

However, it is of paramount importance that the Qualified Person takes steps, within a well-planned Quality Management System, to assure himself or herself that the tasks allocated are in fact being performed satisfactorily. Hence the routine duties of the Qualified Person depend very much upon a team effort wherein the individuals concerned realise the position and responsibility of the Qualified Person and provide every support.

What cannot be over emphasised in this context is the Qualified Person's commitment to meet regularly with professional colleagues in all functional groups and to understand their contribution and impact upon quality.

The certification of a batch prior to release must be performed by a Qualified Person.

8.0 PERFORMANCE OF DUTIES AND REGULATORY COMPLIANCE

8.1 Management, as a requirement of Quality Assurance, should clearly define the areas of work and the method of operating in the absence of the regular Qualified Person.

In the absence of one Qualified Person, the task of certifying batches can only be delegated to another Qualified Person nominated on the Manufacturing Authorisation and who is knowledgeable and experienced with regard to the medicinal products under review.

8.2 Whilst each Qualified Person has a personal and professional responsibility for being certain that the various checks and tests have been carried out, the detail of this work is described in the EU Guide to GMP as normally the responsibility of the Head of Production and the Head of Quality Control who must ensure that appropriately trained and experienced staff are available.

Ultimately the Qualified Person must be satisfied either directly or, more usually, by the proper operation of quality systems, which include appropriate approvals, audits, self-inspections and spot checks that manufacturing, packaging and quality control testing have complied with relevant requirements.

Batch certification without such adequate steps may be regarded as professional misconduct.

8.3 It must be recognised that the Qualified Person depends upon many of his/her working colleagues for the achievement of quality and regulatory compliance in the manufacture of medicinal products. It is therefore of paramount importance that he or she achieves a good working relationship with other persons in positions of responsibility. These are likely to include those responsible for:

- *processing and packing operations*
- *quality control laboratories*
- *validation*
- *application and maintenance of Manufacturing and Marketing Authorisations*
- *provision of engineering services*
- *procurement of starting and packaging materials*
- *storage, transport and distribution*
- *contract services*

8.4 It is recommended that the company and the Qualified Person take the necessary steps to appraise other functional groups, and the responsible people who belong to them, of the role of the Qualified Person within the company and how they should give proper support.

8.5 Ensuring compliance with the conditions of the Marketing Authorisation is a primary duty of the Qualified Person. It is, therefore, essential that the Qualified Person has access at all times to the dossiers upon which Marketing Authorisations have been granted, including any variations affecting such approval. The control of change needs to be rigorously monitored by the Qualified Person especially where there are implications for compliance, quality and patient safety. Particular attention needs to be paid to this when the manufacturer is making products for a Marketing Authorisation holder in a different company.

8.6 The Qualified Person should be present at the manufacturing site for a sufficient proportion of the working time in order to discharge the legal and professional obligations outlined in this Code and to ensure the proper operation of a Quality Management System including the control of any delegated duties.

8.7 Manufacturing Authorisations contain the names of the persons responsible for Production, Quality Control, and the name(s) of the Qualified Person(s). The duties of these members of staff must be clear in their respective job descriptions and they must have the authority required under the relevant EC directives.

9.0 NUMBER AND LOCATION OF QUALIFIED PERSONS

9.1 The provisions in Article 52 of Council Directive 2001/82/EC and/or Article 48 of Council Directive 2001/83/EC. and the principles outlined in the EU Guide to GMP for Medicinal Products only require a company or organisation to nominate one person on a Manufacturing Authorisation to carry out the duties of the Qualified Person provided that person is at the disposal of the company at all times and can carry out the required functions.

9.2 Some organisations may have a complex structure, or operate at several locations, or both, which would make it necessary, where justified, to nominate several Qualified Persons on its Manufacturing Authorisation.

10.0 CONTRACTED QUALIFIED PERSONS

10.1 In a number of cases, especially with smaller companies, a 'Contracted Qualified Person' provides the service. In such cases the duties and responsibilities of a 'Contracted Qualified Person' are the same as those Qualified Persons who are permanently employed by their company; the QP is not an employee of the company but provides his services under contract.

The term 'Contracted Qualified Person' is not a formal title and is used only in the sense of a Qualified Person providing an independent service under contract to a company.

10.2 In addition to compliance with the provisions applicable to all QP's including all the routine duties outlined in this Code of Practice, Contracted Qualified Persons should observe the following:-

- have a clear written contract, which delineates the duties and responsibilities of the Qualified Person – as agreed between the company and the 'Contracted Qualified Person'. Both should sign and retain a copy of the contract;

- be readily available to the staff of the company for advice and discussion, and also be present during regulatory inspections and involved in communications with the inspectors;

- ensure that the company to whom the services are provided will allow free access to any people, information, documentation, premises, procedures etc. which are relevant to the decision-making processes when certifying batches for sale. In addition the company should inform the Qualified Person of any deviations which need to be considered in relation to batch certification. Such deviations should be provided to the Qualified Person promptly and in writing;

- ensure that sufficient spot checks, inspections, and audits of the company (whether in the EU or overseas) are carried out. In particular the 'Contracted Qualified Person' should satisfy himself/herself that an effective pharmaceutical Quality Management System is being operated.

10.3 Particularly for smaller companies, the person acting as contracted QP may agree with the company to provide some of the necessary services such as, for example, staff training, internal audits and maintenance of authorisations, personally in addition to performing strictly QP duties.

10.4 If any doubt exists concerning the duties and responsibilities between the Qualified Person and the company who requires his/her services, it is recommended that he or she should contact their local Regulatory Inspector or their professional body for advice.

10.5 **This Code of Practice should be brought to the attention of the Chief Executive Officer of the company who wishes to have the services of a 'Contracted Qualified Person'.**

11.0 CONTRACT MANUFACTURE AND/OR TESTING

11.1 Where products are manufactured and/or packed under contract there should be a clearly written technical agreement between the contract giver and the contract acceptor. Such an agreement should be reviewed and approved by the Qualified Person engaged by the contract giver and acceptor. The agreement should clearly delineate the areas and responsibilities of both Qualified Persons.

11.2 The contract acceptor, who normally will be required to hold a manufacturing authorisation, may accept full responsibility for batch certification provided that the Qualified Person has all the appropriate information (including access to relevant details in the Marketing Authorisation(s)) and authority to fulfil these duties. Nevertheless the decision concerning responsibility for batch certification remains a matter between contract giver and acceptor depending on the circumstances.

11.3 The provisions in 11.1 apply equally to the testing of samples under contract. The contract testing laboratory may not hold its own manufacturing authorisation but in this case must be authorised on the contract giver's authorisation.

12.0 CONTINUING PROFESSIONAL DEVELOPMENT

12.1 Qualified Persons have a personal and professional duty to keep their knowledge and experience up to date (Annex 16, 8.3, EU Guide to GMP, Volume 4 of the "The Rules Governing Medicinal Products in the European Union"). It is expected that this would cover the current state of pharmaceutical quality management, regulatory aspects and GMP guideline standards, product manufacturing and control technology, and general work practices.

12.2 Records of Continuing Professional Development (CPD) should be kept to reflect this important longer-term aspect of the Qualified Person's continued performance of professional duties.

12.3 Attention is drawn to the individual Member State's statements on CPD, which underline the importance of this aspect of a Qualified Person's performance of duties. These statements appear as Appendix 1 to this Code, and they will also be of value to those Qualified Persons who are not members of any of the three professional bodies.

12.4 In the event of a Qualified Person making a major change in job responsibilities, for example from a company making only sterile dosage forms to one with a wider range of products including solid dose forms, the Qualified Person and the senior management of the company involved should recognise the need for additional education and training and take adequate steps to demonstrate that proper provision is made for this. Such extra training should be undertaken before the Qualified Person acts in a new situation.

13.0 PROFESSIONAL CONDUCT

13.1 Qualified Persons are subject to the overall jurisdiction of the Bye-laws, Charters and Regulations, Codes of Conduct, Disciplinary Regulations and any general guidelines of their own professional body, and should have access to them.

13.2 Qualified Persons have duties not only to their employer but also to the Competent Authorities of the Member States and its inspection service. They must ensure that

appropriate senior company executives are made fully aware of any manufacturing and/or testing difficulties which may cast doubt on the certification of batches or post facto might require a product recall.

13.3 If there is any aspect of the Quality Assurance system which is not in accordance with the Directives and Guidelines for Good Manufacturing Practice then the Qualified Person has a duty to bring this to the attention of Senior Management and ensure that appropriate corrective measures are taken.

13.4 Qualified Persons should establish a good working relationship with Regulatory Inspectors and as far as possible provide information on request during site inspections.

NB. There may be situations outside of site inspections where the Qualified Person may wish to consult with the local Regulatory Inspector for advice or clarification in particular circumstances with which the Qualified Person is faced.

13.5 The following assumption is made by the professional bodies acting jointly when certifying the eligibility of a Qualified Person:

- in co-operation with their employers, Qualified Persons will undertake Continuing Professional Development to maintain and extend their technical and professional competence. (See also Section 12.0 above)

13.6 The following assumptions are made, firstly by the professional bodies acting jointly when certifying the eligibility of a Qualified Person and, secondly, by the Competent Authority when accepting an eligible Qualified Person for nomination on a Manufacturing Authorisation:

- in cases where undue pressures to depart from professional obligations cannot be counterbalanced by reference to this and other relevant Codes of Practice, Qualified Persons, preferably having informed their employer first, should consult the appropriate professional body for confidential advice.

- management has a duty to provide Qualified Persons with appropriate resources and to ensure that Quality Management Systems and communications are working effectively. Therefore, Qualified Persons also have a duty to make representations to management, if necessary in writing, whenever standards appear to be falling short of Good Manufacturing Practice(s). This duty should be reflected by appropriate wording in the Qualified Person's job description.

14.0 DISCIPLINARY PROCEDURES

14.1 Article 56 of Council Directive 2001/82/EC and Article 52 of Council Directive 2001/83/EC. read inter alia:

"Member States shall ensure that the duties of Qualified Persons … are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional Code of Conduct.

Member states may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfil his obligations".

If it were found that a QP had certified in a register or equivalent document a product batch as fit for sale without ensuring that the relevant tests and checks had been carried out, this failure might be a matter for consideration by the appropriate professional body to which he/she might belong as a matter of professional misconduct."

14.2 The UK professional bodies have established disciplinary procedures to deal with cases of possible misconduct. One of the powers is to remove the name of an individual from the appropriate register or registers and they will act together as appropriate in the case of a Qualified Person who is a member of two or three of the Societies. In such cases, professional bodies will inform the Competent Authority.

14.3 The Member State Competent Authority is the body with the power to delete the Qualified Person's name from the Manufacturing Authorisation.

APPENDIX 1

UK statements on CPD

INSTITUTE OF BIOLOGY

Continuing Professional Development Statement

In common with many other professional biologists, Qualified Persons work in a changing scientific, commercial and regulatory environment. This requires individuals to commit themselves to updating their knowledge and skills, in order to maintain their competence to do the job.

Increasingly, there is a demand from employees undertaking such development to have it recognised, and for employers to be able to demonstrate the competence of their employees to regulatory bodies, their customers and the general public. Continuing Professional Development (CPD) emphasises quality and confers a competitive edge.

The Institute of Biology has therefore placed a high priority on the development of a Continuing Professional Development scheme, to ensure that chartered biologists keep up to date and maintain their competence. The Institute is in the process of carrying out a pilot CPD scheme based on national occupational standards for professional biologists developed by the Science, Technology and Mathematics Council. The CPD scheme has been designed as a benefit and to support members in advancing self-education whilst also underpinning professional competence.

The scheme focuses on the demonstration of work place competence maintained by informal and formal activities, such as reading, conference attendance and short courses. The scheme initially is voluntary.

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

Continuing Professional Development Statement

The Royal Pharmaceutical Society of Great Britain (RPSGB) seeks to safeguard and promote the interests of the public and the profession by identifying the fundamental role and accountability of pharmacists. Pharmacists must keep up to date with changes in pharmacy practice, the law relating to pharmacy and the knowledge and technology applicable to pharmacy, and to maintain competence and effectiveness as a practitioner.

The ‘key responsibilities of a pharmacist’ are set out in the RPSGB’s Code of Ethics.

The Code of Ethics states that practising pharmacists are expected to maintain records of their continuing professional development (CPD) and make the records available for review by the Society on request. CPD records should contain evidence that practising pharmacists:

(a) continually review the skills and knowledge required for their field(s) of practice, identify those skills or knowledge in need of development or improvement and audit their performance as part of the review;

(b) plan appropriate learning activities to address identified learning needs and implement their plans;

(c) evaluate what they have learned and effectively translate their learning into improved professional practice.

The RPSGB produces guidance on good practice for ensuring professional competence in Medicines, Ethics and Practice: A Guide for Pharmacists which is sent to all registered pharmacists on an annual basis. This includes guidance on identifying continuing professional development needs, deciding how to meet those needs, recording planning of and participation in CPD and evaluating the outcome of any CPD participation.

All pharmacists, including those eligible to act as Qualified Persons, are encouraged to document any identified training and development needs, how they have planned to meet them and what has actually been done in an attempt to meet them. Pharmacists are advised to retain training records and record CPD in an approved format for this purpose.

Continuing Professional Development is becoming increasingly important in all areas of practice and it is in the interests of all pharmacists to retain evidence/records of participation. Further information about the RPSGB CPD scheme can be found on the RPSGB website at: www.rpsgb.org

ROYAL SOCIETY OF CHEMISTRY

Continuing Professional Development Statement

Continuing Professional Development (CPD) has been defined by the RSC as:

"the responsibility of individuals for the systematic maintenance, improvement and broadening of knowledge and skills to ensure continuing competence as a professional throughout their career".

In today's world, professionals are required to demonstrate that their knowledge and professional skills are being kept up to date. Advances in the chemical sciences and the increasing need to use a variety of skills particularly when working at the interfaces with different scientific areas requires members to develop and maintain a range of skills. This will ensure that they are able to meet the needs of evolving employment requirements.

CPD for RSC members on the Register of Eligible Qualified Persons is important because registrants should be able to demonstrate that their expertise is up to date to ensure that the Register has public credibility. The CPD scheme links to the competencies required for registration as an Eligible Qualified Person.

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Members on the Register of Eligible Qualified Persons are requested to submit a CPD return annually. Participation in the scheme is voluntary, but submission of an appropriate CPD return will be recognised in the Register.

Further information about the RSC CPD scheme can be found on the RSC website at www.rsc.org/members/cpd