**‘Royal Pharmaceutical Society**

**Royal Society of Biology**

**Royal Society of Chemistry**

**Qualified Person:** **Sponsor Form**

**Permanent provisions (Category A applications)**

Please refer to the Guidance Notes for Applicants and Sponsors before completing the form. If you have any queries relating to the application, you should contact your own professional body.

**Applicant’s Name:**

**Sponsor’s Name:**

1. **Professional experience**
2. Please verify that the applicant has obtained at least two years’ practical experience (one year for Pharmacists) in one or more undertakings authorised according to Article 40 of 2001/83/EC or Article 44 of 2001/82/EC to manufacture medicinal products, or in an undertaking authorised according to Article 13 of 2001/20/EC to manufacture investigational medicinal products for clinical trials. The practical experience must be in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.

I verify the above [ ]

1. Please provide the qualifying Manufacturer’s Authorisation number(s) and issue date(s)

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1. **Work place skills and competencies**

Please provide an honest and balanced description of the applicant’s ability to act as a Qualified Person that covers, but is not limited to, the following criteria. For each section, **describe a situation when the applicant demonstrated his/her competence**:

* **Ability to achieve good working relationships with persons in other functions within the company.** For example, describe a time when the applicant built strong collaborative relationships with people outside your immediate work group OR describe a situation where the applicant had to work closely with someone they found difficult to deal with. What did they do or say in this situation?

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* **Communication skills (oral and written).** For example, describe a time when the applicant had to persuade a person or group to accept a decision they were initially reluctant to consider

AND/OR describe a situation where the applicant was required to convey a difficult piece of information in writing.

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* **Assertiveness.** For example, describe a time where the applicant reacted positively and calmly to confrontation OR describe a situation where the applicant made an unpopular decision because they felt it was the right thing to do. How did they cope in this situation?

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* **Flexibility and open mindedness**. For example, describe a time where the applicant adjusted their behaviour having taken on the views of others OR describe a situation where the applicant was required to ‘think on their feet’ due to rapidly changing circumstances.

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* **How the applicant operates under pressure.** Describe an occasion where the applicant has overcome a significant obstacle in order to achieve a goal OR describe a situation where the applicant has had to make difficult decisions under very challenging circumstances.

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* **Planning and organising skills.** For example, describe a situation where the applicant developed a plan for a project they were in charge of completing OR describe a time when the applicant has had to realign his/her own priorities in order to complete a challenging task.

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* **Professional ethics and integrity.** For example, describe an example where the applicant took responsibility for a mistake they had made OR describe an event where the applicant had to advise others that their behaviour or intentions were unacceptable because they were in breach of organisational or ethical standards.

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* **Reliability**. For example, describe a situation where the applicant was required to maintain a high level of focus and effort over a long period of time, and how he/she behaved over this period OR describe how the applicant identifies and ensures that he/she meets the needs of customers and key stakeholders

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* **Problem solving skills.** For example, describe an event where the applicant had to identify risks and potential problems, as well as ways in which these could be addressed OR describe a situation where the applicant had to proactively seek information in order to identify the true underlying cause of a particular problem.

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* **Any special achievements.**

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* **If this is the applicant’s second or subsequent application, please describe how you have helped them to address the concerns of the assessors from their last application:**

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1. **How well you know the applicant professionally:**

Please explain:

(a) your workplace relationship to the applicant during the period of his/her qualifying experience;

(b) how you have supported the applicant and helped him/her to prepare for assessment;

(c) in confirming to us that the applicant has the necessary skills, knowledge and personal attributes to act as a Qualified Person, how you have come to this view.

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1. **Does your current role include acting as a QP? For example, batch certification, batch confirmation, API Declarations, IMP GMP Declarations etc.**

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Length of service on the relevant Manufacturer’s Authorisation(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Additional comments**

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1. **Confirmation**

I confirm that the information provided in the application form is correct. Please list any areas in which you are unable to confirm the accuracy of the information.

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I confirm that the applicant named above has the necessary skills, knowledge and personal attributes to act as a Qualified Person. Please note that the submission of an inaccurate or misleading report will be regarded by the professional bodies as professional misconduct.

**Signature Date**

**Countersignatory** If you are not a Qualified Person, please ensure the report is countersigned by the QP acting for the activities in which the applicant is engaged:

Name and address (of the QP countersigning, if applicable)

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Professional body\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Membership number and designatory letters\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Length of service on the relevant Manufacturer’s Authorisation(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Countersignature Date**