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Role of the Sponsor in Supporting Trainee QPs

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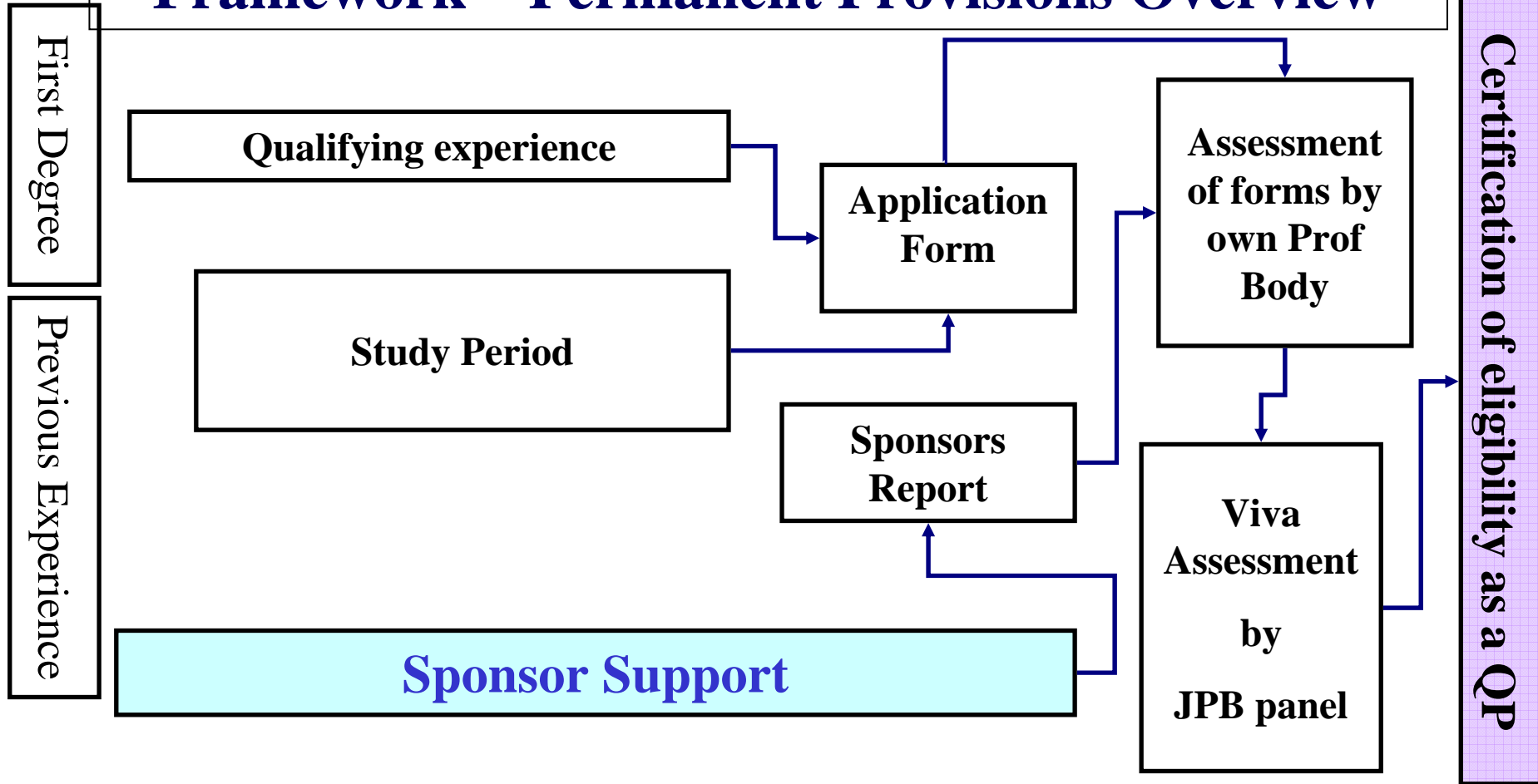
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Framework – Permanent Provisions Overview



Typically this process takes between 2 and 4 years.



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Sponsor requirements

- **The Guidance Notes for Applicants and Sponsors May 2006 gives details of the requirements for the sponsor.**
- **A copy of the Guidance Notes has been provided in your Delegate pack.**



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Sponsor Requirements

- It is not enough to meet the candidate just before the viva and fill in the form.
- You need to be intimately involved in their training and development.
- A clear plan is absolutely essential.
As is flexibility – things will change over this timescale.
- The sponsor should act primarily as a guide or mentor who can assist the aspiring Qualified Person

You should be an emotional resource for the trainee QP as well as a practical one



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Sponsor Requirements

- Before agreeing to act, the sponsor should have formed an impression of the applicant's ability to make difficult ("grey area") decisions and to withstand the pressures that are inevitably associated with the professional duties and responsibilities of a Qualified Person.
- The sponsor should, wherever possible, help the aspiring Qualified Person to relate the theoretical knowledge to the day to day issues involved in the manufacture and control of medicinal products. Integration of the subject matter is important in providing the Qualified Person with a comprehensive body of knowledge.

Is your proposed candidate cut out to be a QP?



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Sponsor Requirements

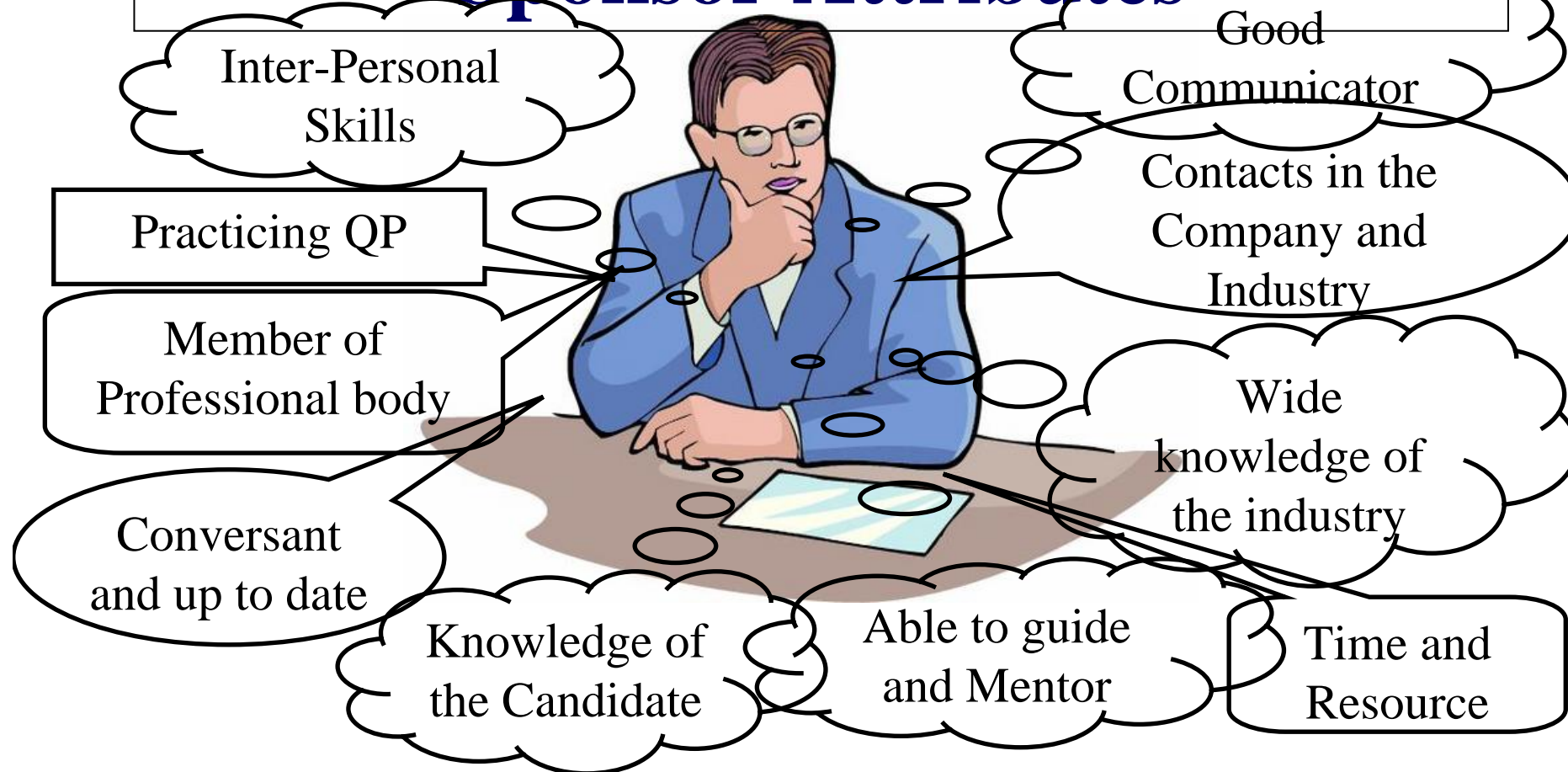
- It takes a lot of time and resource to prepare a candidate for their QP Viva.
- Is your company prepared for the time and resource required over and above any formal training course?
- The sponsor, with their responsibility to both the Candidate and the Company, is best placed to ensure a pass first time.
- Does your company spend time ensuring that both the candidate and the sponsor are suitable?

So what makes a good sponsor and a good candidate?



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Sponsor Attributes

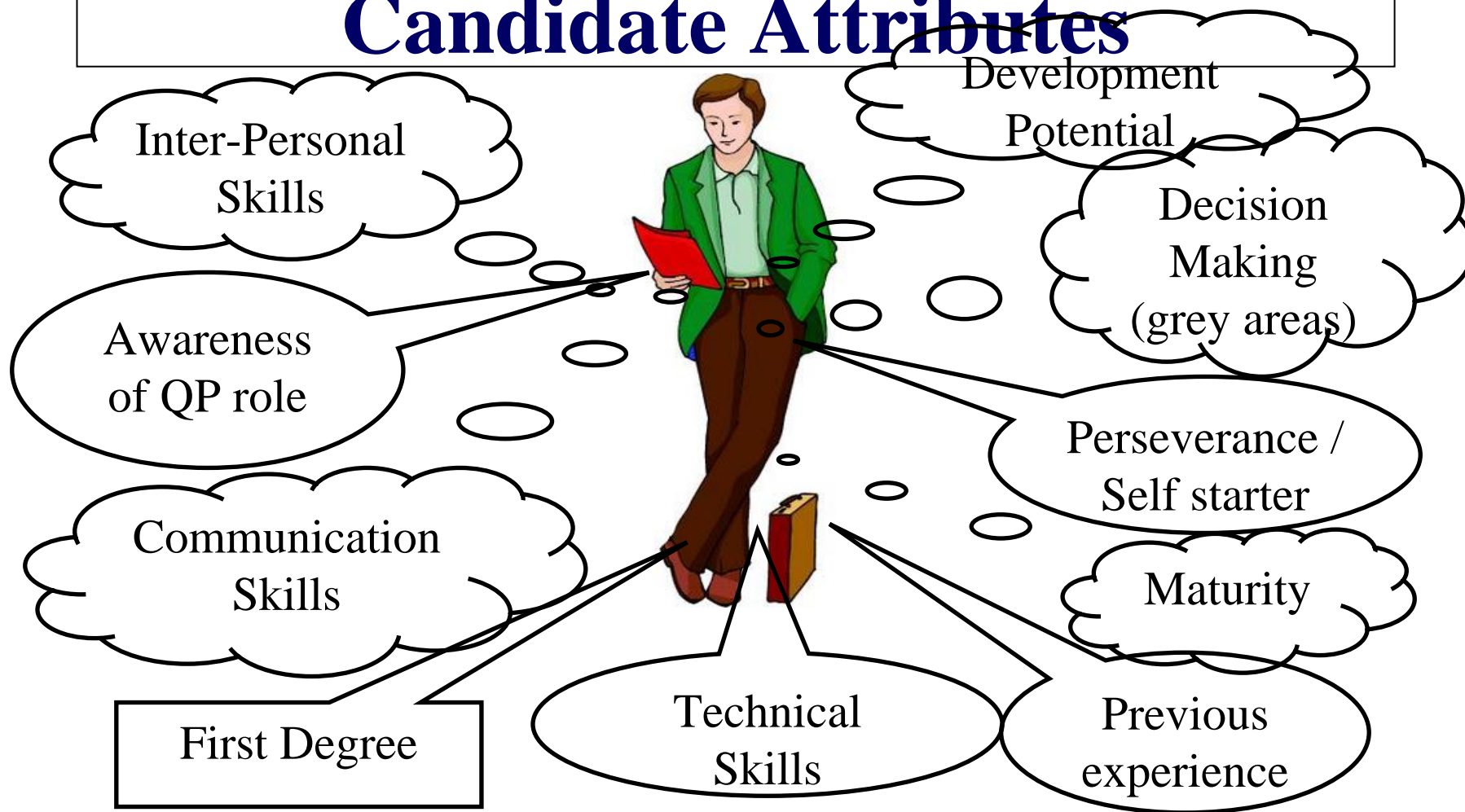


Do you meet the requirements to be a good sponsor?



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Candidate Attributes

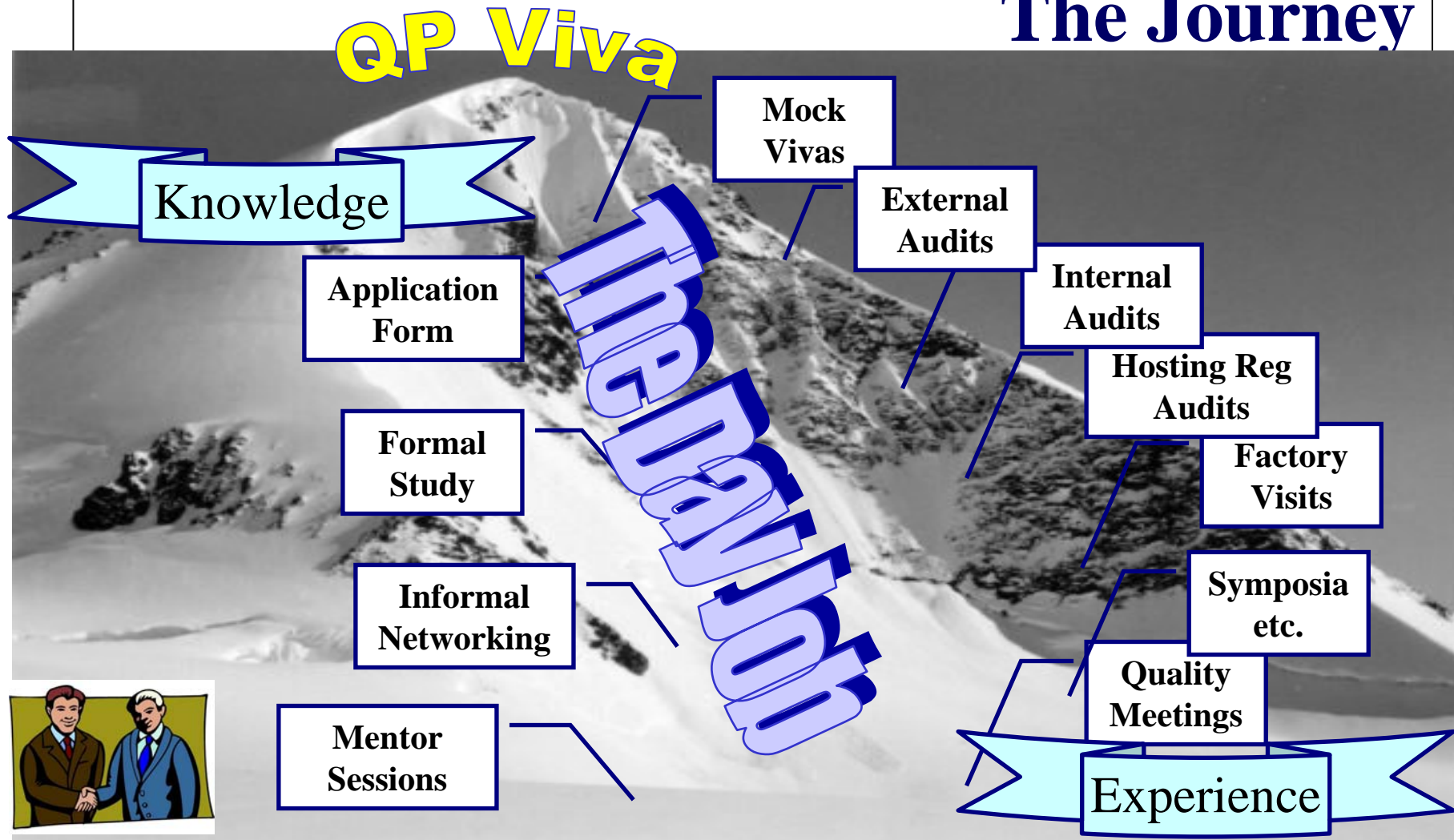


Does the candidate really understand what it is to be a QP?



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The Journey



The sponsor should be with the candidate every step of the way.

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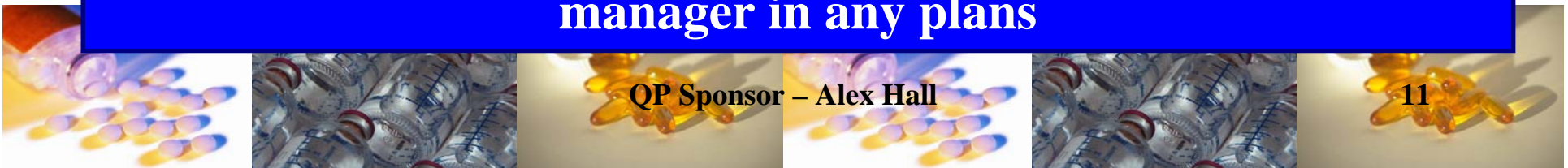
Practical Guidance

- **First meeting**
 - Gap analysis against study guide
 - Diary of events e.g. visits to other departments, sites
- **Experience Gaps**
 - Involve your candidate in day to day quality decision making
- **Knowledge Gaps**
 - Most often covered in formal courses – the sponsor can help the candidate put this into a practical context.

Don't forget to involve and include the candidate's line manager in any plans

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Practical Guidance

- The sponsor should, wherever possible, help the aspiring Qualified Person to relate the theoretical knowledge to the day to day issues involved in the manufacture and control of medicinal products. Integration of the subject matter is important in providing the Qualified Person with a comprehensive body of knowledge.
- Sponsors are urged to ensure that the applicant is fully aware of the basic duties and responsibilities of the Qualified Person and to provide information on the nature and extent of compliance with the Study Guide.



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Practical Guidance - Forms

- **Candidate Application Form**

- The candidate should start to complete the form as soon as possible – Previous experience is often relevant and the form can be used to record experience over the training period.

- **Sponsor Report Form**

- The report is a key part of the sponsor's input and it is not sufficient for the sponsors to simply provide a declaration of belief that an applicant complies with the requirements. It should be a **critical** and **honest evaluation** of the candidate's **technical** and **professional knowledge**. It should also include information on the candidate's **personal attributes** (inaccurate or misleading reports will be regarded as professional misconduct).

The forms are reviewed, prior to invitation to Viva, by two assessors from the candidates own Professional Body.



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Practical Guidance - Viva Preparation

- **Start preparing the candidate as soon as the application is submitted.**
- **Demystify the Viva – explain the process**
 - The JPB officers can provide this if you are not sure.
- **Set up practice sessions where you discuss issues and potential questions**
- **Use your in-house experts to challenge the candidates understanding of the different areas of the Study Guide**

The new study guide emphasises the use of scenario questions that may cover several areas of the study guide



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Practical Guidance - Viva Preparation

- **Set up a more formal 'mock Viva', to give the candidate a chance to get used to the process and reduce nerves on the day.**
- **Encourage the candidate to use:**
 - Thinking time
 - Pictures
 - Questions to define and clarify

The more practice the Candidate gets, the less nervous they are likely to be



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Practical Guidance - Viva Preparation

- **What do the assessors look for?**
 - Their intention is to find out what the candidate knows
 - Factual Questions: There is a right answer e.g “what are the duties of a QP?”
 - Scenario Questions: Not necessarily a right answer e.g. “How would you respond to the suggestion?”

Remember that most candidates leave the Viva saying

“That wasn't so bad after all!”



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Practical Guidance - Viva Preparation

**Your job as sponsor is to ensure that
your candidate is as prepared as
possible**

**Think ‘Driving Test’
not ‘Firing Squad’!!**



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Summary

- The UK has a very formal system in place to certify Qualified Person eligibility.
- Candidates for QP status have a lot to learn in a short space of time.
- The support of the sponsor is key to the success of candidates.
- Being a sponsor to a trainee QP benefits your company, the industry and you.
- It's also a good way to fulfil your own CPD

Should a sponsor require any further advice on fulfilling their role, they should refer to their own professional body.



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Advance Notification

- For more in depth information the Joint Professional Bodies are intending to hold a Training Day for Sponsors in April 2007.
- This will be limited to a small number initially, but, if popular will be repeated.
- Those wishing to take part should watch for announcements on the web or contact the QP officers of the Professional Bodies.



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References

- Study Guide May 2006
- Guidance Notes for Applicants and Sponsors May 2006
- Jane McLauchlin RSC QP Officer
- <http://pharmacos.eudra.org/F2/eudralex/index.htm>



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Useful links

Professional bodies - QP officers

Sadia Khan RPSGB

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<http://www.rpsgb.org/>

Rachael Rackham IOB

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<http://www.iob.org/>

Jane McLauchlin RSC

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<http://www.rsc.org/qp/>

The QP Officers are very friendly and always happy to help



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