

## MATRIX OF COMPETENCY DESCRIPTIONS

### A: APPLICATION OF KNOWLEDGE AND UNDERSTANDING

<p><b>A1:</b> Use specialist experiential knowledge and broader scientific understanding to optimise the application of existing and emerging science and technology</p>	<p><i>You should provide sufficient detail here to show your specialist experiential knowledge and how you have applied it. Further to this, include any examples of where your broader scientific understanding is applied to your area of practice. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>Writing, presenting or reviewing regulatory dossiers, internal papers, reports or standards</i></li> <li>● <i>Conducting appropriate research to facilitate design and development of scientific processes and/or regulatory submissions</i></li> <li>● <i>Participation in multi-disciplinary teams on product development.</i></li> </ul>
<p><b>A2:</b> Exercise sound judgement in the absence of complete information and in complex or unpredictable situations</p>	<p><i>This competency is asking you to identify and be aware of the limit of your own knowledge and professional competency, to demonstrate an ability to manage your own strengths and weaknesses and to recognise the level of risk attached to your actions. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>Considering when you have approached a piece of work or project flexibly and in a novel or different way, or reacted to an unexpected outcome</i></li> <li>● <i>Giving regulatory advice on new products</i></li> <li>● <i>Completing due diligence investigations.</i></li> </ul>
<p><b>A3:</b> Demonstrate critical evaluation of relevant scientific information and concepts to propose solutions to problems</p>	<p><i>You should think of this competency in terms of selecting the best methodology, the subsequent data analysis and conclusions you draw and how you overcome any barriers or issues. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>Engaging in experimental design in compliance with regulatory requirements</i></li> <li>● <i>Reviewing relevant literature, manuals or regulatory documents</i></li> <li>● <i>Sharing your findings with others</i></li> <li>● <i>Research and develop arguments for treatment pathways</i></li> <li>● <i>Critical evaluation of regulatory strategic plans.</i></li> </ul>

### B: PERSONAL RESPONSIBILITY

<p><b>B1:</b> Work autonomously and take responsibility for the work of self and others</p>	<p><i>It is important for this competency to ensure you describe your contribution, responsibility and impact on a certain task and make it clear what you personally have achieved, ie “I” not “we”. In formulating your answers, you should consider the following:</i></p> <ul style="list-style-type: none"> <li>● <i>You will be expected to undertake much of your work without day-to-day supervision and so you should demonstrate that you are able to achieve this</i></li> <li>● <i>You should demonstrate your understanding of when you may need to seek guidance from others and how you would obtain this guidance</i></li> <li>● <i>If you are responsible for managing the work of others, you should clearly describe how you discharge those responsibilities</i></li> <li>● <i>Setting up GLP in a lab.</i></li> </ul>
<p><b>B2:</b> Promote and implement robust policies and protocols relating to health, safety and security</p>	<p><i>You should demonstrate that you understand the policies and protocols related to health, safety and security that apply to the work you are undertaking and describe any responsibilities that you have related to this. Security can include issues related to data, Intellectual Property, confidentiality, prevention of contamination, traceability of documents and information. In formulating your answers, you should consider the following:</i></p> <ul style="list-style-type: none"> <li>● <i>Policies, procedures and protocols that document how relevant aspects of your work must be carried out. Demonstrate that you know where these policies and protocols are documented, and that you are able to apply them in your practice</i></li> <li>● <i>What risks you are aware of related to the security aspects of the work you carry out, and how you seek to mitigate these risks</i></li> <li>● <i>How you “promote” the awareness and application of these policies and protocols with others, especially peers and more junior colleagues</i></li> <li>● <i>Setting up and implementing ISO 9000</i></li> <li>● <i>GDPR, GMP.</i></li> </ul>

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<p><b>B3:</b> Promote and ensure compliance with all relevant regulatory requirements and quality standards</p>	<p>You should demonstrate that you understand which regulatory requirements and quality standards apply to your area of work. In formulating your answers, you should consider the following:</p> <ul style="list-style-type: none"> <li>● Describe what you do to ensure that these requirements and standards are being followed for those activities for which you are responsible</li> <li>● Describe how you “promote” the awareness of regulatory requirements and quality standards among peers and more junior colleagues.</li> </ul>
<p><b>B4:</b> Oversee the implementation of solutions with due regard to the wider environment and broader context</p>	<p>You should demonstrate an understanding of the potential and actual impacts of your work on your organisation, on the profession, on the general public and on the physical environment. Examples could include but are not limited to:</p> <ul style="list-style-type: none"> <li>● Indicating that you are aware of the sensitivity of your work and show how this understanding translates into the ways in which you carry out your work</li> <li>● Showing an awareness of how your profession is portrayed and viewed by the public at large, and how you take responsibility for recognising this in the work you do</li> <li>● Describing how you seek to avoid reputational damage related to the work you carry out</li> <li>● Explaining how you set a good example to others in the way you discharge the responsibilities related to the work you undertake</li> <li>● Taking part in stakeholder meetings with the public or patient groups.</li> </ul>

### C: INTERPERSONAL SKILLS

<p><b>C1:</b> Demonstrate the ability to communicate effectively with specialist and non-specialist audiences</p>	<p>A non-specialist audience is anyone working outside of your particular area of expertise, so it would not necessarily be a non-scientist. Your example(s) should indicate how you have communicated in a way that is effective to each type of audience. In formulating your answers, you should consider the following:</p> <ul style="list-style-type: none"> <li>● Not just the content of the message but also the mode or style of delivery that is adapted according to the audience</li> <li>● The feedback loop to gauge the understanding and improve future communications</li> <li>● Communicating with patients and professionals from other disciplines</li> <li>● Patient information leaflets</li> <li>● Public assessment reports.</li> </ul>
<p><b>C2:</b> Demonstrate effective leadership through the ability to guide, influence, inspire and empathise with others</p>	<p>This competency is about understanding your leadership skills and is not reserved for those in management roles; it is applicable to all. Examples could include but are not limited to:</p> <ul style="list-style-type: none"> <li>● Experience of mentoring or coaching you have had; you should consider how effective this was and the overall impact</li> <li>● Considering when you have managed change within your organisation or overseen the implementation of any new processes</li> <li>● What you do with your team and the outcome/effect.</li> </ul>
<p><b>C3:</b> Demonstrate the ability to mediate, develop and maintain positive working relationships</p>	<p>You should describe or define the “working relationship” and provide at least one example which focuses on your handling of a challenging interpersonal situation and demonstrates your ability to mediate and achieve a positive outcome. You should consider how through your approach you have changed or modified the behaviour or attitudes of others to positive effect. Examples could include but are not limited to:</p> <ul style="list-style-type: none"> <li>● How you have managed the merger or integration of different teams</li> <li>● Managing working relationships across different departments or organisations (eg, in the preparation of a regulatory dossier)</li> <li>● Interactions with committees, competent authorities, working groups or other professional body activities</li> <li>● How you have managed and resolved a difficult relationship situation between members of a team for which you are responsible.</li> </ul>

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### D: PROFESSIONAL PRACTICE

<p><b>D1: Scope, plan and manage multifaceted projects</b></p>	<p><i>Describe a project that you have managed and make it clear the level of autonomy you had while working on the project, especially if you were in a team. You should show how you contributed to determining the resulting courses of action. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>An operational project utilising resources across several disciplines</i></li> <li>● <i>A change management project aligning processes across sites</i></li> <li>● <i>An industry-wide project establishing guidance on technical standards and requirements.</i></li> </ul>
<p><b>D2: Demonstrate the achievement of desired outcomes with the effective management of resources and risks</b></p>	<p><i>Using the project you have discussed under D1, or another project with which you have been involved, you should describe your roles and responsibilities in managing the activities to achieve the desired outcomes. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>Identifying the resources (people and/or money) needed to undertake the activities</i></li> <li>● <i>Monitoring and surveillance of the progress of the activities</i></li> <li>● <i>Identification, evaluation and implementation of changes that may be needed to ensure the activities are successfully completed</i></li> <li>● <i>Identification and management of risks that could impact on the successful completion of the activities.</i></li> </ul>
<p><b>D3: Take responsibility for continuous performance improvement both at a personal level and in a wider organisational context</b></p>	<p><i>Your examples should indicate what actions you take to make improvements to your personal performance and to your organisation as a whole. This could be through encouraging the continuous development of junior staff or through improvements to processes within the organisation. Examples could include but are not limited to:</i></p> <ul style="list-style-type: none"> <li>● <i>Identification of lessons learned from activities undertaken by yourself or by others for whom you are responsible, such as what went well, went badly or was lacking</i></li> <li>● <i>Evaluation of the performance of specialists methods and tools used</i></li> <li>● <i>Development of recommendations for future enhancements or modifications to procedures or working practices in order to achieve performance improvements</i></li> <li>● <i>Description of examples where your actions have led to performance improvement by yourself or others</i></li> </ul>

### E: PROFESSIONAL STANDARDS

<p><b>E1: Demonstrate understanding and compliance with relevant codes of conduct</b></p>	<p><i>You should describe how the codes of conduct/statement of values under which you practice relate to the work that you carry out and give examples of how they govern your professional practice. Within this, you should include any ethical considerations, both in terms of scientific and business practices. Examples you may wish to use may relate to:</i></p> <ul style="list-style-type: none"> <li>● <i>Standards of professional practice in respect of your profession, employer, clients or patients</i></li> <li>● <i>Standards of professional behaviour in respect of attitudes, respect and confidentiality</i></li> <li>● <i>Standards of professional competency in respect of personal development and the development of others.</i></li> </ul>
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