

Regulatory Affairs Specialist Apprenticeship, Level 7: End-point Assessment Plan

Introduction & Overview

This document sets out the requirements for end-point assessment (EPA) for the Regulatory Affairs Specialist apprenticeship standard, level 7. The assessment plan has been written with input from industry experts with extensive years of experience in the Regulatory Affairs sector. It is written for end-point assessment organisations who need to know how EPA for this apprenticeship must operate. It will also be of interest to Regulatory Affairs Specialist apprentices, their employers and training providers.

Full time apprentices will typically spend 30 months on-programme working towards the apprenticeship standard, with a minimum of 20% off-the-job training.

The EPA should only start once the employer is satisfied that the apprentice is consistently working at or above the level set out in the standard, that the pre-requisite gateway requirements for EPA have been met and that they can be evidenced to an EPA organisation. Apprentices must achieve level 2 in English and mathematics prior to taking their EPA. For those with an education, health and care plan or a legacy statement the apprenticeships English and maths minimum requirement is Entry Level 3, and British Sign Language qualifications are an alternative to English qualifications for those whom this is their primary language.

The EPA must be completed within a six month period, after the apprentice has met the EPA gateway requirements.

EPA must be conducted by an organisation approved to offer services against this standard, as selected by the employer, from the Education & Skills Funding Agency's Register of End Point Assessment Organisations.

The EPA consists of 2 distinct assessment methods:

- Project showcase, based on a case study, including report, presentation and questioning
- Viva voce (Synoptic)

Performance in the EPA will determine the apprenticeship grade of fail, pass, or distinction. Within this document references made to healthcare are intended to mean human healthcare or veterinary.

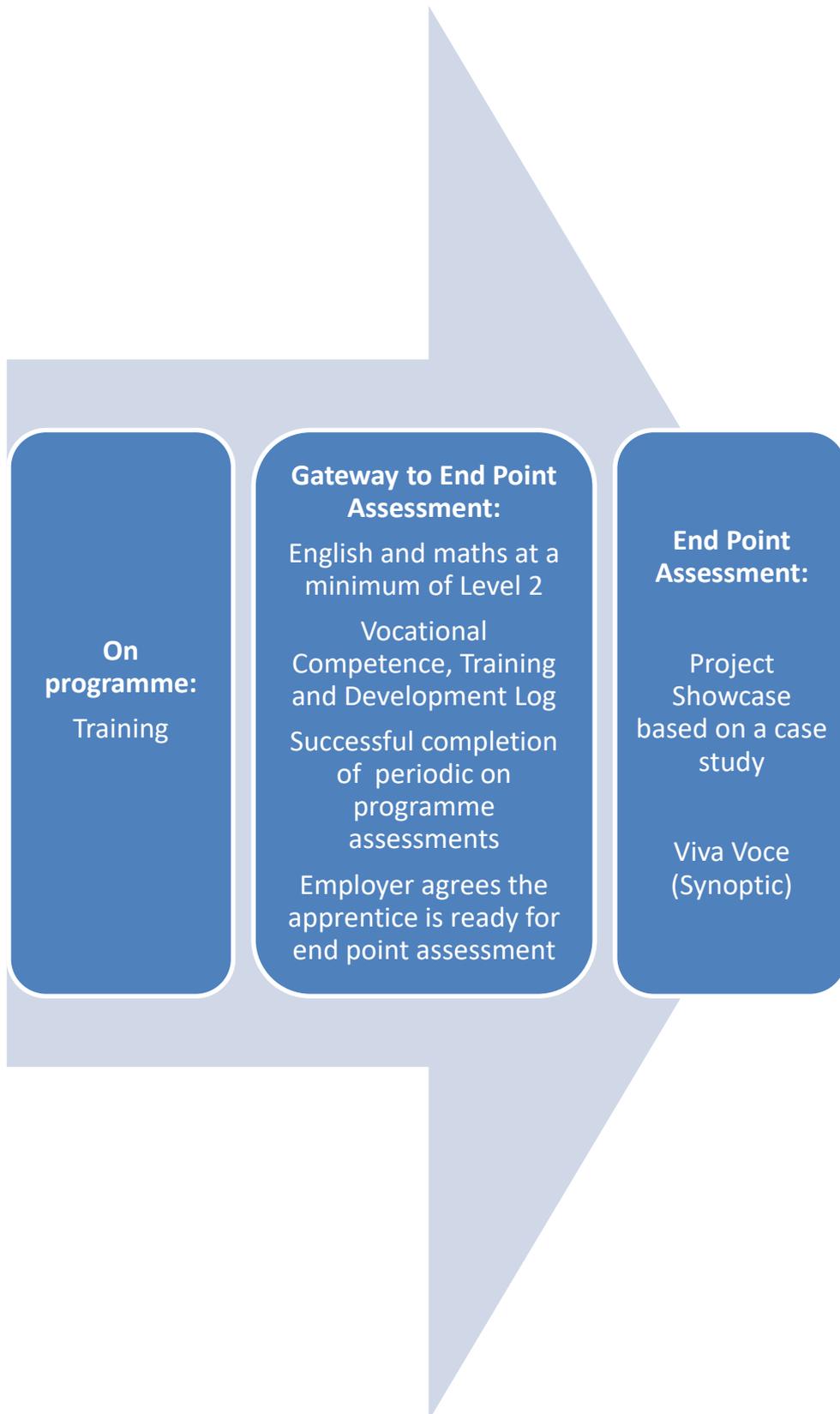


Diagram 1. Typical Regulatory Affairs Specialist Apprenticeship Summary

End-point Assessment Gateway

The EPA should only start once the employer is satisfied that the apprentice is consistently working at or above the level set out in the standard, the pre-requisite gateway requirements for EPA have been met and that they can be evidenced to an EPA organisation. Employers may wish to take advice from their apprentice's training provider(s).

Gateway requirements:

- English and mathematics at level 2
- A completed Vocational Competence, Training and Development Log for use on the Viva Voce

Vocational Competence, Training and Development Log

- The Vocational Competence, Training and Development Log will outline the projects, training, development activities and performance reviews that the apprentice has undertaken during the apprenticeship period
- Details of the projects that the apprentice has undertaken will include a high-level overview of the project, key objectives and deliverables, dates and time periods for the project and a detailed description of the activities of the apprentice in order to achieve the project deliverables
- Details of the training the apprentice has undertaken will include the title of the training course, dates and time period for the training, details of the training provider, a description of the key learnings from the training course and the outcome (if applicable)
- The log should demonstrate how each work project and training activity helps to achieve the Knowledge, Skills and Behaviours (KSBs) set out in the apprenticeship standard
- End Point Assessment Organisations (EPAOs) will receive a copy of the Vocational Competence, Training and Development Log within two weeks of the start of the assessment period to provide sufficient time to review its content
- EPAOs must provide guidance on what format the log might take, including how it will be submitted and stating that it should not include any reflective self-assessment
- The content of the log is expected to be used to support the Viva voce

Table 2: Summary of End Point Assessment

EPA overview				
Assessment Method	Area Assessed	Assessed by	Grading	Weighting
Project showcase, based on a case study, including written report, presentation and questioning	Knowledge, skills and behaviours - as shown in Annex 1	EPAO	Fail/ Pass/ Distinction	50%
Synoptic Viva Voce	Knowledge, skills and behaviours - as shown in Annex 1	EPAO	Fail/ Pass/ Distinction	50%

End-point Assessment Methods, Timescales & Location

The end-point assessment consists of 2 distinct assessment methods:

- Project showcase, based on a case study, including written report, presentation and questioning
- Viva Voce

The assessment methods can be completed in any order, allowing EPAOs flexibility in scheduling and cost-effective allocation of resources.

EPAOs must ensure that the presentation of the project showcase and viva voce are conducted in a suitable controlled environment i.e. quiet room free from distraction and influence, with the necessary equipment required to deliver a presentation (e.g. projection equipment, PowerPoint enabled laptop). It is anticipated that EPAOs will use the premises of the apprentice's employer, where this is practical and agreed by the employer, to minimise costs. They may be conducted face-to-face or via an online platform e.g. video-conferencing. To

prevent misrepresentation EPAOs must ensure appropriate methods are in place should an online option be used. For example, screen share and 360-degree camera function with an administrator/invigilator.

Requirements for each assessment method are detailed below.

Project Showcase

The project showcase focuses on apprentices presenting the approach, findings, recommendations and lessons learned from a case study. The apprentice will choose a case study from a list of three provided by the EPAO based on the area worked on by the apprentice. It includes a report, presentation and questioning.

It must cover:

- What the apprentice set out to achieve, how they approached the work and dealt with any issues
- The key outcomes of the case study
- Recommendations and lessons learned from the case study

Apprentices must complete and submit a report based on the case study to their EPAO. Apprentices must then present their report to their independent assessor. This will be followed by questioning with the independent assessor, clarifying areas of the case study, report and presentation, as needed, and focussing on KSBs assessed by this assessment method that have not already been demonstrated by the report or presentation. The evidence from the report, presentation and answers to questions will be holistically assessed against the KSBs.

Requirements:

- The report must be submitted to the apprentice's EPAO, for review, within 10 weeks of them being provided with the case study details
- The report must be 4000 words +/-10%. It can include photos, diagrams and tables where they add value and clarity to the report, but these will not be included in the word count. No annexes or appendices are allowed.
- Assessors must give an apprentice a minimum of 3-weeks' notice of the time, date and venue for the presentation and questioning, following receipt of the report.

Requirements for the presentation and questioning:

- It will assess the apprentice's presentation and analytical skills, as well as the other KSBs set out in annex 1.
- The presentation will explore the apprentice's ability to apply what they have learnt to their case study
- The presentation must be for a duration of 20 minutes (+10% at the assessors discretion)
- Apprentices may use PowerPoint and presentation aides e.g. handouts as they see fit; technical requirements must be agreed with the EPAO in advance

- Questioning must be for a duration of 25 minutes (+10% at the assessors discretion)
- Questioning must consist of open questions, with follow up questions allowed for clarification. EPAOs must provide sample questions. However, it is not feasible to pre-determine questions: they will depend upon i) the nature of the work upon which the report and presentation is based, ii) what is written in the report and said in the presentation and iii) what the independent assessor decides needs to be clarified
- The presentation and questioning must be recorded by the independent assessor (using written, audio or video recording); a copy of the report, the recording and any presentation material must be retained for quality assurance purposes

Viva Voce

The viva voce takes place between the apprentice and their independent assessor. The independent assessor must prepare areas for discussion following the review of the apprentice's Vocational Competence, Training and Development Log and based on the KSBs to be assessed by this assessment method.

The viva voce will:

- Clarify any questions the independent assessor has from their review of the Vocational Competence, Training and Development Log
- Explore aspects of the work, including how it was carried out, in more detail
- Require the apprentice to draw on their evidence to demonstrate the KSBs

Requirements:

- Apprentices must receive appropriate notice of their viva voce time. There should be a minimum of 3-weeks' notice of the time, date and venue.
- EPAO must structure a series of topic areas for discussion based on the areas of the standard to be tested as set out in Annex 1
- EPAOs must produce sample questions as a guide for independent assessors.
- The viva voce must seek to assess the depth of understanding to determine performance against the grading criteria.
- The viva voce must be completed in a period of 45 minutes (+ 10% at the assessors discretion)
- The viva voce should be recorded electronically, by the independent assessor (using audio or video recording); a copy must be retained for quality assurance purposes
- Independent assessors must assess the viva voce using the grading criteria in annex 2.
- The viva voce must take place in a suitably controlled environment i.e. quiet space, free from distraction.
- Apprentices may refer to their Vocational Competence, Training and Development Log when answering the questions.

Assessment tools and materials

EPAOs will need to create a number of problem/case study scenarios for apprentices to base their project showcase on. It is not anticipated that the EPAO create a huge bank of scenarios to cover all areas of regulatory affairs, all markets and all product types. The intention is that EPAOs would create a number of scenarios, to avoid predictability, that could be tailored to the product type and market in which the apprentice has been trained during their apprenticeship.

Case studies should meet the following requirements:

- The case study should be appropriate to the apprentice's area of work (human/ veterinary healthcare, medical devices, country/region of focus for the apprentice)
- Case Studies should be 300-500 words in length
- The case study should be provided to the apprentice in written format, this can include being provided electronically
- It should be provided to the apprentice within 2 weeks of the EPAO confirming that the apprentice has meet the Gateway requirements

EPAOs must develop and maintain a bank of sample questions for the presentation and viva voce to help with standardisation. The bank of questions must be of sufficient size to prevent predictability and must be reviewed regularly (at least once per year) to ensure they are fit for purpose.

Apprenticeship Grading

EPAOs must individually grade each assessment method – fail, pass or distinction, according to the requirements set out in this plan. Restrictions on grading apply where apprentices re-sit/re-take an assessment method – see re-sit/re-take section below.

An independent assessor must combine the grades of both assessment methods to determine the EPA grade. To achieve an EPA pass, apprentices must achieve a pass or distinction in both assessment methods. To achieve an EPA distinction, apprentices must achieve a distinction in both assessment methods. See grading combinations table below.

Individual assessors' decisions must be subject to moderation by the EPAO – see internal quality assurance section below. Decisions must not be confirmed until after moderation.

Table 3: Grading combinations

Project Showcase	Viva Voce	EPA grade
Distinction	Distinction	Distinction
Pass	Pass	Pass
Distinction	Pass	Pass

Pass	Distinction	Pass
Fail	Fail	Fail
Pass	Fail	Fail
Fail	Pass	Fail
Distinction	Fail	Fail
Fail	Distinction	Fail

Re-sit and re-take information

Apprentices who fail one or more EPA method will be offered the opportunity to take a re-sit/re-take. Re-sits/re-takes must not be offered to apprentice's wishing to move from pass to distinction. A re-sit does not require further learning, whereas a re-take does.

The apprentice's employer will need to agree that a re-sit/re-take is an appropriate course of action. Apprentices should have a supportive action plan to prepare for the re-sit/re-take.

An individual EPA method re-sit/re-take must be taken during the maximum EPA period i.e. 6 months, otherwise the entire EPA must be retaken.

The maximum grade awarded to a re-sit/re-take will be pass, unless the EPAO identifies exceptional circumstances accounting for the original fail.

EPAOs must ensure that apprentices are given a different case study when taking a re-sit/re-take. The viva voce will explore the candidates experience, knowledge, skills and behaviours through the Vocational Competence, Training and Development log. The Vocational Competence, Training and Development log won't change between the original assessment and the re-assessment therefore, the questions won't be exactly the same but may overlap between the original assessment and the re-sit/re-take.

Professional Body Recognition

This apprenticeship is designed to prepare successful apprentices to meet the requirements for registration with The Organisation for Professionals in Regulatory Affairs (TOPRA) as a Member or Registered Member (M TOPRA) as appropriate.

It is also designed such that apprentices would be eligible to apply for professional registration as a Registered Scientist (RSci) through either TOPRA or the Science Council on successful completion. This provides recognition for the standard the apprentice has reached in a way that provides parity with other scientific professions.

End-point Assessment Organisations

Employers must choose an independent EPAO approved to deliver the EPA for this apprenticeship from the Education & Skills Funding Agency's (ESFAs) Register of End Point Assessment Organisations (RoEPAO).

Requirements for Independent Assessors

The EPAO should appoint independent assessors to conduct the presentation with a question and answer assessment and the viva voce. Independent assessors must:

- Be vocationally competent with continuing professional development completed within the last year or be professionally registered with experience of current working practices.
- Have completed an assessment organisation induction
- Review the Vocational Competence, Training and Development Log
- Attend standardisation meetings at least annually
- Be qualified as an assessor or attend training organised by the EPAO

The EPA must be delivered in such a way that no party who has been involved in delivery can make the sole decision on competence. The approach must clearly deliver an impartial result. For this reason, independent assessors appointed by assessment organisations must not be linked to the apprentice, or their training provider or employer.

Quality assurance - Internal

Internal quality assurance refers to the requirements that EPAOs must have in place to ensure consistent (reliable) and accurate (valid) assessment decisions. EPAOs for this standard must as a minimum undertake the following:

- Provide training to independent assessors in relation to systems and process; and assessment practice where required
- Ensure independent assessors have relevant experience and qualifications – as detailed above
- Undertake moderation of independent assessor's work; with a minimum of 10% of each independent assessors assessments sampled, rising where there are potential standardisation issues
- Hold standardisation meetings with independent assessors to provide updates and share good practice at least twice a year (assessors are required to attend at least one of these sessions annually)

- Produce assessment tools and materials to operate the assessment methods in line with good practice, i.e. recording documentation, sample questions, case study scenarios for the project showcase, topics for the viva voce
- Operate a complaints and appeals process; any appeals in relation to the outcome of the end point assessment will be initially managed by the EPAO, and escalated to the external quality assurance body as appropriate
- Seek feedback from apprentices, employers and HEIs/training providers as to satisfaction with the service provided. This feedback will be used to inform service improvements and will be reviewed at regular points throughout the year
- Meet any requirements set in relation to External Quality Assurance

They will also be responsible for undertaking any reporting requirements and provision of information relating to performance and outcomes. They will also report on any concerns identified as to the quality of any on-programme training or assessment practices.

Quality Assurance – External

External quality assurance for this apprenticeship standard will be undertaken by The Organisation for Professionals in Regulatory Affairs (TOPRA).

Implementation

Affordability

The approach presented offers an affordable and scalable solution to end point assessment for this apprenticeship. The approach is robust and will ensure the best use of management time, with an EPA that delivers an effective synoptic assessment at reasonable cost and through a delivery model which minimises time and impact on the apprentice and employer.

EPAOs must seek to respond across a range of geographical locations. This will ensure that independent assessors' time is maximised, and that employer and apprentices have easy access to the EPA with little time spent on travel and associated costs.

The cost of the EPA is anticipated to represent no more than 20% of the apprenticeship funding band.

Volume

It is anticipated that there will be 20 starts per year on the apprenticeship.

Annex 1 – Knowledge, Skills and Behaviours to be assessed by each assessment method

Assessment method	Key
Project Showcase	P
Viva Voce	V

Knowledge statement	Assessment method
1. The regulatory environment	P - to demonstrate environmental knowledge from the case study V – to demonstrate knowledge of the wider environment
2. The regulatory function throughout the product lifecycle	V
3. The evidence for regulatory decision making: science, content and structure	P
4. Regulatory procedures	P - to demonstrate knowledge of regulatory procedures from the case study V – to demonstrate knowledge of additional regulatory procedures
5. Regulatory impact	P - to demonstrate knowledge of regulatory impact related to the case study V – to demonstrate knowledge of the wider impact of regulatory

Skills statements	Assessment method
1. Manage and deliver multiple projects	V
2. Act decisively	V
3. Influence and negotiate	V

4. Think analytically and offer creative solutions	P
5. Present and communicate	P
6. Manage and share knowledge	V
7. Using own initiative to contribute to a team	V
8. Work with IT platforms	V

Behaviour statements	Assessment method
1. Integrity	V
2. Accountability	V
3. Independence	V
4. Commitment to personal development	V
5. Compliance	V
6. Customer focus	P

Annex 2 – Grading Criteria

Annex 2A – Project Showcase Grading Criteria

Area of Standard	Distinction criteria: In addition to the pass criteria the Apprentice must meet the distinction criteria for at least 5 of the 7 areas of the standard.	Pass criteria: the Apprentice must display all of the following	Fail
The regulatory environment	<ul style="list-style-type: none"> • Can explain how the regulatory environment fits into the wider healthcare or animal health environment in which they work • Can identify the consequences and impact of failing to recognise and respond to changes in the regulatory environment in which they work • Articulates how new or future regulatory changes may have an impact on the work they do 	<ul style="list-style-type: none"> • Recognises the regulatory environment in which they work and the key organisations involved • Understands the changes occurring in the regulatory environment in which they work and upcoming changes that have been identified 	Does not meet the minimum criteria for a pass
The evidence for regulatory decision making: science, content and structure	<ul style="list-style-type: none"> • Explains how all the available evidence contributes to regulatory decision making • Understands and explains the risks around regulatory decisions that need to be taken into account and the approach to manage them. 	<ul style="list-style-type: none"> • Demonstrates a systematic approach to regulatory decision-making, taking the key pieces of evidence into account, alongside a sensible approach to content and structure that can be applied to other projects where appropriate 	Does not meet the minimum criteria for a pass
Regulatory procedures	<ul style="list-style-type: none"> • Understands how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing 	<ul style="list-style-type: none"> • Demonstrates knowledge and compliance of the regulatory procedures in the area where they work • Can justify the choice of procedure they have made 	Does not meet the minimum criteria for a pass

Regulatory impact	<ul style="list-style-type: none"> Explains the impact of regulatory processes and new procedures on the whole business/organisation and key stakeholders outside of the business Articulates how future regulatory changes will impact the business environment they work within, including strategies for minimising impact. 	<ul style="list-style-type: none"> Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked 	Does not meet the minimum criteria for a pass
Think analytically and offer creative solutions	<ul style="list-style-type: none"> Demonstrates critical reflection including an explanation of their thinking and quotes best practice Proposing and implementing workable solutions Articulates learning around decision making and solution formulation best practice in their working environment 	<ul style="list-style-type: none"> Able to apply scientific decision-making in different situations Capable of offering different scenarios for consideration when making a decision 	Does not meet the minimum criteria for a pass
Present and communicate	<ul style="list-style-type: none"> Goes beyond just presenting material on slides and provides personal reflection Presents persuasive arguments and recommends the optimal solution to the case study 	<ul style="list-style-type: none"> Demonstrates good presentation practice with a clear and well-structured presentation Presents logical arguments and information in the written report 	Does not meet the minimum criteria for a pass
Customer focus	<ul style="list-style-type: none"> Anticipates potential customers and their needs Understands the impact and consequences of failing to recognise customers and their needs Can define and demonstrate approaches to interacting with customers in order to reach optimal outcomes 	<ul style="list-style-type: none"> Recognises own customers and their needs 	Does not meet the minimum criteria for a pass

Annex 2B – Viva Voce Grading Criteria

Area of Standard	Distinction criteria: In addition to the pass criteria the Apprentice must meet the distinction criteria for at least 12 of the 16 areas of the standard.	Pass criteria: the Apprentice must display all of the following	Fail
The regulatory environment	<ul style="list-style-type: none"> • Can explain how the regulatory environment fits into the wider healthcare or animal health environment in which they work • Can identify the consequences and impact of failing to recognise and respond to changes in the regulatory environment in which they work • Articulates how new or future regulatory changes may have an impact on the work they do 	<ul style="list-style-type: none"> • Recognises the regulatory environment in which they work and the key organisations involved • Understands the changes occurring in the regulatory environment in which they work and upcoming changes that have been identified 	Does not meet the minimum criteria for a pass
The regulatory function throughout the product lifecycle	<ul style="list-style-type: none"> • Detailed understanding of how the regulatory function works within their business and how the work of other functions impacts on regulatory decision-making throughout the product life-cycle • Articulates how they optimised their working method in aligning project outcomes with other functions 	<ul style="list-style-type: none"> • Awareness of how decisions made by the regulatory function impacts on a product's life-cycle 	Does not meet the minimum criteria for a pass
Regulatory procedures	<ul style="list-style-type: none"> • Understand how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing 	<ul style="list-style-type: none"> • Demonstrates knowledge and compliance of the regulatory procedures in the area where they work • Can justify the choice of procedure they have made 	Does not meet the minimum criteria for a pass

Regulatory impact	<ul style="list-style-type: none"> Explains the impact of regulatory processes and new procedures on the whole business/organisation and key stakeholders outside of the business Articulates how future regulatory changes will impact the business environment they work within, including strategies for minimising impact. 	<ul style="list-style-type: none"> Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked 	Does not meet the minimum criteria for a pass
Manage and deliver multiple projects	<ul style="list-style-type: none"> Demonstrates evidence of taking leadership for multiple projects Demonstrates the use of basic project management tools and methods in delivering their projects Understands the consequences and impact of failing to meet the deliverables for their projects 	<ul style="list-style-type: none"> Demonstrates a knowledge of the different projects that they have worked upon and the key deliverables 	Does not meet the minimum criteria for a pass
Act decisively	<ul style="list-style-type: none"> Can explain their reasoning to reach a decision on a complex problem that includes reference to issues outside the areas covered by their area of responsibility Demonstrates the use of formal decision making or problem solving approaches in resolving major challenges within their projects 	<ul style="list-style-type: none"> Gives examples of decisions taken within their regulatory work and can explain how the decision was made 	Does not meet the minimum criteria for a pass
Influence and negotiate	<ul style="list-style-type: none"> Can provide evidence of when they have identified key stakeholders and brought them on board with decisions that have been proposed or made, or outcomes that have been reached 	<ul style="list-style-type: none"> Gives examples of where they have understood the opinions of others Explains how they have helped others to see a different point of view in order to reach a common solution 	Does not meet the minimum criteria for a pass

Manage and share knowledge	<ul style="list-style-type: none"> • Demonstrates proactive sharing of knowledge and the value of doing so. • Able to explain how they have used knowledge to help others understand an issue 	<ul style="list-style-type: none"> • Maintaining a structure to manage knowledge and data • Demonstrates how they have managed sensitivities around sharing knowledge and data 	Does not meet the minimum criteria for a pass
Using own initiative to contribute to a team	<ul style="list-style-type: none"> • Can explain how taking the initiative influenced the actions or behaviours of the team and how this positively impacted the overall success of the team 	<ul style="list-style-type: none"> • Gives examples of when they have used their own initiative in a team environment to positive effect 	Does not meet the minimum criteria for a pass
Work with IT platforms	<ul style="list-style-type: none"> • Can explain how they used databases and systems to achieve business goals – supports explanation with examples of impact on the business • Understands the impact and consequences of incorrect use of databases and systems 	<ul style="list-style-type: none"> • Explains how they used IT systems as directed to retrieve data and conduct analyses as needed 	Does not meet the minimum criteria for a pass
Integrity	<ul style="list-style-type: none"> • Can demonstrate a clear understanding of the importance and effects of integrity on a business and individual. • Can provide examples of when their integrity has been challenged and how they dealt with this. 	<ul style="list-style-type: none"> • Can explain the importance of integrity in their role 	Does not meet the minimum criteria for a pass
Accountability	<ul style="list-style-type: none"> • Demonstrates how they went beyond the level of accountability expected at the stage of development that they had reached, in a safe and appropriate way • Explains the impact if accountability is not clear and can provide examples of when they have taken on accountability to ensure a positive outcome 	<ul style="list-style-type: none"> • Outlining where they took accountability for a role within a key project • Can explain how they had multiple goals for which they were accountable and the role they took to achieve the goals 	Does not meet the minimum criteria for a pass

Independence	<ul style="list-style-type: none"> • Demonstrates autonomous thinking and when they should continue with their own thought processes with awareness of the limits of their responsibilities 	<ul style="list-style-type: none"> • Demonstrates where they have worked alone within a project and what they delivered 	Does not meet the minimum criteria for a pass
Commitment to personal development	<ul style="list-style-type: none"> • Able to critically reflect on self to identify development areas • Took responsibility for developing a plan/vision for further self-development • Can identify reliable sources of information to keep informed of future changes to regulation that affect their chosen field. • Demonstrates that they have sought feedback and guidance from a range of stakeholders on their areas of developmental needs 	<ul style="list-style-type: none"> • Recognises constructive feedback on their strengths and weaknesses and how best to use it to develop further 	Does not meet the minimum criteria for a pass
Compliance	<ul style="list-style-type: none"> • Proactive contribution to changes necessary to maintain compliance and understands consequences of non-compliance. • Explains how they shared knowledge to improve compliance in others 	<ul style="list-style-type: none"> • Demonstrates 100% compliance in company training programmes and with processes 	Does not meet the minimum criteria for a pass