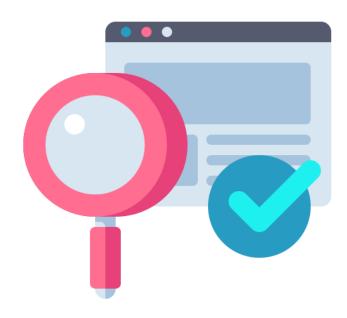openawards

EPA Handbook
ST0586 – Regulatory Affairs Specialist v1.4

EPA HANDBOOK

Version history

Version	Date	Change(s) made	Section(s)	Publication source(s)
1.0	October 2022	New document	All	
1.1	22 February 2023	Content and appendices included	All	RR, JB
1.2	28 Feb. 23	Appendix 6 added	Appendices	JB
1.3	2 May 23	Scrutiny check and redraft completed	All	SR
1.4	3 May 23	Queries resolved	All	RR

Contents

About Open Awards

Set up in 1981 as Open College Network North West Region (OCNNWR) and now trading as Open Awards, we have been in business for over 40 years. During that time, we have helped thousands of learners get started on the education ladder, return to learning, achieve qualifications to help their careers and progress into further and higher education.

We were the first awarding organisation to design qualifications and courses based on credit accumulation so that learners could achieve in bite-sized chunks. We designed the units and qualifications that became the basis of the Qualification and Credit Framework (QCF).

We are more than just another Awarding Organisation. Uniquely, we have deep roots in the education sector as forward-thinking organisations, FE Colleges and Local Authorities, created Open College Networks (OCNs) to promote education and achievement. We have a governance structure, which is drawn from the people who use our services – our providers and centres – so that we can truly say we are "of the sector and for the sector". Our purpose is to meet the needs of our provider organisations and their learners. We are a not for profit organisation and a registered charity and we use our funds to invest in our products and services to support the very organisations that use them.

Open Awards qualifications are approved by the regulators (Ofqual in England and CCEA in Northern Ireland) and are designed to meet the needs of learners and employers. The range of qualifications we offer is designed to meet the aspirations of learners who are seeking a stepping stone to their career, returning to learning or wishing to progress and build their skills and experience. We are constantly adding to our qualification portfolio to ensure that it is fresh and up to date.

We are delighted to have expanded our scope by becoming an end-point assessment organisation (EPAO) for a growing number of apprenticeship standards in England approved by the Institute for Apprenticeships and Technical Education (IfATE). Our EPAO number is: **EPA0565**

Occupational Overview

The Regulatory Affairs Specialist works within an organization to ensure all medicines for human or veterinary use and medical devices are appropriately licensed before being sold or supplied. They develop and implement strategies that allow a company to legally develop, manufacture, market and supply healthcare and/ or veterinary products.

A Regulatory Affairs Specialist is responsible for developing and implementing strategies that allow a company to legally develop, manufacture, market and supply healthcare and/ or veterinary products. The role critically evaluates the evidence generated during the development and use of the product for its suitability to support obtaining and managing marketing authorizations, CE marks and approvals for clinical studies in line with legal requirements. This role may be performed within an organisation that may range in size from innovative SME businesses to major multinational companies. A Regulatory Affairs Specialist may also work within service companies offering consultancy support to manufacturers or in the relevant competent authorities or Notified Bodies where they will be assisting in the review and assessment of regulatory and technical dossiers prior to issuing a licence.

Further details on the knowledge, skills and behaviours associated within the occupational standard are accessible on the IfATE website[1] and can also be found in Appendix 1.

Standard information

Level: 7

Reference: ST0586

Approved for delivery: 08 November 2018

Route: Health and science

Minimum duration to gateway: 30 months (this does not include the EPA period)

Employers involved in creating the standard: Victrex PLC, Brightwake, AstraZeneca, Vectura, TRAC services Ltd, Amgen, Galderma, BD, Norgine, Clinical Professionals, 3M, Amgen, SLE, Johnson and Johnson, Segulah Consulting, Pfizer, Bayer, NSF, Global Regulatory Services Limited

External Quality Assurance Provider: Ofqual

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[1] **https://www.instituteforapprenticeships.org/**

Entry requirements

Individual employers will set their own selection criteria, but entrants will typically already have a degree in science, engineering or law.

Progression opportunities

Apprentices who successfully achieve this apprenticeship could progress into the following job roles: Regulatory Associate, Strategist or Executive, Regulatory Affairs Manager, Regulatory Compliance Professional, Medical Device Competent Person.

Successful completion will enable the apprentice to become a Member or Registered Member (MTOPRA) of the professional body, The Organisation for Professionals in Regulatory Affairs (TOPRA) as appropriate, and to apply for professional registration as a Registered Scientist (RSci) through TOPRA or the Science Council, providing parity with other scientific professions.

On-programme requirements

A summary of the on-programme requirements for each apprentice is outlined below.

- Training to develop the knowledge, skills and behaviours (KSBs) of the occupational standard.

- Training towards English and mathematics Level 2, if required.

- Compilation of a Vocational Competence, Training and Development Log to outline the projects, training, development activities and performance reviews that the apprentice has undertaken during the apprenticeship period, mapped to the KSBs from the occupational standard (Appendix 1).

Registration, Gateway and Booking

Registration with Open Awards

Registration is the point at which an employer signals that it has selected Open Awards as their end-point assessment provider. Employers are encouraged to register their apprentices with Open Awards, through the training provider, as soon as possible. Our EPAO number is: **EPA0565**

Registrations can be made by providers via the EPA Section of Open Awards' Secure Portal. Early registrations enable Open Awards to initiate early dialogue to ensure arrangements can be planned, such as assessor availability, to ensure end-point assessment is delivered as smoothly as possible in a timescale that supports the employer's planned gateway date. It also enables the training provider to access a range of practice and preparation materials, so they and the employer can support the apprentice to prepare for end-point assessment.

Please note that Open Awards are only able to accept registrations from training providers who are currently on the Register of Approved Training Providers (RoATP).

In line with the Education & Skills Funding Agency's (ESFA) requirements, the employer must inform Open Awards of the planned gateway and end-point assessment dates at least three (3) months in advance.

Gateway

Gateway is the point at which the employer reviews their apprentice's knowledge, skills and behaviours, and formally confirms the apprentice has reached occupational competency, completed all the mandatory elements of their apprenticeship programme and are ready for end-point assessment. The training provider may support the employer in making this decision, but the decision is made by the employer, with the apprentice also confirming they are ready for end point assessment.

End-point assessment must be completed by an independent End-point Assessment Organisation (EPAO) selected by the employer, such as Open Awards, from the ESFA's Register of End Point Assessment Organisations (RoEPAO).

The end-point assessment period should only start, and the end-point assessment arrangements confirmed, when:

- the employer is satisfied that the apprentice is consistently working at or above the level of the occupational standard
- all of the pre-requisite gateway requirements for EPA have been met and that they can be evidenced to Open Awards

For this standard, end-point assessment must be completed within a period lasting a maximum of six (6) month(s), beginning when the apprentice has met the end-point assessment gateway requirements.

Gateway requirements

The training provider must provide Open Awards with all required evidence to enable Open Awards to undertake the necessary gateway checks. This evidence includes:

- a fully completed and signed Gateway Agreement and Authenticity Form.
- apprentices without English and mathematics at Level 2 must achieve Level 1 English and mathematics and take the tests for Level 2. The ESFA maintains a list of current and prior qualifications accepted as meeting the minimum English and maths requirements for apprenticeships at Level 2 and above. The most current list can be found on the ESFA website[2]. For those apprentices with an education, health and care plan or a legacy statement the apprenticeships English and mathematics minimum requirement is Entry Level 3 and British Sign Language qualifications are an alternative to English qualifications for whom this is their primary language.
- apprentices must have completed the minimum apprenticeship on-programme duration (typically 30 months from the start date).
- for this standard, apprentices are also required to have completed a portfolio (Vocational Competence, Training and Development Log).
- Apprentices must have successfully completed periodic on programme assessments and have employer agreement that the apprentice is ready for their end point assessment.

Open Awards cannot accept end-point assessment booking requests until the gateway checks have been satisfactorily completed, so failure to submit all the necessary information or evidence will delay this process. Open Awards will contact the training provider if the information or evidence is missing or insufficient, so that this can be rectified as quickly as possible. Open Awards aims to complete gateway checks within five (5) working days from receipt of the gateway declaration and authenticity form, subject to provision of all necessary information and ancillary evidence.

Once gateway checks have been successfully completed, Open Awards will confirm provisional bookings or schedule subsequent bookings.

Booking

Bookings can be made by providers via the EPA Section of Open Awards' Secure Portal. As per ESFA guidance, Open Awards requires at least three (3) months advance notice of the potential gateway date. However, training providers may make

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[2] **https://www.gov.uk/government/publications/english-and-maths-requirements-in-apprenticeship-standards-at-level-2-and-above**

provisional bookings at any point following Open Awards acceptance of an apprentice registration.

Open Awards will endeavour to accept and schedule bookings for end-point assessment to meet the expressed preference dates of the employer wherever possible. However, any provisional booking cannot be confirmed or scheduled by Open Awards until gateway checks have been successfully completed.

Post-gateway, Open Awards normally require a minimum of 10 workings days' notice when provisionally booking an assessment.

Cancelling or rescheduling a booking

Provisional bookings can be re-scheduled or cancelled by providers via the EPA Section of Open Awards' Secure Portal. Confirmed bookings **up to 10 working days** before the assessment day can be re-scheduled at no charge. Confirmed bookings cancelled or re-scheduled with **less than 10 working days'** notice will incur a charge in line with Open Awards fees policy[3].

Assessment plan version

Open Awards will undertake end-point assessment in line with the requirement of the current version of the assessment plan or in line with IfATE directions. Training providers and employers must contact Open Awards to discuss any instance where they believe it is appropriate for assessment to be undertaken in line with a historic/ previous version of the assessment plan. Because Open Awards may need to liaise with either IfATE or the External Quality Assurance Provider to determine whether this is allowable, training providers and employers should be aware this may delay the ability of Open Awards to undertake end-point assessment until resolved.

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[3] Available on the Open Awards Secure Portal **https://portal.openawards.org.uk/Login.aspx**

Identification checks

Open Awards requires the apprentice to present photographic identification to an Open Awards invigilator or assessor immediately prior to each assessment on each assessment day. This is a requirement to ensure Open Awards can confirm an individual completing an assessment is the person they are claiming to be.

The following are acceptable forms of evidence of an apprentice's identification:

- a valid passport (any nationality)
- a signed UK photo card driving licence
- valid warrant card issued by HM Forces or the Police
- other photographic ID card, e.g., employee ID card (must be current employer), student ID card, travel card
- UK biometric residence permit.

Where this identification is not available to be checked, the assessment will not be allowed to commence.

Where an apprentice does not have access to the necessary identification or where the name on the identification does not match the name registered with Open Awards, the training provider must contact Open Awards to arrangement alternative or additional authentication checks to be made.

Data Management

Open Awards has a responsibility under the Data Protection Act to ensure that learners and apprentices are informed of how their information is processed and shared.

Open Awards collects and processes personal learner information for the purpose of: registering learners and apprentices, and awarding learner and apprentice achievements; exercising its functions; and meeting its responsibilities, both statutory and otherwise.

Further information on the personal data and information shared with Open Awards and how we use it and who we share it with can be found in the Privacy Notice: Learner Information which is on the Open Awards website.

Whilst we endeavour to collect only that data for which there is a legal or sound business requirement and to ensure the integrity of the data, we strongly encourage customers to contact us if you believe any data to be incorrect.

Any concerns can be sent to Open Awards by emailing
enquiries@openawards.org.uk

In compliance with ESFA Conditions for being on the register of end-point assessment organisations, Open Awards must retain information about the EPAs undertaken and payment received for six (6) years after the activity took place. This will include details of what assessments were undertaken, against which versions of the standard and assessment plan, when and by whom, along with assessment outcomes and evidence of the internal quality assurance of those assessments. Open Awards is also required to share end-point assessment information with the External Quality Assurance Provider to ensure they are able to undertake their regulatory role. The External Quality Assurance Provider for this standard is Ofqual.

For the purposes of the Data Protection Act and General Data Protection Regulation (GDPR) 2018, Open Awards is the data controller for personal information processed by the organisation.

Assessment

The EPA consists of two assessment methods which are individually graded:

- project showcase, based on a case study, including report, presentation and questioning
- viva voce (synoptic).

Assessment preparation

Assessment specifications (Appendix 3) and assessment records (Appendices 8-9) are available to support training providers and employers post-gateway to ensure apprentices are well prepared for their EPA experience.

Order of assessment methods

The assessment methods can be completed in any order.

Assessment window

The EPA must be completed within a six month period, after the apprentice has met the EPA gateway requirements. Therefore, training providers and employers should ensure that assessments are planned and booked to ensure this timescale can be met.

Project Showcase (based on a case study, including report, presentation and questioning)

Overview

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 Open Awards 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.
- the apprentice's overall approach to the regulatory needs.
- the apprentice's main findings.
- how the apprentice dealt with any issues.
- the key outcomes of the case study and recommendations.
- the lessons learned from the case study.

Apprentices must complete and submit a report based on the case study to Open Awards. 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. The questioning will focus 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 and grading criteria.

Preparing for the Project Showcase Report

After the employer has submitted the apprentice's Gateway evidence to Open Awards and Open Awards has completed the Gateway checks (typically up to 5 days), Open Awards will provide the apprentice with a 'pack' of three (3) case studies.

The apprentice must choose one of these case studies to form the basis for their project showcase report and presentation. The report must be submitted to Open Awards within 10 weeks of the apprentice being provided with case study details so that this can be reviewed by an independent assessor.

Assessment conditions for the project showcase report

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. The apprentice must sign an authenticity statement confirming that their work was produced solely by the apprentice and is current (Appendix 7).

Preparing for the presentation and questioning

The employer must book a slot for the presentation with questions section of this assessment method with Open Awards delivery team to ensure time windows and resources can be reasonably allocated to meet the needs of all parties. This should be a minimum of 3 weeks following the assessor's receipt of the report, so that the apprentice can be given at least 3 weeks' notice of the time, date and venue for the presentation and questioning,

Any technical requirements that apprentices may have for the presentation, such as use of PowerPoint and/or other presentation aides e.g., handouts, must be agreed with Open Awards in advance.

Assessment conditions for the presentation and questioning

The IEPA will assess the apprentice's presentation and analytical skills, as well as the other KSBs and grading criteria set out in Appendices 1 and 2, exploring 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 assessor's discretion) and the questioning must be for a duration of 25 minutes (+10% at the assessor's discretion).

Apprentices may use PowerPoint and presentation aides e.g., handouts as they see fit (as stated above, this must be agreed with Open Awards in advance).

The IEPA will ask open questions guided by a question bank provided by Open Awards, with possible follow up questions used for clarification. Questions are **not** predetermined: 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 will be recorded by the IEPA (using written, audio or video recording); a copy of the report, the recording and any presentation material must be retained for quality assurance purposes.

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 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 (Appendix 1). A suggested format for the log can be seen in Appendix 4, which includes notes on how to use it. The log should **not** include any reflective self-assessment.

Open Awards must receive a copy of the Vocational Competence, Training and Development Log within two weeks of the start of the end-point assessment period to provide sufficient time for the IEPA to review its content. The content of the log will be reviewed by the IEPA to prepare areas for discussion based on the KSBs to be assessed by this assessment method.

Viva Voce

Overview

The viva voce takes place between the apprentice and their IEPA. The IEPA will 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 and which can determine their performance against the grading criteria for this assessment method (Appendix 2).

Preparing for the viva voce

The employer must book a slot for the viva voce with Open Awards delivery team to ensure time windows and resources can be reasonably allocated to meet the needs of all parties. Apprentices should be given at least 3 weeks' notice of the time, date and venue for the viva voce.

Assessment conditions

Open Awards will provide the independent assessor (IEPA) with a series of topic areas and sample questions for discussion based on the areas of the standard to be assessed as set out in Appendix 1. This will enable the apprentice to demonstrate their depth of understanding to determine their performance against the grading criteria.

The viva voce must be completed in a period of 45 minutes (+ 10% at the assessor's discretion) and should be recorded electronically by the IEPA using audio or video recording; a copy of this recording will be retained for quality assurance purposes.

The viva voce must take place in a suitably controlled environment i.e., in a quiet space, free from distraction. Apprentices may refer to their Vocational Competence, Training and Development Log when answering the questions.

IEPAs will assess the viva voce using the grading criteria in Appendix 2.

Independent assessment

The independent end-point assessor (IEPA) will meet or exceed the qualification requirements set out in the assessment plan associated with the standard and be independent of the apprentice, their employer and training provider(s) i.e., there will be no conflict of interest. This IEPA makes the final decisions on the individual assessment method grades and on the overall grade. These decisions are subject to moderation and/ or verification through Open Awards internal quality assurance processes.

Grading

Mapping of KSBs against assessment methods
Appendix 1 maps the individual KSBs to each assessment method.

Aggregation of individual assessment grades into an overall grade
EPAOs will individually grade each assessment method, fail, pass or distinction, according to the requirements set out in the assessment plan. An independent assessor will 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.

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

Reasonable Adjustments and Special Considerations

Open Awards is committed to ensuring access to fair assessment for all learners and to protecting the integrity of assessments and qualifications.

There may be circumstances whereby arrangements need to be made to take account of particular learners' requirements in order to ensure that this is achieved without giving any unfair advantage over other learners.

The Reasonable Adjustments and Special Considerations Policy and Procedures, sets out the principles which should be followed when making decisions about adjustments to assessment. It outlines Open Awards' reasonable steps to ensure it avoids disadvantage (directly or indirectly) in line with the requirements of The Equality Act 2010 (Disability) Regulations 2010. The policy and procedures are accessible through the Open Awards Secure Portal

Reasonable Adjustments

Any action that helps to reduce the effect of a disability or difficulty that places a learner at a substantial disadvantage in the assessment situation. Reasonable adjustments are adjustments made to an assessment for a qualification to enable a disabled learner to demonstrate his or her knowledge, skills and understanding to the levels of attainment required by the specification for that qualification.

Reasonable adjustments must not affect the reliability or validity of the assessment outcomes but may involve:

> • changing the usual assessment arrangements, e.g., allowing a learner extra time to complete an assessment activity

> • adapting assessment materials e.g., by providing large print or providing materials in Braille

> • providing assistance during an assessment e.g., by providing a trained signer, interpreter or a reader

> • changing the assessment method e.g., from a written assessment to a spoken assessment

> • using assisted technology such as screen reading, or a voice activated software.

Reasonable adjustments must be approved and set in place before the assessment takes place. The work produced by the learner will be assessed in the same way as all other learners.

Where the employer and training provider believe reasonable adjustment(s) may be required, this can be identified at the registration stage. Open Awards requires a minimum of 90 days' notice of any request for reasonable adjustments so this can be considered and where approved, arrangements made.

Special Considerations

Adjustments which may be applied after an assessment where the learner has encountered exceptional circumstances that have disadvantaged them during their assessment.

The assessment plan for the apprenticeship standard defines permissible special considerations and the circumstances surrounding the apprentice's end-point assessment that fall within this definition.

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Cancellations or Rescheduled Assessments

Cancellation by the apprentice, training provider or employer

Provisional bookings can be re-scheduled or cancelled at no charge. Confirmed bookings can be re-scheduled at no charge **up to 10 workings days** before the assessment day.

Confirmed bookings cancelled or re-scheduled with **less than 10 workings days'** notice will incur relevant costs associated to the booking.

The 5% apprentice registration fee is non-refundable regardless of withdrawal date.

Cancellation by Open Awards

In the unlikely event that a confirmed booking must be cancelled by Open Awards, it will be rescheduled as soon as possible for a mutually convenient time. There will be no additional charges associated with the rescheduled assessment.

Confirmation of results

Assessment results will be made available to providers via the EPA Section of Open Awards' Secure Portal. Results of assessment will normally be provided to the training provider **within 10 working days** of the assessment being undertaken.

Resits and Retakes

Open Awards provides resit and retake opportunities in line with ESFA requirements unless the assessment plan associated with the apprenticeship contains alternative requirements.

Apprentices who fail one or more assessment method will be offered the opportunity to take a resit or a retake. Open Awards will provide feedback alongside the result notification to all apprentices who fail an assessment method. This feedback will be provided via the training provider, normally **within 10 workings days** of the assessment taking place.

Where the result notification suggests a retake may be appropriate, the ESFA recommend the employer and training provider consider a supportive action plan that responds to the performance weaknesses identified within the feedback. This action plan should clearly state the nature and extent of the re-training and include the estimated time to prepare the apprentice for the retake. When a retake is booked, Open Awards will require confirmation from the training provider that the apprentice has received further training and is ready to be assessed.

A resit involves the apprentice attempting one or more failed assessment components again, without the need to undertake further training.

Open Awards normally require a **minimum of 10 workings days'** notice when booking a resit or a retake. The exception is the online knowledge test when **five (5) workings days'** notice is required.

The number of resits and retakes that can be taken by an apprentice will normally be at the discretion of the employer. The ESFA recommends a limit of two (2) resits or retakes, however, more than two (2) resits or retakes may be taken if available, or unless otherwise specified or limited within the assessment plan.

Resits or retakes are only to be taken in the event of a failure. A resit or retake cannot be taken with the intention of increasing the original grade if an apprentice has passed their EPA. Therefore, feedback will not normally be provided to apprentices who achieve a pass or higher.

The maximum grade that can be achieved for a resit or retake is a pass, unless Open Awards has determined there are exceptional circumstances. Where an

apprentice believes exceptional circumstances impacted on their initial assessment attempt, they must submit a formal request with supporting evidence for exceptional circumstances to be considered, directly to Open Awards **within five (5) working days** of receiving the assessment decision.

The same IEPA who undertook the initial assessment attempt may be allocated by Open Awards to assess an apprentice's resit or retake. This may be a requirement of the assessment plan. The allocation of IEPAs to assessments will be taken by Open Awards based upon the requirements of the assessment plan or operational considerations.

Appeals and Complaints

Open Awards is committed to ensuring that all assessment decisions are consistent, fair and based on valid judgements made by independent assessors.

If an apprentice is satisfied with their result but seeks information as to why a specific grade was awarded, they can request formal feedback through their training provider. This feedback will be limited to justification of the decision and will not be developmental in nature (i.e., indicate how they may have achieved a higher grade). This feedback may take **up to 20 working days** to be provided. Further details are available from Open Awards.

If an apprentice is not satisfied with their result, they can request an enquiry about results which is an informal appeal. Open Awards will review the documentation for administrative errors and correct these if identified. An enquiry about results must be made by the apprentice **within 10 working days** of notification of the results concerned.

Alternatively, or after an enquiry about results, if an apprentice is not satisfied with their result, they may lodge an appeal. Appeals can be made by the training provider on behalf of the apprentice, but they must have the permission of the apprentice to do this.

Appeals made in respect of the final overall grade will result in a delay to the completion certificate being requested by Open Awards. For further details regarding the process, timelines and fees, please refer to Open Awards' Enquiries and Appeals Policy and Procedures which can be found on the Portal.

Completion and Certification

Open Awards will issue a summary of results following successful completion of all EPA assessments. This will be issued to the apprentice via the provider and show the grade associated with each assessment, alongside the overall grade and the date this was awarded.

Open Awards will also request the apprenticeship completion certificate from the IfATE on behalf on an apprentice once they have completed their apprenticeship. As part of the gateway declaration form an apprentice is required to give Open Awards permission to do this on their behalf. Without this permission Open Awards is unable to claim the certificate.

Open Awards will request the certificate once the apprentice has received and agreed the final grade. Where the apprentice does not formally agree the final grade, Open Awards will assume it is agreed once the window for an enquiry about results or appeal is extinguished (**10 working days** from the notification of results). Requests for the certificate are then made **within 20 working days** and in most instances, sooner. IfATE normally send the completion certificate directly to the employer by recorded delivery; this can take **up to 15 working days** to arrive from the date it is requested.

Quality Assurance

Internal quality assurance

Quality assurance is at the heart of Open Awards' practices, and we follow suitably rigorous processes to ensure that the integrity of our assessments is maintained.

Internal quality assurance is the process of reviewing and evaluating assessment practices and decisions to ensure that:

- an identified individual is responsible for coordinating internal quality assurance processes
- there are clear and documented roles and responsibilities for all those involved
- all learners are assessed accurately, fairly and consistently to the right standard
- internal quality assurance is structured and incorporates all of the requirements set out in the assessment plan associated with the apprenticeship standard
- assessment tasks and learner work are sampled appropriately
- good practice is promoted through internal standardisation events and quality assurance meetings
- decisions are supported by full and clear records and action plans that are followed
- internal processes are transparent and regularly evaluated.

External Quality Assurance

External quality assurance for this apprenticeship standard is undertaken by Ofqual.

Maladministration and Malpractice

Maladministration is defined as any activity, neglect, default or other practice that results in an apprentice, training provider or employer not complying with the specified requirements for delivery of end-point assessment.

Malpractice is any act, default or practice which:

- compromises, attempts to compromise, or may compromise, the process of assessment/ examinations, the integrity of any end-point assessment activity or the validity of an assessment result or certificate, including maladministration
- damages the authority, reputation or credibility of Open Awards or any officer or employee
- involves a failure by an apprentice, training provider or employer to provide Open Awards with such necessary information as required to enable it to investigate allegations of suspected malpractice also constitutes malpractice.

An apprentice, training provider or employer must report any allegation of suspected malpractice/ maladministration to Open Awards. Failure to report allegations of malpractice/ maladministration can lead to assessment results not being conferred and certification claims not being processed, and future registrations not being accepted.

Further information is available within Open Awards' Malpractice and Maladministration Policy and Procedures, including how Open Awards will manage alleged or suspected malpractice or maladministration.

Where Open Awards is satisfied on the balance of probabilities that an allegation is substantiated, it reserves the right to impose a range of sanctions on an apprentice and/ or training provider and/ or an employer, depending on the seriousness of the situation and the risk to the interests of learners and the integrity of the end-point assessment and the effect on public confidence in Open Awards. Further information can be found within Open Awards' Sanctions Policy.

Open Awards will ensure that in most cases alleged malpractice is kept confidential between itself and those directly impacted. However, in cases of serious malpractice, Open Awards may exchange information with the regulators, other end-point assessment organisations and other appropriate authorities.

Open Awards Policies and Procedures

Current versions of the following Open Awards policies and procedures, relevant to end point assessment are accessible to training providers through the Secure Portal. Employers and apprentices can obtain copies from the relevant training provider or can be obtained directly by contacting Open Awards.

- End Point Assessment Pricing Policy
- Reasonable Adjustments and Special Considerations Policy
- Data protection
- Enquiries and Appeals Policy and Procedures
- Complaints Policy
- Malpractice and Maladministration Policy and Procedures
- Equality and Diversity Policy
- Sanctions Policy
- Safeguarding Policy
- Conflict of Interest Policy
- Fair Access Policy

In addition, the current version of the following relevant document may be obtained by training providers, employers or apprentices by contacting Open Awards directly:

- Instructions for Conducting Controlled Assessment Remotely

Open Awards recommends that local copies of policies and procedures are not made and referred to as these may not be current.

Fees and Charges

Open Awards standard fees and charges for end-point assessment, including resists and retakes are set out the schedule of fees. The current schedule can be found on the Open Awards' website.

Support

The Open Awards web site **www.openawards.org.uk** is the best source for general information with full listings of our qualifications, news, events, assessment information, policies, and details of our support services.

Support materials and sample assessments for the simulated observation and the professional discussion can be accessed via Open Awards' Secure Portal. A sample online knowledge test is accessible via the XAMS platform. Training providers should contact Open Awards directly to secure access to this resource.

In addition, our experienced customer service team can be contacted on 0151 494 2072 or via email **enquiries@openawards.org.uk.**

Glossary

Assessment	The process of making judgements about the level of occupational proficiency an apprentice can demonstrate when measured against the knowledge, skills and behaviours set out in the standard.
Assessment Criteria	Assessment criteria describe what a learner should be able to do in order to demonstrate competence (i.e., pass).
Authentic	Evidence must be the apprentice's own work.
Completion Certificate	The certificate issued by IfATE which demonstrates an apprentice has successfully completed their apprenticeship.
Diversity	Acknowledging that each individual is unique and recognising individual differences, e.g., culture, ability, gender, race, religion, wealth, sexual orientation, or any other individual characteristic.
EQA	External Quality Assurance
Equality	Fair treatment for all regardless of differences, e.g., culture, wealth, race, gender, ability, sexual orientation or any other group characteristic.
Evidence	How an apprentice demonstrates knowledge, skills or behaviour that can be used to make a judgment of achievement against criteria.
Fair	Ensuring that everyone has an equal chance of getting an objective and accurate assessment.
Gateway	The point at which the employer decides the apprentice is occupationally competent and ready to undertake end-point assessment.
Holistic	Holistic assessment is identifying how evidence can relate to and be cross referenced to other units rather than taking a unit by unit approach.
Independent assessment	Assessment decisions made by an assessor and end-point assessment organisation who have no relationship with the apprentice, training provide or employer and therefore, have no interest in the assessment result.
Independent end-point assessor (IEPA)	The assessor who assesses the apprentice during end-point assessment.
IQA	Internal Quality Assurance.
Learning Outcomes	Learning outcomes describe what an apprentice should know and understand by the end of a unit.

Reliable	Reliable evidence indicates that the apprentice can consistently perform at this level. A reliable method of assessment will produce consistent results for different assessors at each assessment.
Simulation	Where simulation is allowed it must replicate working activities in a realistic workplace environment. A realistic working environment is one which replicates what is likely to happen when an individual is carrying out their normal duties and activities at their employer's premises.
Sufficient	Enough evidence as specified in Evidence Requirements or Assessment Strategy.
Valid	Evidence must be relevant to the learning outcome and assessment criteria i.e., capable of measuring the knowledge or skills in question. For example, a written test cannot measure a candidate assessor's ability to provide feedback to learners.
XAMS	The Open Awards platform used for online assessments and tests.

Appendix 1 Knowledge, Skills and Behaviours (to be assessed by each assessment method)

Project Showcase KSBs

Core Knowledge	
KSB reference	**KSB content**
The regulatory environment (related to the case study)	
K1.1	The regulatory environment in which they work, the organisations involved and how legislation is developed.
K1.2	The differences and similarities between the major regulatory environments, be they sectoral (e.g., medicines or devices) or geographic (e.g., UK, EU or other regions).
K1.3	Potential and actual future developments in the regulatory environment and their implications.
The evidence for regulatory decision making: science, content and structure	
K3.1	The fundamentals of drug and device development and the regulatory requirements.
K3.2	The importance of Good Manufacturing, Laboratory and Clinical Practice and Quality Systems.
K3.3	The need for scientific data (for example clinical evaluation or toxicology), its evaluation, interpretation and drawing conclusions.
K3.4	The identification of gaps in data, their implications and proposing solutions.
K3.5	The rationale for the choice of scientific technique, procedures and methods used.
K3.6	The requirements for clinical development and the conduct of clinical trials.
K3.7	The content and structure of the regulatory documentation and technical files.
K3.8	The importance of product information (for example labelling and patient information) and identification
K3.9	The differences in the regulatory documentation between major regulatory markets.
K3.10	How the benefit/risk of a product is determined.
Regulatory procedures (related to the case study)	
K4.1	The theory and practical reality of different regulatory procedures.
K4.2	The strategy for choosing and using the different regulatory procedures and product classifications.
Regulatory impact (related to the case study)	
K5.1	The impact of regulatory decision-making on the business, patients and future developments.
K5.2	Scientific progress in areas of interest.
K5.3	The roles and responsibilities of themselves and other stakeholders and how they interact in the delivery of healthcare.

Core Skills	
KSB reference	**KSB content**
Think analytically	
S4.1	Engage in research and the evaluation of data to assess its suitability to support risk and safety arguments in a structured and logical manner; alert stakeholders to gaps in evidence.
S4.2	Create and offer alternative approaches to mitigate and manage risk where required.
S4.3	Manage the development and application of evidence-based strategies for operational plans.
S4.4	Demonstrate self-direction and originality in problem solving, practise with a high level of autonomy.
Present and communicate	
S5.1	Develop and deliver high level materials that present and communicate complex research information and data analyses to a wide variety of audiences in different settings and through multiple media.
S5.2	Written and oral communication that is effective when influencing, negotiating, facilitating and resolving conflicts in risk and safety management with stakeholders.
S5.3	Develop and deliver management level presentations which resonate with senior stakeholders, both business and technical.

Core Behaviours	
KSB reference	**KSB content**
Customer focus	
B6.1	A commitment to meeting the needs of all stakeholders within and outside the organisation in the best interests of the end user and/ or patient.

Viva Voce KSBs

Core Knowledge	
KSB reference	**KSB content**
The regulatory environment (the wider environment beyond the case study)	
K1.1	The regulatory environment in which they work, the organisations involved and how legislation is developed.
K1.2	The differences and similarities between the major regulatory environments, be they sectoral (e.g., medicines or devices) or geographic (e.g., UK, EU or other regions).
K1.3	Potential and actual future developments in the regulatory environment and their implications.
The regulatory function throughout the product lifecycle	
K2.1	The role and importance of the Regulatory Affairs function and how it fits into the product lifecycle.
K2.2	The optimum development pathway which may include expedited pathways.
K2.3	Regulatory strategy (in a global environment).
K2.4	How to enable successful interactions between the relevant regulatory authorities and industry.
K2.5	The importance of other key functions such as quality management systems, risk assessment, health economics, marketing, commercial, their product lifecycle expectations and the impact on patient access to products.
K2.6	The post-marketing requirements.
K2.7	The requirements and procedures for product lifecycle management.
K2.8	The importance of vigilance/ pharmacovigilance and risk management.
K2.9	Quality and compliance standards.
Regulatory procedures (beyond the case study)	
K4.1	The theory and practical reality of different regulatory procedures.
K4.2	The strategy for choosing and using the different regulatory procedures and product classifications.
Regulatory impact (beyond the case study)	
K5.1	The impact of regulatory decision-making on the business, patients and future developments.
K5.2	Scientific progress in areas of interest.
K5.3	The roles and responsibilities of themselves and other stakeholders and how they interact in the delivery of healthcare.

Core Skills	
KSB reference	**KSB content**
Manage and deliver multiple projects	
S1.1	Simultaneously coordinate and plan multiple activities/projects in a highly regulated environment, ensuring completion to time, within budget and to an acceptable quality.

S1.2	Deal with complex issues both systematically and creatively.
Act decisively	
S2.1	Seek and use evidence-based strategies to take decisions in the absence of complete data and in complex and unpredictable situations impartially, fairly and on merit, without bias in an open and transparent manner.
S2.2	Recognise when it is appropriate to refer the decision.
S2.3	Think critically, take accountability and lead decision making processes, outlining any omissions and justifications of the decisions taken.
Influence and negotiate	
S3.1	Recognise negotiation strategies and use them with direct and diplomatic approaches, obtaining and maintaining the trust and respect of other stakeholders whilst managing complex interdependencies.
Manage and share knowledge	
S6.1	Research and organise data from various sources, storing the results in a way that optimises retrieval.
S6.2	Develop and manage a network of contacts to share appropriate information and advice.
S6.3	Know when to share information and who to share it with.
S6.4	Use knowledge to improve the efficiency of work where possible.
Using own initiative to contribute to a team	
S7.1	Work autonomously on specific areas of responsibility, in particular leading the development and implementation of the regulatory strategy, whilst interacting with colleagues to contribute to the delivery of project outcomes, recognising the contribution of other functional team members.
Work with IT platforms	
	Select and use appropriate and required IT systems in support of the regulatory function.

Core Behaviours	
KSB reference	KSB content
Integrity	
B1.1	Value honesty, act and take decisions in accordance with the law and corporate objectives.
B1.2	Recognise and respect confidentiality.
B1.3	Understanding and respect for the rights and protection of participants (human and animal) in the development process.
Accountability	
B2.1	Openness to the scrutiny of others to ensure accountability for the decisions or actions taken and the identification of lessons learnt.
B2.2	Take personal responsibility for working professionally.
B2.3	Meeting business needs through leading and managing regulatory deliverables for assigned projects.
Independence	
B3.1	Work autonomously, recognising when it is appropriate to seek input from management or others, contribute and communicate effectively within a wide, multi-disciplinary team.

Commitment to personal development	
B4.1	Take leadership to define and commit to personal development by developing their scientific and regulatory knowledge as the environment evolves.
B4.2	Ensuring an understanding of how developments in science, medicine, healthcare, and regulation will impact on future regulatory strategies and data requirements.
B4.3	Demonstrate the independent learning ability required for continuing professional development including critical reflection.
Compliance	
B5.1	A positive attitude to compliance, influencing colleagues to be compliant and speaking up if errors or potential problems are identified.

Appendix 2 Grading Criteria

Appendix 2A Project Showcase Grading Criteria

Area of Standard	Pass criteria: *The apprentice must display all of the following*	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.*	Fail
The regulatory environment	• 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.	• 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.	Does not meet the minimum criteria for a pass
The evidence for regulatory decision making: science, content and structure	• 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.	• 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.	Does not meet the minimum criteria for a pass
Regulatory procedures	• Demonstrates knowledge and compliance of the regulatory procedures in the area where they work. • Can justify the choice of procedure they have made.	• Understands how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing.	Does not meet the minimum criteria for a pass

Regulatory impact	• Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked.	• 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	Does not meet the minimum criteria for a pass
Think analytically and offer creative solutions	• Able to apply scientific decision-making in different situations. • Capable of offering different scenarios for consideration when making a decision.	• 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.	Does not meet the minimum criteria for a pass
Present and communicate	• Demonstrates good presentation practice with a clear and well-structured presentation. • Presents logical arguments and information in the written report.	• Goes beyond just presenting material on slides and provides personal reflection. • Presents persuasive arguments and recommends the optimal solution to the case study.	Does not meet the minimum criteria for a pass
Customer focus	• Recognises own customers and their needs.	• 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.	Does not meet the minimum criteria for a pass

Appendix 2B Viva Voce Grading Criteria

Area of Standard	Pass criteria: *The apprentice must display all of the following*	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.*	Fail
The regulatory environment	• 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.	• 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.	Does not meet the minimum criteria for a pass
The regulatory function throughout the product lifecycle	• Awareness of how decisions made by the regulatory function impacts on a product's life-cycle.	• 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.	Does not meet the minimum criteria for a pass
Regulatory procedures	• Demonstrates knowledge and compliance of the regulatory procedures in the area where they work. • Can justify the choice of procedure they have made.	• Understand how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing.	Does not meet the minimum criteria for a pass
Regulatory impact	• Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked.	• Explains the impact of regulatory processes and new procedures on the whole business/organisation and key stakeholders outside of the business.	Does not meet the minimum criteria for a pass

		• Articulates how future regulatory changes will impact the business environment they work within, including strategies for minimising impact.	
Manage and deliver multiple projects	• Demonstrates a knowledge of the different projects that they have worked upon and the key deliverables.	• 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.	Does not meet the minimum criteria for a pass
Act decisively	• Gives examples of decisions taken within their regulatory work and can explain how the decision was made.	• 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.	Does not meet the minimum criteria for a pass
Influence and negotiate	• 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.	• 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.	Does not meet the minimum criteria for a pass
Manage and share knowledge	• Maintaining a structure to manage knowledge and data. • Demonstrates how they have managed sensitivities around sharing knowledge and data.	• 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.	Does not meet the minimum criteria for a pass

Using own initiative to contribute to a team	• Gives examples of when they have used their own initiative in a team environment to positive effect.	• 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.	Does not meet the minimum criteria for a pass
Work with IT platforms	• Explains how they used IT systems as directed to retrieve data and conduct analyses as needed.	• 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.	Does not meet the minimum criteria for a pass
Integrity	• Can explain the importance of integrity in their role.	• 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.	Does not meet the minimum criteria for a pass
Accountability	• 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.	• 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.	Does not meet the minimum criteria for a pass
Independence	• Demonstrates where they have worked alone within a project and what they delivered.	• Demonstrates autonomous thinking and when they should continue with their own thought processes with awareness of the limits of their responsibilities.	Does not meet the minimum criteria for a pass

Commitment to personal development	• Recognises constructive feedback on their strengths and weaknesses and how best to use it to develop further.	• 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.	Does not meet the minimum criteria for a pass
Compliance	• Demonstrates 100% compliance in company training programmes and with processes.	• Proactive contribution to changes necessary to maintain compliance and understands consequences of noncompliance. • Explains how they shared knowledge to improve compliance in others.	Does not meet the minimum criteria for a pass

Appendix 3 Assessment Specifications

ST0586	Assessment requirements
Project Showcase	Comprises of: • a **4000-word report** to be submitted within **10 weeks** of the apprentice receiving the case study details • a presentation which should last **20 minutes** (+10% at the assessor's discretion) and then questioning which should last **25 minutes** (+10% at the assessor's discretion). This assessment will be recorded. Online and undertaken in-person or remotely using video conferencing or MS Teams / Zoom. The report: • the report must be submitted to Open Awards, 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. The presentation: • will explore the apprentice's ability to apply what they have learnt to their case study. • must be for a duration of **20 minutes** (+10% at the assessor's discretion). • may be delivered via PowerPoint and presentation aides e.g., handouts as they see fit; technical requirements must be agreed with Open Awards in advance. • questioning must be for a duration of **25 minutes** (+10% at the assessor's discretion). • questioning must consist of open questions, with follow up questions allowed for clarification. • 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. Fail: the apprentice did **not** meet all the pass criteria Pass: the apprentice achieved all the pass criteria Distinction: the apprentice achieved all the pass **and 5** out of **7** of the distinction criteria

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.
45 minutes duration (+10% at the assessor's discretion)	Requirements are as follows: • 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. • the viva voce must seek to assess the depth of understanding to determine performance against the grading criteria. • 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 the assessment plan. • 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. Fail/ Pass/ Distinction Fail: the apprentice did not meet all the pass criteria Pass: the apprentice achieved all the pass criteria Distinction: the apprentice achieved all the pass criteria **and 12** out of **16** of the distinction criteria

Appendix 4 Vocational Competence, Training & Development Log

Vocational Competence, Training & Development Log

Apprentice name:	Click or tap here to enter text.
Job title/ role:	Click or tap here to enter text.
ILR number:	Click or tap here to enter text.
Employer/ Provider name:	Click or tap here to enter text.
Apprenticeship standard:	**ST0586 Regulatory Affairs Specialist**

- **Introductory Notes**
- 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 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 Vocational Competence, Training and Development 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.
- Open Awards should 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.
- You may use the format provided in the table below which can be uploaded along with documented evidence to Open Awards Secure Portal.
- Evidence should not include any reflective self-assessment.

Key responsibilities	Off the job training activity	Hours spent on the activity	Start date/ End date	On the job competence	Evidence of competence uploaded/ Evidence reference	KSB criteria demonstrated
Creating and implementing regulatory strategies in agreement with key stakeholders						
Carrying out research to create and contribute solutions to regulatory issues						
Project managing license applications to agreed targets						
Providing guidance on regulatory information and input across functional teams						
Preparing and delivering regulatory operational plans						
Being accountable for ensuring optimal interactions between stakeholders						
Complying with processes, data requirements and standards						

Key responsibilities	Off the job training activity	Hours spent on the activity	Start date/ End date	On the job competence	Evidence of competence uploaded/ Evidence reference	KSB criteria demonstrated
Mitigating and managing risks						
Using professional knowledge and judgement to evaluate data, to determine its suitability for use and to identify gaps in the data provided.						

Confirmation

The Vocational Competence, Training & Development Log has been checked by the training provider to ensure it:

- is compiled during the on-programme period of the apprenticeship
- contains sufficient pieces of evidence to cover the nine (9) occupational duties and the KSBs outlined in the standard.

Apprentice signature:	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Employer/ Provider signature:	Click or tap here to enter text.	Date:	Click or tap to enter a date.

Appendix 5 Vocational Competence, Training & Development Log Authentication Statement

Authenticity & currency - The evidence you submit **must**:

- belong to you
- have been produced by you
- be current, i.e., has been gathered during your apprenticeship.

For the purposes of clarity where the phrase 'portfolio' is used, this is taken to mean Vocational Competence, Training and Development Log.

Apprentice name:	Click or tap here to enter text.
Job title/ role:	Click or tap here to enter text.
ILR number:	Click or tap here to enter text.
Employer:	Click or tap here to enter text.
Standard name:	**Regulatory Affairs Specialist**
Standard code:	**ST0586**

	Please tick (✓)
I **confirm** that the evidence I have submitted within the portfolio is my own work.	☐
I **understand** that my results may be invalidated if I have submitted evidence that does not belong to me, and which has not been clearly acknowledged.	☐
I **confirm** that the evidence I have submitted within the portfolio was created by me pre-gateway during my apprenticeship.	☐
I **confirm** that the evidence I have submitted within the portfolio meets the requirements of the apprenticeship assessment plan.	☐

This statement **must** be submitted by the apprentice along with their portfolio.

Apprentice signature:	Click or tap here to enter text.
Date:	Click or tap to enter a date.

All information provided on this form will be held securely and only used for the purposes provided. Full details on how we use and protect your data are available in our Privacy Notice.

Open Awards tries to meet the highest standards when collecting and using personal information. Customers are encouraged to email info@openawards.org.uk if you believe any data to be incorrect, unfair, misleading or inappropriate.

Appendix 6 Project Showcase, Report & Presentation Apprentice Instructions

Project Showcase, Report & Presentation Apprentice Instructions

Apprentice Instructions

You will receive a pack of three case studies from Open Awards. Each case study will present a scenario in which appropriate regulatory activities need to be carried out and challenges to meeting these need to be overcome.

1. Choose **one** case study from those presented to you.

2. Write a report based on the case study that includes as a minimum:
   a. what you set out to achieve.
   b. your overall approach to the regulatory needs.
   c. the main findings of your research.
   d. how you dealt with any issues.
   e. the key outcomes and recommendations.
   f. the lessons learned from the case study.

Your report should be 4000 words +/-10%. In addition to the word count, your report may include photos, diagrams and tables where they add value and clarity. No annexes or appendices are allowed. You may structure the report in any way you deem appropriate.

After you have completed and submitted your report to Open Awards:

3. create a presentation of the **main** points of your report to present to an independent assessor. You may use PowerPoint and presentation aides e.g., handouts to aid you in your presentation.

After you have delivered your presentation, the assessor will ask you some questions to clarify relevant aspects of your presentation and to assess you against the grading criteria. You may prepare notes to refer to during this part of the assessment if you wish.

Appendix 7 Project Showcase & Report Authentication Statement

Authenticity & currency - The work you submit **must** have been produced by you and must be current.

Apprentice name:	Click or tap here to enter text.
Job title/ role:	Click or tap here to enter text.
ILR number:	Click or tap here to enter text.
Employer:	Click or tap here to enter text.
Standard name:	**Regulatory Affairs Specialist**
Standard code:	**ST0586**

	Please tick (✓)
I **confirm** that the evidence I have submitted within the project showcase and report is my own work.	☐
I **understand** that my results may be invalidated if I have submitted work that does not belong to me, and which has not been clearly acknowledged.	☐
I **confirm** that the work submitted within the project showcase and report was created by me post-gateway during the end-point assessment period.	☐
I **confirm** that the work submitted within the project showcase and report meets the requirements of the apprenticeship assessment plan.	☐

Apprentice signature:	Click or tap here to enter text.
Date:	Click or tap to enter a date.

The work you submit must be current **and** produced by you.

Appendix 8 Project Showcase, Report & Presentation Assessment Record

Apprentice name:	Click or tap here to enter text.
ILR number:	Click or tap here to enter text.
Employer name:	Click or tap here to enter text.
Apprenticeship standard:	**ST0586 Regulatory Affairs Specialist**
IEPA name:	Click or tap here to enter text.
Location:	Click or tap here to enter text.
Date Customer Proposal Report marked:	Click or tap to enter a date.
Project Showcase Report word count (3600 – 4400 words)	Click or tap here to enter text.
Date of assessment (presentation):	Click or tap to enter a date.
Photographic proof of identity provided:	Choose an item. **Reasonable adjustments approved:** Choose an item.
Notes on reasonable adjustments (if applicable):	Click or tap here to enter text.
Total assessment time:	Click or tap here to enter text.

Introductory notes for presentation

- The presentation must be carried out under controlled conditions in a suitable environment.

- The IEPA must introduce themselves and confirm their identity to the apprentice and employer/ representative (and others present if appropriate).

- The IEPA must agree with the employer/ representative how disruptions will be managed (e.g., alarms and emergencies) including confirming evacuation procedures.

- The apprentice must provide photographic proof of their identity before the assessment commences. Where this is not provided, the assessment must **not** proceed.

- If at this stage the IEPA believes there is a conflict of interest, the assessment should **not** proceed, and they should contact Open Awards for guidance.

- If reasonable adjustments have been requested and approved by Open Awards, the IEPA should record this and confirm that the apprentice is aware of those adjustments before starting.

- If the presentation is undertaken remotely, please record the system used (e.g., Zoom, MS Teams) and the location of both the IEPA and the apprentice.

- The IEPA should confirm the apprentice is ready to be assessed and understands the assessment parameters.

- The apprentice will have **20 minutes** to undertake the presentation and **25 minutes** to answer IEPA questions, both durations can be increased by 10% at the IEPA's discretion to allow the apprentice to complete a part of their presentation or to complete answers they have started during IEPA questioning.

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Regulatory environment	Recognises the regulatory environment in which they work, and the key organisations involved.	Explains how the regulatory environment fits into the wider healthcare or animal health environment in which they work.	Choose an item.
	Understands the changes occurring in the regulatory environment in which they work and upcoming changes that have been identified.	Identifies 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.	
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
The evidence for regulatory decision making: science, content and structure	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.	Explains how all the available evidence contributes to regulatory decision making.	Choose an item.
		Understands and explains the risks around regulatory decisions that need to be taken into account and the approach to managing them.	
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Think analytically and offer creative solutions	Able to apply scientific decision-making in different situations	Demonstrates critical reflection including an explanation of their thinking and quotes best practice	Choose an item.
	Able to consider different scenarios when decision-making	Proposes and implements workable solutions	
		Articulates learning around decision making and best practice in formulating solutions in their working environment	
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Regulatory procedures	Demonstrates knowledge and compliance of the regulatory procedures in the area where they work.	Understands how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing.	Choose an item.
	Justifies choosing a specific procedure.		
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Regulatory impact	Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked.	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.	Choose an item.
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Present & communicate	Demonstrates good presentation practice with a clear and well-structured presentation.	Goes beyond just presenting material on slides and provides personal reflection.	Choose an item.
	Presents logical arguments and information in the written report.	Presents persuasive arguments and recommends the optimal solution to the case study.	
Comments on evidence presented to justify assessment decisions			

Key area	Pass criteria	Distinction criteria	Outcome
Project Showcase, Report & Presentation - Grading			
Customer Focus	Recognises own customers and their needs.	Anticipates potential customers and their needs.	Choose an item.
		Understands the impact and consequences of failing to recognise customers and their needs.	
		Defines and demonstrates approaches to interacting with customers in order to reach optimal outcomes.	
Comments on evidence presented to justify assessment decisions			

Overall summary on evidence presented to justify assessment decisions
Project Showcase Report   Click or tap here to enter text.
Presentation   Click or tap here to enter text.

Question and answer session

Click or tap here to enter text.

Post assessment
- The apprentice must **not** be given an indication of what grade they may have achieved as the recommended grade to be awarded is subject to internal quality assurance by Open Awards. However, the IEPA must provide the apprentice of an indication as to when they can expect to receive their results.
- The IEPA must clearly explain the appeals, retakes and resits process to the apprentice.

Notes on grading
All pass criteria are required to be achieved to achieve a Pass; if they are not all achieved, the outcome is a Fail.
All pass and **5** out of **7** distinction criteria are required to be achieved to achieve a Distinction

No. of pass criteria not met	Click or tap here to enter text.
No. of pass criteria met	Click or tap here to enter text.
No. of distinction criteria not met	Click or tap here to enter text.
No. of distinction criteria met	Click or tap here to enter text.
Recommend grade awarded	Choose an item.

The apprentice must **not** be given an indication of what grade they may have achieved as the recommended grade to be awarded is subject to internal quality assurance by Open Awards.

Developmental feedback for improvement in the event of a recommended Fail grade (This will be sent by Open Awards to the apprentice and employer)				
Click or tap here to enter text.				
Recommend (Select from dropdown menu)	Resit	Choose an item.	Retake	Choose an item.

Confirmation
I confirm that this is an accurate record of the assessment undertaken and that the evidence presented during the assessment by the apprentice meets the requirements of the standard for authenticity, currency, sufficiency, independence, reliability and validity.

IEPA Signature:	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Name of LIEPA (if sampled)	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Signature of LIEPA	Click or tap here to enter text.	LIEPA Ref:	Click or tap here to enter text.

Appendix 9 Viva Voce Assessment Record

Apprentice name:	Click or tap here to enter text.
ILR number:	Click or tap here to enter text.
Employer name	Click or tap here to enter text.
Apprenticeship standard:	**ST0586 Regulatory Affairs Specialist**
IEPA name:	Click or tap here to enter text.
Location:	Click or tap here to enter text.
Date of assessment:	Click or tap to enter a date.

Photographic proof of identity provided:	Choose an item.	**Reasonable adjustments approved**	Choose an item.
Start time:	Click or tap here to enter text.	**Finish time:**	Click or tap here to enter text.

Introductory notes

- The viva voce must be carried out under controlled conditions in a suitable environment.
- The IEPA must have reviewed the apprentice's Vocational Competence, Training and Development Log in advance.
- The IEPA must introduce themselves and confirm their identity to the apprentice and employer/ representative (and others present if appropriate).
- The IEPA must agree with the employer/ representative how disruptions will be managed (e.g., alarms and emergencies) including confirming evacuation procedures.
- The apprentice must provide photographic proof of their identity before the professional discussion commences. Where this is not provided, the assessment must **not** proceed.
- If at this stage the IEPA believes there is a conflict of interest, the assessment should **not** proceed, and they should contact Open Awards for guidance.
- If reasonable adjustments have been requested and approved by Open Awards, the IEPA should record this and confirm that the apprentice is aware of those adjustments before starting.
- If the viva voce is undertaken remotely, please record the system used (e.g., Zoom, MS Teams) and the location of both the IEPA and the apprentice.
- The IEPA must confirm the apprentice is ready to be assessed and understands the assessment parameters.
- The professional discussion **must last for 45 minutes** (+10% at the IEPAs discretion to allow an apprentice to finish the answer they are giving)
- There are 15 key areas that must be assessed. The IEPA must ask the apprentice sufficient questions to be able to assess all key areas. Contributions made by the apprentice to one discussion prompt or question may provide (and are likely to provide) evidence against multiple grade descriptors.

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
The regulatory environment	Recognises the regulatory environment in which they work and the key organisations involved.	Explains how the regulatory environment fits into the wider healthcare or animal health environment in which they work.		Choose an item.
	Understands the changes occurring in the regulatory environment in which they work and upcoming changes that have been identified.	Identifies 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.		
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
The regulatory function throughout the product lifecycle	Demonstrates awareness of how decisions made by the regulatory function impacts on a product's life-cycle.	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.		Choose an item.

Comments on evidence presented to justify assessment decisions

Key area	Pass criteria	Distinction criteria	Question reference	Outcome

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Regulatory procedures	Demonstrates knowledge and compliance of the regulatory procedures in the area where they work. Justifies choosing a specific procedure.	Understands how other regulatory procedures, and the timing of those procedures, impacts on the work that they are doing.		Choose an item.

Comments on evidence presented to justify assessment decisions

Key area	Pass criteria	Distinction criteria	Question reference	Outcome

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Regulatory impact	Demonstrates awareness of the impact of regulatory processes and new procedures on the specific areas in which they have worked.	Explains the impact of regulatory processes and new procedures on the whole business/organisation and key stakeholders outside of the business.		Choose an item.
		Articulates how future regulatory changes will impact the business environment they work within, including strategies for minimising impact.		
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Manage and deliver multiple projects	Demonstrates a knowledge of the different projects that they have worked upon and the key deliverables.	Demonstrates evidence of taking leadership for multiple projects.		Choose an item.
		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.		
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Act decisively	Gives examples of decisions taken within their regulatory work and can explain how the decision was made.	Explains their reasoning for reaching 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.		Choose an item.
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Influence and negotiate	Gives examples of where they have understood the opinions of others.	Provides 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.		Choose an item.
	Explains how they have helped others to see a different point of view in order to reach a common solution.			
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Manage and share knowledge	Maintains a structure to manage knowledge and data.	Demonstrates proactive sharing of knowledge and the value of doing so.		Choose an item.
	Demonstrates how they have managed sensitivities around sharing knowledge and data.	Explains how they have used knowledge to help others understand an issue.		

Comments on evidence presented to justify assessment decisions

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Using own initiative to contribute to a team	Gives examples of when they have used their own initiative in a team environment to positive effect.	Explains how taking the initiative influenced the actions or behaviours of the team and how this positively impacted the overall success of the team.		Choose an item.
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Work with IT platforms	Explains how they used IT systems as directed to retrieve data and conduct analyses as needed.	Explains how they used databases and systems to achieve business goals – supports explanation with examples of impact on the business.		Choose an item.
		Understands the impact and consequences of incorrect use of databases and systems.		

Comments on evidence presented to justify assessment decisions

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Integrity	Explains the importance of integrity in their role.	Demonstrates a clear understanding of the importance and effects of integrity on a business and individual.		Choose an item.
		Provides examples of when their integrity has been challenged and how they dealt with this.		

Comments on evidence presented to justify assessment decisions

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Accountability	Outlines where they took accountability for a role within a key project.	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.		Choose an item.
	Explains how they had multiple goals for which they were accountable and the role they took to achieve the goals.	Explains the impact if accountability is not clear and can provide examples of when they have taken on accountability to ensure a positive outcome.		
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Independence	Demonstrates where they have worked alone within a project and what they delivered.	Demonstrates autonomous thinking and when they should continue with their own thought processes with awareness of the limits of their responsibilities.		Choose an item.
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Commitment to personal development	Recognises constructive feedback on their strengths and weaknesses and how best to use it to develop further	Critically reflects on self to identify development areas.		Choose an item.
		Takes responsibility for developing a plan/vision for further self-development.		
		Identifies 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.		
Comments on evidence presented to justify assessment decisions				

Key area	Pass criteria	Distinction criteria	Question reference	Outcome
Compliance	Demonstrates 100% compliance in company training programmes and with processes	Proactive contribution to changes necessary to maintain compliance and understands consequences of noncompliance.		Choose an item.
		Explains how they shared knowledge to improve compliance in others.		
Comments on evidence presented to justify assessment decisions				

Overall comments on evidence presented to justify assessment decisions
Click or tap here to enter text.

Post assessment
- The apprentice must **not** be given an indication of what grade they may have achieved as the recommended grade to be awarded is subject to internal quality assurance by Open Awards. However, the IEPA must provide the apprentice of an indication as to when they can expect to receive their results.
- The IEPA must clearly explain the appeals, retakes and resits process to the apprentice.

Notes on grading
All pass criteria are required to be achieved to achieve a Pass; if they are not all achieved, the outcome is a Fail.
All pass and **12** out of **16** distinction criteria are required to be achieved to achieve a Distinction.

No. of pass criteria not met	Click or tap here to enter text.
No. of pass criteria met	Click or tap here to enter text.
No. of distinction criteria not met	Click or tap here to enter text.
No. of distinction criteria met	Click or tap here to enter text.
Recommend grade awarded	Choose an item.

Developmental feedback for improvement in the event of a recommended Fail grade (To be sent by Open Awards to the apprentice and employer)			
Click or tap here to enter text.			
Recommend (Select from dropdown menu)	**Resit** Choose an item.	**Retake**	Choose an item.

Confirmation

I confirm that this is an accurate record of the assessment undertaken and that the evidence presented during the assessment by the apprentice meets the requirements of the standard for authenticity, currency, sufficiency, independence, reliability and validity.

IEPA Signature:	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Name of IQA (if sampled)	Click or tap here to enter text.	Date:	Click or tap to enter a date.
Signature of IQA	Click or tap here to enter text.	IQA Ref:	Click or tap here to enter text.

All information provided on this form will be held securely and only used for the purposes provided. Full details on how we use and protect your data are available in our Privacy Notice.

Open Awards tries to meet the highest standards when collecting and using personal information. Customers are encouraged to email info@openawards.org.uk if you believe any data to be incorrect, unfair, misleading or inappropriate.

Optional section - IEPA self-reflection on assessment (e.g., link to CPD plan)
Click or tap here to enter text.

Appendix 10 EPA Planning Form

EPA Planning Form

openawards
Qualified

This form is applicable to any End-point assessment (EPA) activity where the assessment(s) is undertaken at a venue not directly managed by Open Awards and to which the independent End-point assessor (IEPA) is required to attend in-person (i.e., the assessment(s) is undertaken face-to-face and not remotely).

The form must be fully completed by the provider or employer (as appropriate) and uploaded to the Open Awards Secure Portal at the same time as the assessment(s) is booked. Where remedial actions are identified, these must be addressed prior to the assessment day.

Full address of assessment venue	Click or tap here to enter text.
Location IEPA should report to upon arrival	This is important on large sites where there may be multiple receptions/ entrances e.g., "*Reception in Building 'C' on the attached map*" Click or tap here to enter text.
Name of contact person at venue	This person will be responsible for meeting the IEPA on arrival, providing an appropriate health & safety briefing and must be available throughout the assessment(s) to deal with queries from the IEPA or emergencies Click or tap here to enter text.
Telephone of contact person at venue	Landline Click or tap here to enter text.
	Mobile Click or tap here to enter text.
Access arrangements	Is there anything the IEPA should be aware of. E.g., postcode to use with Sat Nav if different from above, car parking arrangements on/ off site, access from nearest train station Click or tap here to enter text.
Specific requirements the IEPA should be aware of	E.g., is PPE required and if so, is the IEPA expected to provide this or will it be provided for them Click or tap here to enter text.
Name of person completing this form	Click or tap here to enter text.
Job title/ position	Click or tap here to enter text.
Date form completed and uploaded to Open Awards Portal	Click or tap to enter a date.

Any other relevant information that would help the IEPA plan for the EPA. E.g., challenging customers may be present or goods delivery is expected on the day of assessment. Click or tap here to enter text.

	Yes/No	If 'No', what remedial actions will be put in place to address this prior to the assessment(s)
There is a current health & safety policy in place for the venue which covers the EPA activities, the apprentice, the IEPA and other visitors undertaking quality assurance of the assessment(s)	Choose an item.	Click or tap here to enter text.
There is appropriate liability insurance in place which covers both the apprentice, IEPA and other visitors undertaking quality assurance of the assessment(s)	Choose an item.	Click or tap here to enter text.
The provider/ employer will undertake an appropriate risk assessment relevant to the assessment(s) and share this with both the apprentice and the IEPA	Choose an item.	Click or tap here to enter text.
The apprentice will have access to any Personal Protective Equipment required and received prior training in its use and storage. This PPE will be fit-for-purpose.	Choose an item.	Click or tap here to enter text.
There is adequate, accessible and signed posted first aid provision including first aid personnel and medical supplies available on the day of the assessment(s)	Choose an item.	Click or tap here to enter text.
An emergency contact at the venue will be available for duration of the EPA	Choose an item.	Click or tap here to enter text.
There are appropriate means of fire detection and raising the alarm in the event of a fire	Choose an item.	Click or tap here to enter text.
There is an emergency procedure (e.g., fire or first aid) in place which will be communicated to the apprentice and IEPA before the assessment(s) commence	Choose an item.	Click or tap here to enter text.
The venue and the assessment environment are safe and hazards appropriately managed in line with current best practice	Choose an item.	Click or tap here to enter text.
Welfare facilities (e.g., toilets, washing, eating and changing) are adequate, safe, healthy, clean and accessible to the IEPA	Choose an item.	Click or tap here to enter text.
All necessary safety notices (e.g., warning signs, fire-related, first aid) are displayed	Choose an item.	Click or tap here to enter text.
All machinery and equipment required is in good working order, meets appropriate legal standards and has been maintained by a competent person	Choose an item.	Click or tap here to enter text.

Appendix 11 Example template email to the Apprentice

Subject: Your scheduled Regulatory Affairs Specialist Project Showcase / Viva Voce

Dear Insert Apprentice's Name,

Your regulatory Affairs Specialist project showcase / Viva voce has been scheduled for **insert date and time**.

Your assessment will be invigilated by an invigilator from Open Awards. Your invigilator's name is insert **invigilator's name**.

Your assessment will be invigilated via the Zoom/Teams link below.

Insert Zoom link

Your invigilator will be present 15 minutes prior to the scheduled assessment start time.

You will need to be registered for a Zoom account for the assessment to take place. This is a free registration. If you do not already have a Zoom account- you can register here. –

Zoom registration- https://zoom.us/freesignup/

Your assessment itself will be displayed and conducted via Open Awards' XAMS secure platform.

Your log in details for your assessment will be provided to you by your invigilator prior to the start of your assessment.

XAMS can be accessed using the link below:

https://player.xams.co.uk/clients/openawards

Please read the attached guidance prior to your assessment. If you have any questions, please contact your Provider.

Important: Please complete and return the attached *Apprentice contact details for OA EPA Invigilation Form.* **Please note we must receive this form at least 24 hours prior to your assessment. If this form is not returned, your assessment will not be able to go ahead.** Please return the form to customerservices@openawards.org.uk

If for any reason you are unable to attend your assessment as scheduled, please contact **customerservices@openawards.org.uk**

As your assessment is taking place outside of business hours, (Monday-Thursday 09:00-17:00 & Friday 09:00-16:00); should you have any issues or concerns at the time of the assessment, please dial 01514944346 to speak to our Duty Manager.

Should you have any general queries please call the customer services team on 0151 494 2072, or email **customerservices@openawards.org.uk.**

The very best of luck with your assessment.

Appendix 12 Project Showcase and Viva Voce (remote) - Instructions for Apprentices

Introduction
The following guidance sets out everything you will need to know to prepare for your remote showcase or viva. It is important that you read and understand these instructions before sitting your test.

Necessary equipment
To perform your showcase and / or viva, you need to have the following equipment:
- a good quality laptop or PC with a minimum screen size of approx. 14" and minimum resolution of 1024 x 768, with access to Microsoft Power Point for the presentation element
- a stable internet connection with at least 3mbps.
- an integrated (i.e., fixed) webcam on your PC/ laptop or a portable webcam.
- if using a PC/ laptop with an integrated webcam, a reflective surface (e.g., a mirror) must be available. This will be used to show the invigilator the space immediately surrounding your screen and keyboard.

The room
Your test must take place in a room in which you feel comfortable and where you are unlikely to be disturbed. You should choose a space with adequate warmth, ventilation and lighting. If you cannot use overhead lighting (e.g., ceiling lights), your lamp cannot be positioned behind you as it would make it difficult for the invigilator to see you. Please do not sit with your back to a window. Make sure your workspace and chair are in a good condition and comfortable, so they don't distract you.

Nobody else can be in the same room while your showcase is taking place (unless you have been given prior permission by Open Awards to be supported during your assessment(s)).

You must not wear any hats, sunglasses and headphones (except where your provider has given you permission to use headphones/ headset connected to the computer audio).

Hearing aids are only permitted if requested prior to the test and your provider has given you permission to use them.

Hints and tips
- We advise that you go to the toilet before your assessment(s) as you will **not** be able to leave the room once it has started.
- You must remove all distractions. If you have children try and schedule your showcase for a time when they are not going to disturb you.
- If you live with other people, advise them in advance that you are undertaking assessment(s) remotely.

- Place an Assessment in Progress poster/ sign outside the room.
- Try to make sure you don't have a lot of background noise as this may distract you.
- Check all of your equipment before the assessment(s) begins.
- If using a laptop, make sure it is plugged in rather than relying on the battery life.
- Log into the system at least 30 minutes before the scheduled start time in case you have any technical issues to sort.

Before the assessment(s) (Project Showcase and / or Viva Voce)

If you have any questions about this guidance document, please contact your provider immediately to make sure you understand and are able to comply with the conditions.

If your invigilator finds that you have not fully met the controlled conditions requirements, your assessment(s) will not be able to take place and there may be an additional charge to resit.

Pre-assessment(s) checks

The link to the online session will be sent to you at least 30 minutes before your assessment is scheduled to start. This will give you time to download any required software and check the functionality of your audio and visual equipment. You will be able to join the session immediately, but the assessment will not be visible to you until it has been opened by the invigilator at the scheduled start time.

You will need to verbally confirm your identity and show photographic ID (e.g., passport, driver's license or college issued ID card) to the invigilator via the webcam. If you are not able to provide the required identity documents, you will not be able to perform the assessment(s) and it will need to be rescheduled.

The assessments will be video recorded. Once you have completed the identity checks the invigilator will advise you that the recording function will be activated, and the recording will start.

You must enable your webcam and microphone. The invigilator may ask you to move your chair or webcam so that you are clearly visible and centred within the screen.

The invigilator will give you clear instructions regarding the controlled conditions of the remote assessment and require you to confirm that you have fully understood these instructions before the assessment can start.

The invigilator will also undertake several checks to ensure that the remote assessment is set up correctly. The invigilator will complete a checklist covering the following items:
- confirmation that the visual and sound quality is working adequately both for you and for the invigilator
- confirmation that the visual and sound quality is working adequately for all additional apprentices taking part in discussions (English Speaking Listening and Communicating tests only)

- confirmation that your PC / laptop is plugged in /has sufficient charge
- a thorough sweep of the room to ensure it is fit for purpose. If you have a fixed webcam, this will include asking you to use a reflective surface (e.g., a mirror) to allow the invigilator to see the sides of your screen and around your keyboard.
- a check of electronic devices to ensure that all mobile phones or other electronic devices are switched off and smart watches have been removed and placed out of reach
- confirmation that no food is visible and any fluids within the test room are in a clear container with no label
- the invigilator will ensure that you understand there is no smoking or vaping during the test
- confirmation that calculators (where permitted) meet requirements of the test (i.e., not scientific calculators)
- confirmation that calculators (where permitted) are placed out of reach for Part A of Functional Skills maths tests
- confirmation that all dictionaries (where permitted) meet the requirements of the test.

During the assessment(s)

Once the invigilator is satisfied that your room meets controlled requirements, and they can see your entire screen, they will share the test login details with you and you can start the showcase.

You must not open any other windows or applications during the test as your invigilator will see if you do this and may stop the test.

During the test, the invigilator will be able to view you and your room through your webcam as well as being able to view your PC/ laptop screen. The invigilator will pay attention to any behaviour that may suggest revision notes or mobile devices are being used. The invigilator will challenge you about any suspicious behaviour or activity and they may ask you to undertake additional thorough sweeps of the room with the webcam (or mirror) before allowing you to continue with the test. They will stop the test if the controlled conditions cannot be met.

You can only interact with the invigilator if you believe the test platform is not functioning as it should.

Pay attention to the countdown clock in the on-screen window. This will change colour from white to amber when you are entering the last ten minutes of your assessment. The invigilator will also verbally advise you of this.

If you have been awarded extra time, this will be scheduled into your test automatically.

After the assessment

Once you have completed the assessment, or at the end of the allocated time, the invigilator will tell you that it is finished and undertake some final checks.

To maintain the confidentiality of the assessment, you **must not** write down any of the questions on paper as this may result in disqualification from the assessment and the qualification. The invigilator will ask you to show them any notes you made during the assessment, via the webcam, ensuring that they are legible and visible in the video recording without being blurred.

The session will then be ended, and the invigilator will stop the recording.

Your provisional results may take up to five (5) working days from the date of the assessment to arrive. Your provider will contact you once the results are available.

Appendix 13 Remote assessment

Open Awards recognises that remote assessment may present an attractive proposition to employers to overcome workplace challenges, e.g., limited physical access to enable the IEPA to observe the apprentice.

However, remote assessment itself has challenges and Open Awards are likely to require confirmation or reassurance that:

- remote observations etc., can be live-streamed, not recorded.
- remote assessment will be supported by video conferencing facilities/ technology which is sufficiently stable to enable the apprentice and IEPA to effectively communicate.
- imagery will be of sufficiently high-quality resolution to allow an IEPA to clearly view in detail the apprentice and any evidence.
- the technology used will accommodate the maximum possible duration of the assessment; not the assessment governed by the capacity of the technology.
- any live stream must remain on the apprentice throughout the assessment.
- the employer accepts that any break in the live-stream or where the IEPA is unable to see the apprentice or communicate with them may result in the assessment being cancelled and count as an assessment attempt; the employer may be required to pay for the resit.
- the employer will be able to supply at their expense someone to support the observation workplace (e.g., holding a camera) who does not have a supervisory relationship with the apprentice and who has sufficient health and safety awareness so as not endanger themselves or others whilst they are undertaking the support role.

The above list is not exhaustive and may vary depending upon the assessment method and associated requirements set out in the assessment plan. Where the assessment plan does not explicitly allow for assessment to be undertaken remotely, Open Awards may have to seek clarification from the External Quality Assurance Provider as to whether remote assessment is permissible. Therefore, employers must liaise directly with Open Awards at the earliest possible opportunity to enable a determination to be made as to whether remote assessment is viable and valid.

Open Awards
17 De Havilland Drive,
Estuary Commerce Park
Speke
Liverpool
L24 8RN

Tel: **0151 494 2072**

Email: **info@openawards.org.uk**

Website: **www.openawards.org.uk**