

ST0586: Level 7 Regulatory Affairs Specialist End-Point Assessment

Occupational Profile

Regulatory affairs is the role within an organization that ensures all medicines for human or veterinary use and medical devices are appropriately licensed before being sold or supplied. This licence is either:

- granted by the relevant competent authority (e.g. the UK Medicines and Healthcare Products Regulatory Agency or the European Medicines Agency) based on an evaluation of scientific data submitted by the supplier, or
- demonstrated by compliance with the appropriate laws through a system of conformity assessment, declaration of conformity and involvement of Notified Bodies (e.g. British Standards Institute)

The processes, data requirements and formats to present the data to obtain a licence are established in law. Regulatory affairs also update the licence particulars during the product's lifecycle. 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.

By meeting their responsibilities, a Regulatory Affairs Specialist takes a leading role to ensure products comply with the regulatory requirements to receive an initial licence for marketing. They also develop and manage the regulatory strategy that ensures further changes to the licenced product continue to meet the regulatory requirements. Failure to meet these responsibilities could result in the product either not getting to the market or the product having to be withdrawn from the market. This could result in significant financial, legal and reputational implications for the company and impacts the availability of healthcare products for patients or animals.

Depending on technical field e.g. human or animal pharmaceutical or medical device, key responsibilities of a Regulatory Affairs Specialist would include:

- Creating and implementing regulatory strategies in agreement with key stakeholder
- 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
- 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

End-Point Assessment

The Regulatory Affairs Specialist Standard is assessed through two End-Point Assessment (EPA) methods as set out in the assessment plan (<https://www.instituteforapprenticeships.org/>)

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

Performance in the EPA will determine the apprenticeship grade of fail, pass or distinction.

Apprentices must spend a minimum of 12 months, typically 30 months, on programme (excluding the EPA period), including a minimum of 20% off the job training. The EPA of an Apprentice should only start once the employer is satisfied that the Apprentice is consistently working at or above the level set out in the Apprenticeship Standard, and that the prerequisite Gateway requirements for EPA have been met.

Gateway requirements for End-Point Assessment

- Level 2 in English and Mathematics (GCSE equivalent A-C / 4-9)
- Successful completion of periodic on programme assessments
- Vocational Competence, Training and Development Log

Marshall Assessment will provide the following documents which must be used as part of the Gateway process:

- Gateway Declaration – Training Provider
- Gateway Declaration – Employer
- Gateway Declaration – Apprentice
- Viva Voce evidence Tracker
- Vocational Competence, Training & Development Log (Marshall template available, but existing template can be used if applicable)

Prior to Gateway, employers and providers must ensure that sufficient on-programme assessments have taken place to ensure that the Apprentice is competent against all the Knowledge, Skills & Behaviours (KSBs) and their associated grading descriptors. The EPA must be completed within a six-month period once the Gateway requirements have been met and the EPA period entered.

A summary of the assessment methods and how Marshall Assessment deliver them has been provided below. Further support can be found in the following documents which will be provided as part of our EPA support and customer / Apprentice engagement pack.

- Project Showcase Guidance – detailed guidance to help you prepare for the showcase including the grading descriptors that must be met and example material.
- Project Showcase report mapping.
- Viva Voce Guidance – detailed guidance to help you prepare for your viva including how to compile the Vocational Competence, Training and Development Log and the grading descriptors that must be met.

Project Showcase – Report, Presentation & Questioning

Laptop / PC with webcam with audio & video capabilities required as delivery will be remote via Microsoft Teams unless otherwise specified.

Team's link will be tested prior to the agreed date of assessment.

Takes place in a quiet location, free from distraction or influence.

Session will be recorded for quality and training purposes in line with GDPR and Marshall Assessment Data Protection Policy

Timescales:

10 weeks to write report for Project Showcase presentation

Presentation - 20 mins (+10% at the IA's discretion)

Questions – 25 mins (+10% at IA's discretion)

Grading outcomes – Fail / Pass / Distinction

- This will focus on the Apprentice presenting the approach, findings, recommendations and lessons learned from a Case Study most relevant to their area of work (Advanced Therapies, Medical Devices or Medicine).
- The Case Study will be provided by Marshall Assessment within 2 weeks following Gateway acceptance and the start of the EPA period.
- The Apprentice will then have a maximum of **10 weeks** to write and submit a Report which must cover: What they set out to achieve, the key outcomes of the Case Study, recommendations & lessons learned.
- The Report must be 4000 words (+/- 10%) and can include photos, diagrams and tables (these will not be included in the word count). No annexes or appendices will be accepted. References are not included in the word count.
- Following submission of the report to Marshall Assessment, the Apprentice will be given a minimum of **3 weeks'** notice of the date for the assessment of their presentation of their Project Report. Any reports submitted beyond the 10 week deadline will be graded a Fail – the EPA can proceed, but the final result of the EPA will be capped at a Pass (as with a resit or retake) unless there are mitigating circumstances, application form available from Marshall Assessment.
- On the agreed date, the Apprentice must present their Project Report to the Marshall Independent Assessor (IA), who will be assessing their presentation and analytical skills alongside the Knowledge, Skills and Behaviours (KSBs) assigned to this element, as set out in the Project Showcase Guidance.
- The presentation should demonstrate the Apprentice's ability to apply what they have learnt during their time on-programme to the Case Study tasks.
- Apprentices may use applications such as Microsoft PowerPoint, and handouts as they see fit to support the presentation. Any specific technical requirements should be agreed and arranged before the day of assessment.
- Following the presentation of the Report, the Marshall IA will ask a series of open questions, with follow up questions as/ when required for clarification.
- Marshall Assessment will provide a series of example questions to aide preparation; however, it is not feasible to predetermine questions, they will depend upon the nature of the work upon which the report and presentation is based, what is written in the report and said in the presentation and what the IA decides needs to be clarified.
- All responses to the questions asked will be recorded on Marshall Assessment's evidence recording paperwork along with an audio recording of the assessment, and will be submitted for Internal Quality Assurance, along with the Report, Presentation, recording of the presentation delivery, and any additional support materials (handouts etc.) before a final grade is confirmed.
- Apprentices will be graded against the specified Pass / Distinction criteria outlined in the Project Showcase guidance and Report Mapping document.
- All pass criteria must be met to achieve a Pass overall, and can be met through either the report, the presentation, or the Q&A. To achieve a Distinction, in addition to the pass criteria the Apprentice must meet the distinction criteria for at least 5 of the 7 areas of the standard. A fail in any 1 area will result in an overall Fail.

Viva Voce

Laptop / PC with webcam with audio and video capabilities required as delivery will be remote over Microsoft Teams unless otherwise specified

Takes place in a quiet location, free from distractions.

Session will be recorded for quality and training purposes in line with GDPR and Marshall Assessment's Data Protection Policy.

Timescale:
45 mins (plus 10% at the discretion of the IA).

Grading outcomes –
Fail / Pass / Distinction

No other personnel present unless pre-arranged for Quality Assurance

- For the Viva Voce, the Apprentice will be required to submit a Viva Voce evidence Tracker at Gateway.
- The Viva Voce evidence Tracker should be completed and map to evidence in the Apprentice's Vocational Competence Training and Development Log /portfolio of evidence, which should demonstrate how each work activity and training activity contributes to the achievement of the Knowledge, Skills and Behaviours (KSBs) and the associated grading descriptors as set out in the apprenticeship Standard.
- Marshall Assessment will require the Training & Development Log of evidence and a copy of the Viva Voce evidence Tracker at Gateway to enable time to review the mapped content ahead of the discussion.
- The Apprentice will receive at least 3 weeks' notice of the time / date of their Viva Voce, but this will usually follow the Showcase.
- The Marshall Independent Assessor (IA) will lead a discussion on a 1:1 basis following a review of the Apprentice's Viva Voce evidence Tracker and supporting evidence provided in the Log.
- The Viva Voce will clarify any questions the Marshall IA has from the review of the evidence in the Vocational Competence Training and Development Log and will explore aspects of the work, and how it was carried out, in more detail.
- The Marshall IA will be seeking to assess the depth of understanding from the responses given to the questions to determine performance against the grading criteria.
- The Marshall IA will take notes during the discussion and the assessment will be recorded to ensure fair marking and Internal Quality Assurance of the responses given.
- Apprentices will be graded against the specified pass / distinction grading criteria.
- To achieve a PASS - all pass criteria must be met through either the review of the mapped evidence provided in the Vocational Competence Training and Development Log, or the Viva Voce.
- To achieve a DISTINCTION the Apprentice must meet all of the pass criteria, and must meet the distinction criteria for at least 12 of the 15 KSB areas of the standard. A fail in any one area will result in an overall FAIL.

Remote Assessments - any breaks in connectivity will be dealt with in the following way:

- A short break of up to 10 mins will be acceptable, this must be recorded by the IA and they will confirm the test can continue once connectivity has resumed.
- If there is a break in connectivity once a question has been asked, once resumed, the IA will ask a different question.
- If the break is during a response – the Apprentice will be allowed to continue as long as the break is less than 5 minutes. More than this, a new question will be asked.

Grading outcomes

A distinction grading must be awarded in **both** elements for a **DISTINCTION** grade overall. A fail grading in either element will result in an overall **FAIL**. A pass in both, or a pass and a distinction will result in an overall **PASS**.

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

Evidence from the EPA is submitted for Internal Quality Assurance review **before confirmation of any results**. Final grades will usually be released to the Training Provider by Marshall Assessment. Following confirmation of results from Marshall Assessment, the Apprentice or Training Provider have 15 working days to request a review of the grade awarded. Appeals policy is available at <https://www.marshall-assessment.com/our-policies>. If no request is made, the certificate claim will then be submitted to the Apprenticeship Service (this may take up to 4 weeks to arrive following a claim being made) and will be sent directly to the Employer unless otherwise specified.

All relevant policies relating to End-Point Assessment are available to download from [Marshall-assessment.com](https://www.marshall-assessment.com)

The Knowledge, Skills and Behaviours required to be met for this Standard are listed in the assessment plan and also below. A detailed guidance pack with assessment criteria, amplifications, exemplifications, mock material where appropriate and support to prepare for EPA will be provided on registration with Marshall Assessment as the EPAO.

Link to IfATE Assessment Plan

<https://www.instituteforapprenticeships.org/apprenticeship-standards/regulatory-affairs-specialist-v1-0>

Knowledge, Skills & Behaviours statements	
Knowledge	
K1	The regulatory environment: to demonstrate knowledge of the wider environment
K2	The regulatory function throughout the product lifecycle
K3	The evidence for regulatory decision making: science, content and structure
K4	Regulatory procedures: to demonstrate knowledge of additional regulatory procedures
K5	Regulatory impact: to demonstrate knowledge of the wider impact of regulatory
Skills	
S1	Manage and deliver multiple projects
S2	Act decisively
S3	Influence and negotiate
S6	Manage and share knowledge
S7	Using own initiative to contribute to a team
S8	Work with IT platforms
Behaviours	
B1	Integrity
B2	Accountability
B3	Independence
B4	Commitment to personal development
B5	Compliance