EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

Competence requirements and training needs for Quality Assessors

Expert Group of Pharmaceutical Quality Assessors
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Table of content

1. Introduction

This document is part of a strategy from the Heads of Medicines Agencies to ensure harmonised and high quality performance standards of assessment in the European Medicines Regulatory Network. The document outlines a set of recommendations for the competence requirements and training needs of quality assessors. The key objectives of this document are to define competence criteria for quality assessors and to establish a consistent framework against which training needs can be identified and planned to meet those requirements. These proposals should not be understood as mandatory requirements to be met by National Competent Authorities but as a useful instrument to the professional development of quality assessors.

2. Grades of Quality Assessors:

2.1 Definitions

To assign responsibility and determine development needs, quality assessors can be placed into one of three grades.

Quality Assessor Grade 1

This grade is a career entry level. The individual who operates at this level is at a junior or more established stage in their own professional career but is likely to be inexperienced in assessment work or new to the competent authority. Work carried out by individuals in this grade is performed under the supervision of more experienced assessors.

Previous experience in assessment is not mandatory for quality assessors at entry level. The type and complexity of work that may be undertaken by a Grade 1 assessor depends on the experience of the individual and business needs. Assessors with limited experience require significant support and supervision to attain the necessary skills. Assessors who operate under supervision are encouraged to think for themselves and to take responsibility for their own work. As part of their development they should also work towards reducing the level of supervision and introducing greater independence.

Quality Assessor Grade 2

This is a career grade. The job holder has demonstrated that he/she is competent to work independently and without supervision and that he/she has the necessary technical and organisational skills to work on a broad range of active substances, dosage forms in both national and European procedures. It is important that Grade 2 assessors continue to develop in the job to enable them to take on more complex applications as their training and competence develops. Training and development of Grade 2 assessors should be supported by management to ensure the development of expertise in all competent authorities and to help ensure consistency of assessment activities across the EU.

Quality Assessor Grade 3

Grade 3 consists of more experienced assessors who are expected to make an advanced contribution to the assessment and may be recognised as an expert in a particular field, based on increased breadth or depth of skills. In addition, a Grade 3 assessor should have knowledge and personal skills appropriate to mentoring and development of less experienced staff to enable them to work independently. In addition, a Grade 3 assessor should be able to assess a wide range of applications, including those with novel or complex issues, to ensure product compliance with regulatory requirements in accordance with required timescales. In addition the individual should have an up-to-date knowledge of the broader regulatory environment and processes that affect the operations (and therefore assessments) of the organisation.

General comments

Within each grade the extent of training needed depends on the previous experience of the individual; training is therefore customised accordingly. Delegation of work from higher graded assessors to lower levels is optional. In such cases, the lower graded assessor works under supervision and responsibility of the higher graded assessor.

2.2 Key criteria

The key criteria to analyse the roles are as follows:

A) Scientific knowledge and skills - the knowledge and skills required to achieve the overall purpose of the job, gained through education, training and experience (in house and external).

B) Regulatory knowledge and experience - the regulatory knowledge and understanding to achieve the overall purpose of the job gained through training and experience both internal and external.

C) Challenge within the role - the quality of thinking demanded of the job holder to solve problems and the application of knowledge in order to identify solutions. Assessment of the degree to which procedural guidelines are available and peer review and support is required.

D) Decision making/level of responsibility - the level of scope the role holder has for providing advice and making decisions. The degree of discretion the job holder has to act, the necessity for work to be checked and signed off and the availability of advice from colleagues.

E) Social skills and attunement to internal and external context - the nature of communications and the level at which the role holder is required to operate both within the organisation and externally, required awareness of assessment context (patient, pharmaceutical company, national and international review situation).

Within each of the key criteria progression is associated with increased competency in a cumulative manner. This can be illustrated in the form of a profile matrix (see table 1). Each assessor grade can be compared to this 'matrix' to determine the skills set and competencies required for the assessor to perform at that level.

This profile provides a framework against which it is possible to identify the expectations of assessors at each grade, the degree of supervision required, and which can be used as a development tool/pathway for assessors.

2.3 Learning Curve

It is important to specify that besides defining the key criteria for the assessor grades and their increasing levels of progression within each job there is also a clear learning curve/development pathway for assessors. The Grades 1 to 3 are defined such that a career development plan is possible from one grade to the next. One could see the grades as development phases from junior through the intermediate to senior level.

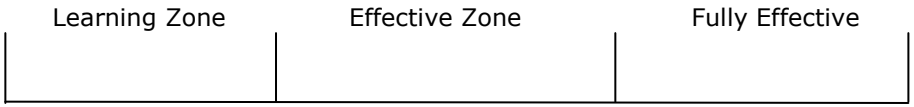
The speed with which an assessor will get to grips with the job at a new level and can move through the learning curve will vary depending on:

- their aptitude for the work,
- the level and relevance of their previous experience,
- the degree of support and training provided.

Therefore a degree of flexibility must be built into the development of individual induction/development programmes to reflect these differences and meet individual needs.

In addition the individual may be developing or have developed either one or more defined areas of expertise or will have a broader understanding across a range of subject areas.

So for each role the following progression can be envisaged:



2.4 Learning Curve Implications

1. The impact of introducing a learning curve concept is seen in the role profile matrix in the creation of 'new entrant' and 'post induction' profiles within Grade 1.

2. With regard to Grade 2 and Grade 3 as most appointments are made internally, in the event that an external candidate is appointed at this level, an induction programme can be developed at that time based on the competence criteria of lower Grades.

3. The three zones of the learning curve are reflected in the work allocation grids:

    a. **The learning zone** relates to the new entrant role. New entrants will initially be concentrating on gaining an understanding of the activities of the competent authority and becoming familiar with the key activities and responsibilities of the job.

    b. **The effective zone,** which refers to the majority of role holders, indicates that the role holder has gained sufficient experience and is competent to deliver on all the main aspects of the job.

    c. **The fully effective zone** is generally where an individual has gained such experience that they not only fulfil the main activities of the role but whose performance in each area is exemplary. Such individuals are also likely to have greater responsibilities, a wider remit and undertake the most complex assessments. They may be working towards becoming (or become) an expert in a particular scientific field, (depending on the grade).

3. Profile Matrices

3.1 Profiling the three grades of assessors

Table 1 – Profile Matrix to create a job profile

Key Requirements	Grade 1 The individual is at a junior level in their own professional career and inexperienced in the organisation activities. This person has an understanding of the organisation activities and is progressing his/her professional career.	Grade 2 The individual is established in their own professional career and has demonstrated competence in the key aspects of the job.	Grade 3 The individual in this role will be expected to make an advanced contribution to the organisation and may be recognised as an expert in a particular field.
Scientific Experience	Must hold a degree in pharmacy or other relevant scientific discipline. The individual may have limited relevant experience, however must be able to demonstrate a general knowledge of the key scientific activities relevant to the role. May be new to the organisation and require an understanding of its key activities.	Must hold a degree in pharmacy or other relevant scientific discipline. Significant relevant experience is required. Must demonstrate a broad knowledge across a range of scientific activities or may be beginning to develop a specialist level of knowledge in one or more scientific areas.	Must hold a degree in pharmacy or other relevant scientific discipline. Has an up to date knowledge of a broad range of scientific activities in addition to specialist knowledge in one or more relevant scientific areas. Is recognised both within the organisation and by peers outside as an expert/opinion leader.
Regulatory Knowledge	The individual is developing knowledge of regulatory activities, however should be able to demonstrate a basic knowledge and understanding of medicines control and regulation in national and European systems and procedures.	Must be able to demonstrate a good working knowledge and experience of one or more areas of regulatory activity within the organisation and a broad knowledge across the national and European systems and procedures.	Demonstrates a detailed working knowledge and experience of all relevant regulations in one or more areas of regulatory activity within the organisation. May provide input into the development of key regulatory systems policies or definitive guidelines as a recognised expert (both within and outside the organisation). Provides authoritative leadership in dealing with the most difficult technical or regulatory issues and makes them accessible to others.
Challenge	Works in a relatively narrowly defined area of assessment. Must meet volume, time and quality targets. Work will be monitored. After appropriate level of exposure to main activities of the job, the appropriate level of peer review required will be determined. Focus on position and function within local organisation; limited role in international procedures (under	Work on assessments in a specified area and may work on a range of assessments including more complex cases. Must meet volume, time and quality targets; Challenges are within previous experience requiring the application of acquired knowledge and experience and the selection of proven solutions. Local peer review procedures are followed with regard to approval of assessment reports. May act as a peer reviewer/mentor for the work of less	Works largely on own initiative and effectively evaluates the most complex assessments. Either a more broadly defined or a specialist role within the competent authority. Challenges are frequently complex, requiring the application of research and newly assimilated knowledge. Solutions require creative and innovative thinking based on the breadth and depth of knowledge and experience.

	supervision only)	experienced colleagues. Active role within local organisation. Role in international procedures and organisation under supervision or autonomously.	Acts as a peer reviewer/mentor for the work of others. Participates autonomously in international assessment context. Represents home organisation at international level.
Decision Making	Working to broaden assessment experience, will seek advice before making routine decisions. Decisions are guided by standards and practices with limited scope for interpretation and variation.	Identifies key issues and critically evaluates scientific information with minimal support. Will seek advice on decisions outside routine matters. Makes consistent and reliable judgements on scientific and regulatory issues. May be required to consult with more experienced colleagues.	Assesses (and/or supports the assessment of) a range of the most sensitive or complex issues. Coaches others, advises colleagues in own area of specialisation and provides technical support where required. May act as a mentor to colleagues. Operates in a supervisory role within the department and provides support to management in the operation of the department.
Language requirements **English**	Good command of English At least **Level B.2** according to Language levels of the Common European Framework of Reference (CEF)	Very good command of English At least **Level C.1** according to Language levels of the Common European Framework of Reference (CEF)	Very good command of English At least **Level C.1** according to Language levels of the Common European Framework of Reference (CEF)
Additional skills which are not a requirement but are recommended for development throughout the career path			
Social skills and attunement	Ability to understand and transfer information on moderately complicated areas. Ability to prepare general documentation in relation to the role.	Successfully transfers knowledge on complicated matters. Writes critical assessment reports, briefings or position papers or contributes to guidelines as part of a team and makes effective presentations on scientific/regulatory issues. Works effectively with external groups (e.g. advisory bodies/Boards) collecting and critically evaluating relevant scientific/regulatory knowledge. Sits on committees national and/or international committees	Writes and critically evaluates written assessment reports and presentations. Makes individual contributions to other professional or representational activities. Successfully transfers knowledge on highly complex matters. Influential in international networks, collects and critically evaluates new and evolving information and influences standards and opinions. May represent the Agency on Scientific/Regulatory policy issues.

The nature of work that can be assigned to each role and its respective ‘zones’ and application of the matrix to determine the degree of review and sign off that is required in each role.

3.2. Work allocation per grade

Grade 1 Pharmaceutical Assessor – work allocation

Learning Curve	Objectives/Capability	Work assigned	Review/Support
Learning Zone New Entrant (up to 6 months)	Completed organisational induction programme. Familiarisation of work. Understanding of key processes. Review and familiarise relevant SOP's and standard procedures.	Assessment categories to be determined against current skill base and work requirements, if problems occur they must be raised with a Pharmaceutical assessor at Grade 2 or above. Within identified categories: Variations (national and MRP/DCP) when acting as CMS, Less challenging applications (e.g. generics, line extensions, parallel product authorisation, etc) when acting as CMS, and where appropriate and based on individual capability, when acting as RMS, or New applications for generics, line extensions independent of role of the member state, Chemical substances, non-complex dosage forms, Herbal medicinal products and homeopathic preparations (if applicable).	All work supervised and/or monitored.
Effective Zone Post induction (6-12 months**)**	Demonstrates familiarity with standard procedures and processes. Demonstrates understanding and familiarity with key elements of the job.	Assessment categories to be determined by management based on skill base and work requirements, if problems occur they must be raised with a Pharmaceutical assessor at Grade 2 or above. Within identified categories: Variations (national and MRP/DCP) when acting as CMS and RMS, Less challenging applications (e.g. generics, line extensions, parallel product authorisation, etc) when acting as CMS and at national level, and where appropriate and based on individual capability, when acting as RMS, Renewals, or New applications for generics, line extensions independent of role of the member state including various substances (also semi-synthetic) and variable dosage forms,	Appropriate level of supervision to be determined.

		Type I variations, Herbal medicinal products and homeopathic preparations (if applicable).	
Fully Effective Post induction (up to 2 years)	Carries out the full breadth of tasks for the job.	Assessment categories to be determined by management based on skill base and work requirements, if problems occur they must be raised with a Pharmaceutical assessor at Grade 2 or above. Within identified categories: Variations(national and MRP/DCP) when acting as CMS or RMS, Less challenging applications (e.g. generics, line extensions, parallel product authorisation, etc) when acting as CMS and RMS and at national level, Renewals, or New applications for generics, line extensions independent of role of the member state including various substances and variable dosage forms, Type I variations, Type II variations, Veterinary applications of any kind, Herbal medicinal products and homeopathic preparations (if applicable).	Appropriate level of supervision (especially for new kinds of applications/dosage forms) and peer review to be determined.

Grade 2 Pharmaceutical Assessor – Work allocation

Learning Curve	Objectives	Work assigned as appropriate	Review/Support
Learning Zone (Up to 6 months or as required depending on skill base)	Works independently and takes responsibility for decision-making and sign-off of applications. To further develop assessment skills set and improve efficiency and understanding of the job role.	Work assigned by management based on previous skill base and work allocation of department. Work that can be assigned includes: Variations (national and MRP/DCP) when acting as CMS or RMS, Less challenging applications (e.g. generics, line extensions, parallel product authorisation, etc) when acting as CMS, national and RMS, Renewals, Specific veterinary dosage forms (e.g. premixes for medicated feeding stuffs/oral powders for use in drinking water, intramammary preparations (veterinary only), Herbal medicinal products and homeopathic preparations (if applicable).	Assessors work independently without close supervision. Local peer review procedures are followed with regard to approval of assessment reports.
Effective Zone	Demonstrates familiarity with standard procedures and processes. Demonstrates understanding and familiarity with key elements of the job.	General Pharmaceuticals. New applications, Renewals, Variations (all types) (National, CP MRP/DCP, when acting as CMS or RMS). All active substances and pharmaceutical forms including complex ones such as inhaler products (human products only), radiopharmaceuticals (human products only), etc. Specific veterinary dosage forms (e.g., premixes for medicated feeding stuffs / oral powders for use in drinking water, intramammary preparations (veterinary only). Herbal medicinal products and homeopathic preparations (if applicable).	Local peer review procedures are followed with regard to approval of assessment reports. May act as a peer review for colleagues.
Fully Effective	Carries out the full breadth of tasks for the job.	General Pharmaceuticals. New applications, Renewals, Variations (all types) (National, CP MRP/DCP, when acting as CMS or RMS). All active substances and pharmaceutical forms including complex ones such as inhaler products (human products only), radiopharmaceuticals (human products only), etc. Participation in the EDQM Experts' activities e.g. CEP procedure (if relevant). Specific veterinary dosage forms (e.g., premixes for medicated feeding stuffs / oral powders for use in drinking water,	Local peer review procedures are followed with regard to approval of assessment reports. Acts as peer review for colleagues.

		intramammary preparations (veterinary only). Herbal medicinal products and homeopathic preparations (if applicable). Scientific Advice.	

Grade 3 Pharmaceutical Assessor – Work allocation

Learning Curve	Objectives	Work assigned as appropriate	Review/Support
Fully Effective	Demonstrates extensive knowledge of all relevant procedures and processes. Demonstrates full understanding of the key elements of the job. Carries out the full breadth of tasks for the job.	All types and complexity of applications and activities.	Provides support to colleagues at all grades. Discusses complex issues with the team. Acts as peer review for colleagues at all grades. Provides support to management in the operation of the department.

In the tables describing work allocation per grade, the terms 'supervision' and 'peer review' are used.

Supervision is especially relevant when the assessor is relatively inexperienced and needs a supervisor responsible for and authorises the assessment. Supervisors may generally need to actually access the dossier themselves to check the assessment proposed.

Peer reviewing is seen as evaluation of assessments on a more or less equal level, where appropriate. Peer review applies on assessments by independent, authorised assessors only.

4. Training

The skill levels, experience and areas of interest of the person who is assigned to a particular job are compared against the matrix and the work allocation framework to determine where they sit against the requirements of the job. This forms part of a 'gap analysis'. This process should be carried out on joining, when appointed to a new job and at regular intervals during the performance evaluation programme.

The matrix and the work allocation framework are useful tools to identify and develop a training programme for quality assessors in each grade (learning zone). Any identified training needs should be considered for inclusion in the training programme for quality assessors in each grade.

4.1 Training programme

The induction/training programme should be developed and put in place for ***each individual*** to support them in:

- fully matching the requirements of the job,
- ensuring their continued development,
- identifying the nature and type of work that can be assigned to them,
- meeting the requirements of the quality system.

4.2 Training process

New entrants to Grade 1 should be assessed and mapped against the requirements of the job. This should determine the type of work, which can be carried out at present and, where appropriate, a rotation programme to ensure they gain exposure to the key areas. Over time all staff should receive the necessary training and support to meet the requirements of their role. It must be emphasised that the ultimate responsibility for this task rests with management.

In order to systematise and document development of an individual a process should be put in place that ***certifies*** that the necessary training has taken place (every piece of work that was carried out by an individual as quality assessor should be appropriately documented).

The key steps of the procedure are:

- a new piece of work is assigned to an individual,
- guidance/training is provided by more senior colleagues (where appropriate) during the process,
- individual completes the piece of work,

- outputs are reviewed and signed off by more senior colleagues in accordance with local procedures, which in turn may be countersigned by another colleague/management, depending on the nature of the work and the significance of the findings (e.g. potential serious risks to public health),
- Trained/accredited status is awarded on ***demonstration*** that:
  - the individual is capable of completing the work to a suitable quality standard in accordance with the deadline,
  - is aware of the key issues relating to the product,
  - understands the implications/impact of the relevant legislation and guidelines,
  - has gained sufficient practical experience of that type of work by completing a sufficient number and range of activities,
- Depending on the piece of work 'trained status' may be awarded only on the completion of a number of similar pieces of work.

4.3 Trained/accredited status

Any documentation relating to the awarding of trained/accredited status should be prepared and signed in accordance with local procedures, as appropriate. An individual may attain a trained/accredited status to perform certain pieces of work without supervision or they may be considered trained/accredited to perform all types of work within the remit of their job. The documentation supporting this may include the following key elements:

- it identifies the individual,
- it identifies the trainer,
- it identifies the type of work as per the technical specification,
- it outlines the steps taken to achieve competency,
- a statement from the trainer that the individual has completed the training process,
- a statement from the individual that they are now competent to complete this type of work,
- a commitment that peer support and guidance will always be available,
- a section to be completed by the trainer regarding the effectiveness of the training and recommendations for further training, and degree of support e.g. continued sign off or reduction in supervision.

Annex 1 Overview of knowledge and skills to be developed in relation to key criteria

The table below summarises requirements in terms of skills, general and scientific knowledge for quality assessors. It is intended to be used in connection with the profile matrix and can be used to define training needs for individual assessors.

General skills required from quality assessors: application of scientific skills (A)
Personal characteristics: self-dependency, efficiency, self-organization, ability to prioritize work, attention to detail, ability to estimate risk and identify correlations (logical thinking), ability to follow standardised procedures,
Ability to actively apply the concepts of the General Quality related Guidelines and related Q&A documents,
Ability to apply the concepts of the product specific Guidelines and Ph Eur monographs if applicable for the specific products or techniques,
The ability to evaluate suitability of data for assessments and to identify when to investigate/validate further,
The ability to assess applications to ensure product compliance with regulatory requirements in accordance with required timescales,
Understanding his/her shortcomings in knowledge and experience and knows when to ask for advice either from another assessor, or from a specific expert, according to the operational procedures that are applicable,
Ability to judge when to get in contact with a toxicological or clinical (pharmacokinetic) assessor to discuss items that are shared in the quality, toxicological or clinical dossiers, in view of a consistent assessment in these assessment fields,
Basic IT skills,
Ability to write clear and comprehensive Assessment Reports,
Ability to raise relevant and appropriate deficiency points and awareness of the impact of the questions asked to the applicants,
Social skills (acceptable interactions with colleagues, etc.) and ability to attune to relevant internal and external context,
Sufficient knowledge of written English to express themselves in a concise and clear way (note: the levels should be laid down according the EU classification framework or equivalent),
Awareness of the impact of the proposed design and presentation of the product and instructions for use, on practical use by the patient and/or health care professional.

Regulatory knowledge requirements for quality assessors (B)
Basic knowledge of the legislative system governing the process of approval of medicinal products in the Union (directives and regulations) and in the respective Member State (national law), General knowledge of the differences in procedures (national/MPR/DCP/CP) and the differences in assessment reports that are applicable for these procedures and stages of an application (e.g. D70, D120, variation reports etc.), Basic knowledge on different types of legal basis for new applications, e.g.: generic and mixed applications, well established use, biosimilars, new active substance, full applications for existing substances, informed consent applications, fixed dose combinations, General knowledge of Quality Regulatory Framework with hyperlinks to Guidelines (e.g. EMA, HMA, EDQM, (V)ICH), General knowledge of Quality Working Party and EMA Scientific Committees Knowledge of the general chapters and general structure of the European Pharmacopoeia and the National Pharmacopoeia in respective Member State, and should be able to use them, Knowledge on how the Pharmacopoeial Monographs are prepared, Knowledge of the content of the national assessment policy (if applicable) and ability to apply this in the assessments, The assessors should have sufficient knowledge and understanding of GMP, Sufficient knowledge of CTD format and content of a dossier (CTD and NTA format in case of veterinary medicinal products), Internal assessment templates.
Basic knowledge requirements relevant for 'Challenge within role' and 'Decision making' (C/D) Detailed information about current regulatory and scientific guidelines relevant for Pharmaceutical assessment can be found at the following websites: - European Medicines Agency: www.ema.europa.eu - Notice to Applicants, Volume 2: www.ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm - ICH: www.ich.org - VICH: www.vichsec.org

Training program on basic knowledge of regulatory and scientific guidelines relevant for pharmaceutical assessment should include, but not be limited to the following topics: General aspects of assessment, Active substance, Pharmaceutical Development, Manufacture of the medicinal product, Impurities, Specifications, analytical procedures and validation, Excipients, Container closure systems, Stability, Specific types of products, SmPC, Patient leaflet and labelling, Bioequivalence assessment, including bioanalytical methods used in the BE assessment, Dissolution testing, PAT/Quality by design, New analytical methods, Fermentation products and their specific requirements, Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.
Practical Training
It is recommended to include a practical training as part of the training program. If possible the individual could:

- participate in meetings of Scientific Committees and Working Parties of the EMA, - attend other scientific meetings to become familiar with discussions at EU level (e.g. assessors trainings, trainings organized by the EDQM, etc), - join a GMP inspection at a national or EU level.
Awareness of and attunement to internal and external context & social skills (E)
The individual should be familiar with the decision making processes at a national level and actively contribute to or participate in this process at his/her specific level in the organization. Participation in at least one meeting where the decisions are made is recommended, Individuals operating as peer reviewer or coach of colleagues should have sufficient didactic and social skills, and where relevant managerial skills, Individuals operating in an international decision making context may benefit from international negotiation skills, Awareness of social and/or politically relevant topics in relation to Quality assessment.