# A guide to defining the competence required of a consultant in clinical chemistry and laboratory medicine

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#### **Abstract**

A definition has been agreed for the most senior professional (consultant) in clinical chemistry and laboratory medicine. A model job description for a consultant has been determined, which is intended to act as a toolkit to assist employing authorities and professional bodies to define the role of individual consultant posts. A total of 86 competences for a consultant have been designated and expressed in the form of simple generic proficiency standards. These competences have been allocated to six broad areas: clinical [13]; scientific [15]; technical [12]; communication [12]; management and leadership [20]; professional autonomy and accountability [14]. The competences are intended to be illustrative rather than definitive and to enable the duties of any consultant post to be defined. Assessment of competence is likely to entail consideration of qualifications, registration status, continuing professional development and performance review. The project is intended as a guide to European societies of clinical chemistry and laboratory medicine. The guide should be capable of local interpretation to encourage a greater degree of commonality in the role of the consultant whilst protecting national identity. The guide should stimulate international understanding and collaboration and contribute to an overall improvement in the quality of practice.

**Keywords:** assessment of competence; clinical chemistry and laboratory medicine; consultant competences; definition of consultant; European Union; model job description.

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#### Introduction

The European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4) is the overarching body that represents the professional interests of clinical chemistry and laboratory medicine (CCLM) in the European Union (EU). Membership of EC4 comprises the relevant national societies from each of the EU member nations (1). In its strategic plan for the period 2005–2008 EC4 specifies a number of goals, two of which are:

- Co-operation in the recognition of professional qualifications of the profession in compliance with the principles of free movement of professionals within the EU; and
- Co-operation and recognition of equivalence of standards in the field of training specialists in clinical chemistry and laboratory medicine, irrespective of their varying academic background.

In furtherance of these goals the Executive Board of EC4 established a Working Group to produce a guide to explain the roles undertaken by the most senior professionals in CCLM and the competences required to undertake those roles. This paper is the report of that Working Group, which has been endorsed by the Executive Board of EC4 after two rounds of consultation with each of the national societies.

The Working Group undertook to produce a generic guide rather than specific rules. This decision recognises that the roles of senior professionals in CCLM will differ according to the background of the individual professional, the country in which he/she works and the terms of employment (2). The guide is intended to be equally applicable to senior professionals who have initial training in medicine, chemistry, pharmacy or any other relevant science discipline. The purpose of this document is to provide a framework that is capable of interpretation by national societies of CCLM for use in individual EU countries and which will help to deliver a common approach to the definition of competence at the highest level of the profession and so facilitate the free movement of senior professionals within the EU.

There is no single name for the most senior professional in CCLM that is universally recognised by all 25 nations in the EU. For the purposes of this guide the Working Group has adopted the title 'consultant', which is widely used in the English speaking world to describe a doctor or specialist who holds the highest hospital appointment in his/her specialty and is ultimately responsible for the patients in his/her care. One of the points of interpretation for each national society is the selection of the title that best describes this role in that country.

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#### Methods

The Working Group examined the limited literature that could be found on the definition of competence in a senior professional in CCLM. This included literature from the Royal College of Pathologists (3) and the Association of Clinical Scientists (4) in the United Kingdom, The Union of European Medical Specialists (5) and The EC4 European syllabus for postgraduate training in clinical chemistry (6). Reference was also made to the description of a laboratory director as defined in the Directive ISO 15189:2003 (7). Thereafter, the Working Group adopted an iterative process to agree the competence requirements for a consultant in CCLM. The Working Group consulted regularly with the Executive Board of EC4 and twice with the national society members of EC4. This document is the outcome of this method of working.

### Definition of a consultant in clinical chemistry and laboratory medicine

A consultant is defined as a senior professional with responsibility for the design, development, delivery and direction of a clinical and/or scientific service in the area of CCLM. A consultant functions as an autonomous practitioner within a clinical team and within the overall strategic plan of his/her employing authority and is accountable for service quality, including data interpretation and clinical liaison. A consultant has demonstrated competence to a level consistent with the requirements of a European Specialist in Clinical Chemistry and Laboratory Medicine (Eur-ClinChem) (8) and undertakes continuing professional development.

According to this definition there were approximately 20,000 consultants in the 15 nations that constituted the EU at the beginning of 2004 (9).

## Model job description for a consultant in clinical chemistry and laboratory medicine

#### a) Description to be completed for each specific post

Title of post:	
Grade of post:	
Location of post:	
Accountable to:	
Accountable for:	
Scope of post:	

- b) Main duties of post This section lists the main duties of a 'typical' consultant in CCLM. These have been listed in broad functional groups. Not every consultant will be required to undertake all these duties (e.g., research and teaching roles may be restricted to larger laboratories) but he/she will undertake duties from each group. The duties for each specific consultant post should be specified in a job description. The following will be expected of the consultant.
- i) Clinical practice, advice and interpretation
  - To participate as a member of the clinical team and communicate on a regular basis with

- users of the service in order to ensure that it is consistent with their requirements;
- To offer clinical guidance and scientific advice to other health professionals on the selection, performance and interpretation of clinically relevant investigations to facilitate the diagnosis, treatment, monitoring and understanding of health and disease in normal subjects and patients;
- To participate in the direct clinical care and management of patients as appropriate to initial education and training; and
- To participate as required in an out-of-hours clinical advisory rota, which will usually involve availability for telephone or electronic contact rather than physical presence in the laboratory.

#### ii) Performance and quality

- To be responsible for the overall quality of the laboratory service in line with appropriate national and international standards;
- To be responsible for the selection, implementation and performance of analytical methods and instrumentation;
- To ensure participation and satisfactory performance in appropriate internal, regional, national and international quality assessment schemes;
- To contribute to the selection of laboratory information and communication technology and to ensure that it is compatible with analytical instrumentation and any host information system; and
- To initiate and participate in clinical audit and audit of the laboratory service;

#### iii) Professional responsibility

- To maintain up-to-date knowledge of clinical, scientific and technical developments within the discipline;
- To ensure that service provision is based on the best available evidence;
- To participate in continuing professional development and maintain appropriate records:
- To provide professional advice, as appropriate, to individuals, organisations and government; and
- To behave in a professional manner at all times and to comply with appropriate registration requirements, including legal and ethical standards and codes of conduct.

#### iv) Training and research

- To initiate, supervise and collaborate in research and development projects on relevant clinical and scientific problems within appropriate ethical standards;
- To be responsible for the training of health professionals in the discipline of CCLM; and
- To provide relevant teaching and training at varying levels for health professionals and students outside the discipline.

#### v) Management

- · To participate in the overall management of the discipline and related services as required by the employing authority;
- · To discharge an agreed level of responsibility for the financial and personnel management of the clinical laboratory;
- · To participate in the process to recruit staff in the discipline; and
- · To participate in and be subject to regular performance review or staff appraisal.

#### Competences required of a consultant in clinical chemistry and laboratory medicine

A consultant requires the core knowledge and skills to work in the specialty; these are generally obtained from formal training programmes. In addition, a consultant requires higher level competences that focus on the ability to take responsibility for autonomous practice. Higher level competences are usually attained from experience in practice.

In the following paragraphs competences are listed as generic proficiency standards under six major headings. These should be regarded as minimum proficiency standards consistent with consultant status. These generic proficiency standards need to be defined for each individual consultant post, according to the roles associated with that post. Therefore, not every consultant will be required to acquire all of the competences, but he/she will be required to demonstrate those competences that are required to fulfil the duties of the post as defined in the job description.

- a) Clinical competences Clinical competences are required to enable the consultant to have a detailed understanding of normal physiology and the pathology of disease and may include specialist knowledge in one or more areas.
- Knowledge of normal human physiology in order to provide a foundation for the understanding of disease processes;
- Understanding of the underlying mechanisms of the pathology of disease with particular relevance to the discipline;
- · Ability to understand the effects of diagnostic or therapeutic procedures and their impact on laboratory parameters;
- Ability to advise on the choice of samples and aspects of patient preparation relevant to the
- Ability to interpret results from investigations relevant to the discipline within the wider context of the clinical situation taking account of any pre- and post-analytical variables;
- Ability to recognise the significance of changes in relevant signs, symptoms and laboratory parameters and relate them to specific diseases or conditions;
- Experience in the clinical decision-making process, including understanding the significance of the

- results from an investigation, independent interpretation and the giving of advice on subsequent investigations or management;
- · Ability to devise an investigation strategy taking into account the full clinical picture;
- Possession of sufficient clinical knowledge to be able to communicate the relevance of laboratory results to clinical and other professional colleagues and to patients and their representatives, as required;
- · Ability to participate in multidisciplinary clinical meetings to represent the practice and relevance of the discipline;
- · Ability to participate in and lead clinical audit initiatives to establish the effectiveness of investigations;
- · Expertise in the clinical and scientific aspects of one or more specialist areas of medicine; and
- · Possession of medical practitioner skills and experience for the direct investigation and management of patients in one or more areas of the discipline.
- b) Scientific competences Scientific competences are required to enable the consultant to make effective use of knowledge and data in problem solving, troubleshooting, innovation and appraisal.
- · Knowledge of the science that underpins the discipline and the broader aspects of medicine and clinical practice;
- · Maintenance of an up-to-date understanding of the scientific and technical aspects of the discipline;
- Awareness of scientific developments within the discipline and their likely impact on service provision:
- · Understanding of evidence-based medicine and how to apply levels of evidence to optimising service provision within the discipline and production of relevant guidelines for investigation;
- Knowledge of basic statistics and predictive values and an appreciation of their relevance to the science of the discipline;
- Understanding of the advantages and limitations of common procedures and methods used within the discipline to investigate patients;
- · Ability to recognise and define problems and progress through investigation to solution;
- · Ability to design and introduce new methods or improvements to existing methods;
- Ability to read and critically appraise the literature;
- Experience of searching for information, critical appraisal of information and integration into the knowledge base;
- · Ability to critically review evidence, formulate hypotheses, design and conduct appropriate experiments, evaluate and disseminate results;
- · Competence in writing reports and scientific publications;
- · Ability to support and lead ethically approved research and development programmes in the discipline, including the supervision of junior colleagues;

- Ability to contribute to individual and/or collaborative research programmes, including those beyond the discipline; and
- Ability to referee scientific endeavour in the form of publications or project proposals.
- c) Technical competences Technical competences are required to enable the consultant to understand analytical techniques and good laboratory practice and to advise on technical troubleshooting and innovation.
- Ability to practice with due regard for personal safety and the safety of colleagues and patients;
- Understanding of the principles of the techniques and methods employed in the discipline;
- Proficiency in the commonly used techniques and methods in the discipline;
- Proficiency in basic information technology skills, as required by the discipline;
- Detailed knowledge of the underlying principles and limitations of techniques and methods employed in relevant specialist areas of the discipline;
- Ability to interpret quality control and quality assurance data and take appropriate restorative action when performance deteriorates;
- Understanding of methods of calibration and traceability;
- Ability to use knowledge of basic analytical principles to resolve problems related to samples, reagents or methods;
- Ability to design, implement and evaluate procedures for troubleshooting poorly performing methods;
- Ability to design and implement protocols for the introduction of new or improved methods;
- Ability to design and implement protocols for equipment procurement and evaluation; and
- Understanding of relevant European and ISO directives and the impact that they have on the availability and performance of methods for the discipline;
- d) Communication competences Communication competences are required to enable the consultant to communicate effectively within the discipline, to users of the discipline and to the wider clinical, scientific and political community.
- Ability to use information technology and modern methods of communication and to understand the requirements for back-up, security and the regulations for legal and ethical use of information;
- Understanding of the benefits of advanced information technology as a means of improving communication using unified coding and electronic networks:
- Ability to lead a group discussion and chair a committee meeting effectively;

- Ability to present findings in both written and spoken media through reports, scientific papers, posters, seminars, tutorials and lectures;
- · Ability to train colleagues in defined areas;
- Ability to communicate effectively with colleagues within the discipline and with users of the service;
- Ability to communicate the achievements and needs of the discipline within the employing authority and the wider clinical community;
- Awareness of the opportunities for and limitations of promoting the discipline in the wider political and public arenas;
- Ability to represent the discipline in multidisciplinary meetings and strategic planning operations;
- Experience of external clinical audit as a means of delivering improvement to both service quality and appropriateness of testing;
- Awareness of the importance of teamwork in the development of the discipline and the profession; and
- Active participation in relevant professional bodies and multidisciplinary scientific and clinical conferences and meetings;
- e) Management and leadership competences These competences are required to enable the consultant to manage staff, financial and physical resources and to show leadership in team building and strategic direction.
- Understanding of the basic principles of management related to the discipline;
- Understanding of the range of tasks and skills necessary for the effective management of the service;
- Understanding of the role and contribution of the service in the wider clinical environment;
- Ability to manage health and safety issues related to the discipline;
- Understanding of the principles of quality assurance, audit and accreditation relevant to the practice of the discipline;
- Ability to introduce and maintain a quality system that accords with international standards of quality management for a medical laboratory (7, 10, 11);
- Ability to manage personnel issues, including training, record keeping and codes of behaviour;
- Ability to educate and train relevant staff in the theory and practice of the discipline;
- Understanding of basic aspects of financial management as they apply to the discipline;
- Ability to manage the physical resources used for the provision of the service;
- Understanding of all administrative tasks within the department and ability to exercise leadership to ensure their completion;
- Understanding of the principles of risk management and the ability to assess the risks associated with procedures;
- Ability to take a leadership role in strategic planning for the discipline with the knowledge of recent developments and the needs of users;

- · Ability to lead and motivate a team of staff within the discipline with sensitivity and direction;
- · Possession of leadership skills to ensure effective staff management, including the development of an appropriate skill mix, recruitment, workforce planning, training, performance review and continuing professional development;
- Ability to undertake effective performance review or appraisal of senior colleagues;
- · Ability to fulfil the requirements of business planning, budgeting and resource management;
- Ability to manage research and development projects and programmes;
- Ability to justify to clinical colleagues individual diagnostic and therapeutic procedures in the laboratory repertoire and to utilise evidence in support of clinical service development; and
- Ability to represent the discipline at local, regional and national level in the healthcare community and more widely, as appropriate.
- f) Professional autonomy and accountability competences These competences are required to enable the consultant to understand and practice professional accountability for his/herself and to demonstrate professional autonomy and accountability for others.
- Ability to practice in a non-discriminatory manner within the legal and ethical boundaries of the profession and in line with appropriates codes of con-
- · Ability to maintain confidentiality and to understand the need for informed consent where appropriate;
- · Ability to exercise a professional duty of care by understanding and respecting the needs of patients and users of the laboratory service;
- Knowledge of the limits of his/her personal scope of practice and when to seek advice;
- Understanding of the need for the maintenance of accurate and legible records appropriate to the scope of practice;
- · Understanding of the need for career-long continuing professional development and performance review;
- · Understanding of the obligation to maintain and demonstrate competence in all areas related to the iob role:
- · Recognition of the need for effective self-management of workload and the ability to practise accordingly;
- Ability to work in partnership with other professionals as appropriate;
- Ability to define the limits of practice of appropriate staff working in the discipline;
- Understanding of the need for regular performance review or appraisal of staff working in the profession and for appropriate support measures;
- · Acceptance of responsibility for the scope and quality of the service provided and for its strategic development;

- · Acceptance that the laboratory service must work within the corporate strategy and be part of the corporate governance of the overall health institution or parent company; and
- · Awareness of the need for recording and investigating all complaints about the service and for corrective action.

#### Assessing the competence of a consultant in clinical chemistry and laboratory medicine

The detailed assessment of competence will vary with the country and the employing authority involved and so this document aims only to give broad guidelines. There are at least three levels of assessment.

- a) Professional qualifications Professional qualifications and experience should be assessed as part of the appointment procedure for a consultant. Qualifications should be of an appropriate academic content, standard and duration for the specific consultant post. In general, formal educational requirements should comply with the syllabus and duration of study prescribed for a European Specialist in Clinical Chemistry and Laboratory Medicine. Assessment of professional qualifications and experience by an expert from outside the employing authority may be part of the appointment procedure.
- b) Registration status Many European countries have a requirement for professional registration with an appropriate national body in order to be able to practice. In a growing number of countries this is a legal requirement and in some there are separate registers for medical and non-medical practitioners. Clearly, any consultant in CCLM must comply with the registration requirements of the country and staff group in which he/she practices. In addition, the European Specialist in Clinical Chemistry and Laboratory Medicine is a high level registration that equates to the minimum standard to practice as a consultant and it provides a useful benchmark of competence. European registration is increasingly recognised as an aid to free movement between countries of the EU.
- c) Continuing professional development and performance review Throughout Europe, consultants in medical and clinical disciplines are increasingly required to undertake continuing professional development and to submit themselves for regular performance review. It is likely that this combination of criteria will develop into the main route for the ongoing assessment of consultant competence. Responsibility for continuing professional development is that of the individual consultant, who is required to produce evidence of relevant education, achievement and experience. Evidence of continuing professional development is part of the performance review process, together with a more formal process to assess compliance with the proficiency standards for the individual consultant post. In some European coun-

tries the performance review process is linked to reregistration and renewal of the licence to practice.

#### **Discussion**

The Executive Board of EC4 has agreed the published definition of a consultant in CCLM. In so doing, EC4 recognised that in many EU countries the name consultant is not applied to the most senior professional working in the profession. Therefore, in keeping with the purpose of the generic guide, it is recommended that individual national societies adapt the definition to best describe the name and role of the most senior professional in CCLM in accordance with practice in their country.

The Working Group recognised that each individual consultant role will differ and will have its own particular duties and responsibilities. Therefore, a specific job description is required for each and every consultant in CCLM. It is for individual employing authorities to specify the duties and responsibilities of the consultants that they employ. Professional bodies may have a role in assessing the content of job descriptions prior to the appointment process. Against this background, the model job description presented in this report can do little more than point to the key elements that should be considered for inclusion in individual job descriptions.

A number of different approaches can be taken for designation of the competences required to undertake the role of a consultant in CCLM. In this project the Working Group identified six broad areas of job function and wrote competences in the form of simple proficiency standards. There is no clear distinction between clinical, scientific and technical competences and there is some overlap between leadership and professional accountability. However, the Working Group believes that breaking the competences down into these areas will aid understanding and it hopes that this format will help employers to determine the competences required to fulfil individual consultant roles. It will also enable some degree of assessment of each proficiency standard as a means of assessing continued competence.

The recorded competences are intended to be illustrative rather than definitive. Certain consultant roles may require competences that have not been included in this study. It is also most unlikely that any individual consultant role will require all the published competences. For example, a medical practitioner with clinical responsibility for direct patient investigation and management will require different competences from a scientist who has a strong element of research and development in his/her job description. The intention of the published competences is to enable the duties of any consultant position to be defined, both at the time of appointment and at regular intervals thereafter as the job role evolves.

The definition of the role of a consultant in CCLM and the publication of consultant competences are in

line with the overall strategic aim of EC4 to recognise the equivalence of standards of practice across the EU. EC4 believes that this guide will assist improvement of the overall quality of practice of CCLM, will encourage a greater degree of commonality whilst protecting important national identity, and will assist individual consultants to obtain employment in compliance with the principles of free movement of professionals within the European Union.

#### Acknowledgements

The authors acknowledge the expert opinion and advice from the Executive Board of EC4 and from several EU national societies during the consultation phases of the project.

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Received March 31, 2005, accepted April 4, 2005