

# **Competence Profiles – Guidance for applicants and Assessors**

## **PART 2 – INDUSTRY CLASSIFICATION (BI) – BIOMEDICAL ENGINEERING**

### **Introduction**

Biomedical engineering covers a very varied and diverse range of products and services. Typical employers may be engaged in the design or manufacture of medical implants, surgical instruments and supporting medical equipment, aids for the disabled, physiotherapy and occupational therapy equipment, and patient monitoring devices, as well as drug delivery and musculo-skeletal analysis equipment. There is also a large range of engineering rôles involved in research in this field.

Due to the very close interaction between human life and products in this area, this is an industry that is closely controlled by company, national and international standards and procedures. It is also an area where litigation is not uncommon. Engineers working in this area will need to be very aware of the particular requirements in their own field, and this will require a great attention to detail and thoroughness in their way of working.

The rôles an engineer may take in this field are very varied, but could include design engineering, project management, development and testing, and research, among others. The requirements in each of these fields will be very different but, in all cases, applicants should be able to demonstrate technical expertise, active interest and achievement in their chosen area, along with an appreciation of the business requirements and governing procedures of their organisation.

In order to assess professional engineering responsibilities within this area, it is necessary to judge an individual's competences, active interest and achievement, as distinct from investigating time spent in designated posts previously deemed to meet the Institution's requirements for Membership. The method of assessing the various elements of competence within sections A to E, in accordance with the benchmark profile for Membership (normally a minimum of three sections at level 3 plus two sections at level 2), is fully described in Part 1 of this manual.

The biomedical engineering criteria against which applicants should be assessed are;

- Appropriate education
- Experience
- Achievement
- Commitment to biomedical engineering over a period of time
- Competence
- Institution participation
- Influencing others (education, media contact, leadership, careers guidance, etc.)
- Contribution to the image and profile of biomedical engineering.

### **Requirements for election or transfer to Member**

Specific job titles have been avoided in the following descriptions, since experience shows that similar levels of professional responsibility in different companies often have very different titles; conversely, the same title often has very different meanings in different organisations.

Generic job titles or rôles which may be suitable for election or transfer to member include Design Engineer, Project Engineer, Bio-engineer, Analyst, Research Engineer / Associate and Development Manager.

### **Assessment of competences**

Professional mechanical engineering responsibilities for the positions described above will depend to a large extent on the nature and size of the company and department. Levels of responsibility in the test, design and analysis functions may be reflected in supporting areas such as planning. This reinforces the importance of carefully assessing applicants' personal responsibilities and competences, together with their direct input to projects in their work area and their degree of supervision. In addition, clear and

comprehensive organisation charts will be key to the appraisal process. **It will not be appropriate to recommend election to Member on the basis of job title or grade alone.**

Where an applicant appears to spend the **majority** of his time in project management, assessors may find it useful to refer to the section entitled 'Engineers in Project Management Rôles' which appears later in this manual.

#### Competence statements A and B

Successful applicants will be able to demonstrate their use of a combination of general and specialist engineering knowledge and understanding to optimise the application of existing and emerging technology in their chosen field within the biomedical industry. Evidence of competence, active interest and achievement produced at interview may include drawings, calculations and computer analysis, design studies, test reports, research papers, computer models, patent applications and photographs.

Applicants engaged primarily in project management should provide evidence of responsibility for technical specifications, technical risk management and evaluation of technical solutions. Project Management experience whereby the Management activities are devoid of any specific biomedical engineering content need to be treated with caution. There are many functions within the biomedical industry (finance, manufacturing, management etc) that have no biomedical content. Some Managing Directors of Biomedical companies and Heads of academic Engineering Departments that include a biomedical division show no interest in biomedical engineering.

Examples of activities which engineers employed in these rôles would be expected to carry out include:

- Participation in a cross-functional team in the design, development, validation and manufacture of new medical products.
- Research of new technologies, materials or further investigation of existing research in the field of biomedical engineering.
- Provision of specialist services to a company, such as specialist development or testing, computer modelling, etc.
- Project management of new product development including resource planning, technical decision-making, risk analysis and communication with clinicians.

#### Competence statement C

Traditional management structures have changed in many instances over recent years. Also a large number of engineers are employed in specialist areas such as research or consultancy. As such, engineers in various job rôles will often have significant responsibility for management of their own time to meet deadlines, resource planning, project planning, whilst not having a traditionally management rôle. (Again, real bioengineering and medical content must be apparent, in addition to management skills)

Typical activities demonstrating leadership and management skills may be:

- Planning and managing project teams. These are likely to be multidisciplinary and may well involve clinicians, academics and industrialists on the same project.
- Participation in team decision-making.
- Development of junior engineers and technicians.

### Competence statement D

Communication and interpersonal skills should be assessed by consideration of both the Professional Review Report and interview performance. Assessors should look out for a report which has a logical structure, clearly aimed at providing a portfolio of evidence against each of the five competence statements, while providing a qualitative description of activities and achievements.

Assessment of verbal communication skills should analyse the ability to give clear, concise and relevant answers that address the question without undue digression and provide sufficient, but not superfluous detail.

Additional evidence of competence in this area may be sought by investigating:

- Whether the applicant routinely makes presentations to in-house management at various levels, clinicians, and others; subjects could include project plans, technical product information, and research papers.
- Other written reports and verbal presentations that the applicant routinely makes.
- Patent applications.

### Competence statement E

The observance of safe working procedures, including compliance with internal and national codes of practice, is inherent in virtually all engineering activities in biomedical product development and manufacture. Similarly, there are codes that cover the design and manufacture of biomedical products. Applicants should be able to demonstrate their commitment to observing and promoting the use of any such codes that are relevant.

Evidence of professional integrity and commitment should include a Self-Development Action Plan, in any convenient format, outlining how the applicant intends to maintain and enhance competence through personal development. The Plan should include short, medium and long-term goals and explain how these are likely to be achieved. Assessors should be aware that SARTOR 3 interprets Continuing Professional Development (CPD) as commencing at the point where Chartered status is attained; therefore applicants are not required to provide a record of courses attended, etc., when applying for corporate membership.

Examples of CPD activities recognised by the Institution as acceptable include:

- extra qualifications such as an MBA, Diploma in Engineering Management
- any relevant technical or business courses
- conducting or attending workshops
- attending, presenting or participating in seminars and conferences
- presenting or attending lectures
- writing technical papers
- reading technical articles and journals
- distance or open learning
- secondments and job rotation
- updating in own and other fields of work
- Institution meetings or events
- active IMechE committee work
- MPDS mentoring
- being an IMechE interviewer
- learning a foreign language
- involvement in government activities
- community and charity work

### **Requirements for election or transfer to Fellow**

Applicants will generally, but not necessarily, have significant responsibilities for resources (both financial

and manpower) and also have wide understanding of strategic, commercial and financial issues. They are likely to be experts in their particular fields, and “champions” for their directorate, company or industry sector.

The following senior engineering posts should be considered as generally likely to meet the requirements for the class of Fellow:

Director

Head of a Division

A famous inventor, highly reputable author or media presenter, educationalist, or opinion leader

In addition, depending on the precise level of responsibility and the technical and managerial content, it is possible that heads of departments within such areas, and in some cases their first line managers, may meet the requirements for Fellow.

Valid applications for election or transfer to Fellow may be received from other engineers with (a) senior management and commercial responsibilities or (b) established reputations in important positions of responsibility in engineering science or practice. Applicants would be expected to participate in external forums, for example by promoting the importance of engineering issues in debate with Government and other bodies, via the Institution. In any case, an involvement in the professional development of young engineers would be expected, as would documentary evidence of Continuing Professional Development.

Further examples of suitable CPD activities not covered under the requirement for Competence Statement E above include:

- MPDS mentoring
- Acting as an IMechE Membership Panel interviewer

For candidates applying directly for the class of Fellow, a Professional Review Report similar to that required for the class of Member would be required in addition to an interview. In particular, this report must contain additional supporting evidence detailing:

- The position of senior engineering responsibility held by the applicant
- The applicant's contribution to the professional development of young engineers
- How the applicant intends to keep up to date regarding developing technologies, from both a technical and a commercial standpoint.

Finally, a Development Action Plan detailing a future programme of CPD would be required from applicants in either category (transfer from Member or direct election).