

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

### **PHARMACEUTICAL INDUSTRIES**

#### **Introduction**

Throughout the pharmaceutical industry, mechanical engineers are likely to be involved in a wide range of tasks requiring a professional (i.e. Chartered or Incorporated) level of competence. The structure of pharmaceutical companies has been changing rapidly in recent years and the introduction of various types, levels and grades of engineer has arisen out of many factors; for example, new company structures, new methods of working, new product introductions, novel drug delivery systems/devices, improved speed to market, new technology and the global pressures demanding ever more efficient facilities and production processes. In short, the emphasis on constant change throughout industry is a major factor in the changing responsibilities of a professional engineer working within pharmaceuticals.

These changes in direction, products, technology, working practices and levels of activity in many companies now mean that an engineer's professional development is far from straightforward. For example, an engineer may move from directing many subordinates on a large design and development project, to working alone on a quality system (e.g. to satisfy new business requirements) and then on to training or support duties for a shop-floor operation.

Another significant factor governing engineers' functions and activities in pharmaceuticals is that of scale. In its early stages a potential new drug will involve the use of laboratory scale equipment, if the product potential is realized then it must be "scaled-up" for routine manufacture using much larger scale equipment, typically involving batch production, although in some circumstances continuous production methods are used.

Increasing specialization within pharmaceuticals has brought about legitimate new employment opportunities for the chartered and incorporated mechanical engineer, where unlikely-sounding job titles may conceal solid engineering activity. For example, in the past it was relatively rare for packaging to be a function associated with sustained formal engineering duties. This is no longer true, with packaging (as with many other functions) requiring a detailed, in-depth engineering knowledge of materials, control systems and opto-electronics, as well as complex mechanics. Engineers working with packaging often lead aspects associated with the introduction of a new delivery device, these devices are often highly complex assemblies which require specialist engineering knowledge in order to achieve viable manufacturing operations.

There is a notion that engineers can operate in cross-disciplinary roles nowadays. These can embrace mechatronic system approaches (i.e. integrated mechanical and electrical/electronic structures and devices, under microprocessor control) and have particular validity in the use of robotic and automated systems. For example: R&D functions developing products, devices and specialist facilities, pharmaceutical production processes, assembly of the drug delivery devices/systems, maintenance of highly specialized facilities, construction of production facilities and associated service/support facilities, continuous improvement of process operations, etc.

Applications for Membership need to be carefully assessed on the basis of an applicant's individual duties and authority. In order to assess professional

engineering responsibilities against the varied and changing background outlined above, it is now necessary to judge an individual's competences, 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. Information from MPDS and in-house development schemes may also assist in this area.

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

The structure of a typical pharmaceutical company will comprise the following main functions or departments associated with engineering disciplines:

Technical – projects, design, development, R&D  
Operations - production, production development, procurement, maintenance

Each of these main areas is likely to have a director or senior manager in charge of them. Many larger pharmaceutical companies often have the bulk of these activities split between different sites, or will have duplicates on many sites.

These areas will incorporate a significant engineering content and the head of each section or department within those functions may be expected to fulfill the Institution's requirements for the class of Fellow (see below for details) and certainly those for the class of Member.

Each functional head will have a number of subordinate staff, under the following typical categories:

Team Leader(s) \*  
Senior Engineers  
Engineers  
Technical Support Staff

\* This title should not be confused with the term "Team Leader" used by some older factories for functions that approximate to the old Foreman or Charge Hand level.

With the move towards "flat" or matrix-type organisational structures, the distinctions between the various categories are less clear-cut than hitherto and all staff are often on a single salary structure and common terms of employment. Team Leaders' work can typically include staff management, project management, planning, control, operation and technical leadership and might well fulfill the Institution's requirements for the class of Member. Team Leaders in this context are likely to have overall responsibility for a number of projects.

Senior Engineers assist Team Leaders in any of the work areas mentioned above but with less emphasis on project and budget planning. Their responsibilities can be appropriate to the grades of MIMechE or AMIMechE, depending on detail. The same may be true of the Engineer grade, where some individuals can have wide experience in various areas but may not have pursued wider management activity. In certain cases, therefore, the responsibilities of these "Engineers" may approach those appropriate to MIMechE level.

## Assessment of Competence

Professional mechanical engineering responsibilities for the positions described above will, of course, depend to a large extent on the particular location, the type of facility and the individual's job description.

Be aware of those companies who split the company functions up between different sites e.g. most product development at one site, production at another and maybe a centralized Engineering function for national or international projects. Particular attention must be paid to the amount of experience and involvement applicants have had in these other areas to build an all-round appreciation of their professional competences. This reinforces the importance of carefully assessing applicants' personal responsibilities, 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 no longer be appropriate to recommend election to Member on the basis of job title or grade alone.**

### 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 pharmaceutical industry, be it in research & development, projects, design, operations, maintenance, engineering services, or in any of the other areas outlined above.

Applicants engaged primarily in project engineering or management should provide, and assessors should seek, evidence of responsibility for technical specifications, technical risk management, evaluation of technical solutions and monitoring against technical performance standards.

However, in either situation, applicants should demonstrate evidence to show that they apply engineering principles in a competent and professional manner in their work, whether this is in predominately engineering areas or other cross-disciplinary activities.

Examples of situations or activities that may give mechanical engineers the opportunity to achieve and demonstrate professional competence in these areas include:

- Theoretical design or feasibility studies for new drug delivery systems or devices, new manufacturing technologies or processes either in a design and manufacturing environment or in a specialist department of a consultancy.
- Participation in the evolution, development, manufacture and commissioning of new manufacturing lines or equipment, including performance evaluation and the investigation of operational failures. Examples include novel processing techniques or materials handling methods, unconventional processes or advanced technologies.
- Applying knowledge to enhance existent manufacturing processes and improve efficiency through challenging the status quo. There would be clear evidence of the use of problem solving tools corrective action.
- Secondment in any of the above areas, particularly to remote or overseas locations, where support facilities may be severely limited. (Secondments to in-house production development departments and equipment manufacturers would also be expected to provide opportunities for the development of professional engineering expertise and technical judgement.)

### Competence statement C

As many pharmaceutical companies now operate a matrix management structure, applicants are not necessarily expected to have line management responsibility or experience in order to meet the required level of competence in this section. Also, engineers who have moved into highly specialist technical roles, e.g. in headquarters engineering departments or design, may have minimal management responsibilities; such applicants would be expected to have a high degree of autonomy in planning and monitoring their activities and care should be taken to explore the interface between them and their colleagues and supervisors.

Examples of situations or activities that may give engineers the opportunity to achieve and demonstrate competence in these areas include:

- The planning and personal supervision of production start-up and commissioning projects, including the control of contract staff.
- Active participation in design review of new and existing processes, equipment or devices.
- The periodic review of production and/or operational strategies for existing manufacturing and the formulation of new procedures and systems for additional items and novel processes.
- The in-house training and development of technicians, skilled craftsmen and junior engineers, possibly on a project-by-project basis.
- The budgetary control of capital or revenue projects, large or small.
- Leading or heavily involved in Quality initiatives that deliver benefit to the business via improved customer service, product quality or operational efficiencies.

### Competence statement D

Communication and interpersonal skills should be assessed by consideration of both the Professional Review Report and interview performance. Assessors will be looking for a report which has a logical structure, clearly aimed at presenting 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 analyze 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, outside clients and contractors; subjects could include project plans, business plans, specialist topics, etc.
- Whether the applicant is involved in contract liaison and negotiations - systems, procedures, method statements, quality programs, safety, etc.

### Competence statement E

The observance of safe working procedures, including compliance with internal and national codes of practice, is inherent in virtually all aspects of the pharmaceutical industry. Similarly, there are codes that cover the design and manufacture of all equipment and components. Applicants should be able to demonstrate their commitment to observing and promoting the use of any such codes that are relevant

and they should demonstrate a clear understanding of regulatory demands associated with their role and the role of others who they closely interact with.

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.

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

Applicants for Fellowship must hold a position of senior responsibility and must also demonstrate evidence of active CPD, including the promotion of the engineering industry and support for young engineers.

As outlined above, the following senior engineering posts within a pharmaceutical company should be considered as generally likely to meet the requirements for the class of Fellow:

- Director
- Operations, Engineering or Technical Manager
- Project or Product Manager
- Engineering Specialist/Expert

The scale of responsibility for the posts can generally be verified by establishing the budgetary levels associated with it. Annual figures exceeding half a million pounds could be expected.

Applicants will generally 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, e.g. product design, product or process development or a particular production technology and “champions” for their site, manufacturing unit, company or industry sector.

Valid applications for election or transfer to Fellow may be received from other engineers with established reputations in important positions of responsibility in engineering science or practice. This applies to engineers both in pharmaceutical companies and in firms which design and/or supply design or other expertise for the pharmaceutical industry. In addition to demonstration of achievements and standing in their field of 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.