A Review of Science-based Skills Requirements in R&D and Manufacturing at Pfizer (Sandwich)

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Foreword

The skills pipeline in the UK is increasingly recognised to be in decline in many sectors and especially in those that supply scientifically qualified entrants to companies engaged in research and development (R&D). Across the UK there are many taskforces and work groups being set up to identify the key issues in the provision of skills and to put measures in place to address them. For Pfizer as a major employer in South East England in the R&D and manufacturing sectors, the aims of this report were fourfold:

- To raise awareness of the types of skills needed in pharmaceutical R&D
- To survey the specific reasons for skills-related recruitment difficulties across the UK R&D and manufacturing divisions
- To quantify the current activities being undertaken by Pfizer to address them
- To provide suggestions to education providers that could enhance the number and quality of scientifically skilled entrants

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Executive summary

- The research and development of new medicines is a long, complex and expensive process that carries an inherently high rate of compound attrition.

- The Pharmaceutical Industry needs multi-disciplinary R&D teams of high calibre skilled science graduates to prosecute its work.

- There needs to be a heightened awareness of the wide range of career opportunities in pharmaceutical R&D amongst education providers, science students and graduates

- Across all R&D specialities, the commonest areas of skills deficiencies at entrant level are 1) poor basic knowledge of the key principles of the discipline, 2) inability to apply learnings and 3) low levels of practical skills.

- Pfizer directly and significantly supports the skills agenda with a range of in-house and external activities, however, our resources are limited.

- To aid the optimisation of undergraduate course content in order to meet the needs of a wide range of R&D organisations, a recommendation is for education providers to identify areas of synergy and overlap in specific skills needs between various types of employer.

- Failure to produce the required quantity and quality of skilled science graduates will inevitably advantage the emerging territories in the Far East to the detriment of UK plc.

1. Introduction

Pfizer Global Research and Development (PGRD) is the world's largest privately funded biomedical R&D operation with an annual R&D budget of approximately $7.5 billion covering 11 therapy areas. Sandwich Laboratories are the European R&D headquarters with approximately 3,500 employees in R&D and manufacturing. It is the largest R&D site in Europe for both human and animal healthcare with over £1 billion having been invested in the site over the last 5 years and an R&D expenditure of £600 million in 2005.

Historically, this level of investment in the UK has been maintained because of the adequacy of supply and quality of "home grown" scientific graduates. In turn this has enabled many unique medicines to be discovered and developed at Sandwich.

2. The skills gap

However, it has been noted that the UK pharmaceutical skills pipeline is in decline in many key areas including *in vivo* sciences (physiology, pharmacology, toxicology, pathology), clinical research and experimental medicine, chemical sciences, engineering, mathematics and statistics. Across all these disciplines, common areas of skills deficits have been recognised. These include a low and apparently declining interest in academia with a lack of relevant courses at all levels, as well as a lack of awareness with regard to career possibilities in pharmaceutical R&D. Consequently, the size of many candidate pools are very small and key areas of skills, especially those that relate to the "application" of knowledge are deficient. Specifically the latter include low demonstrable 1) abilities to perform practical procedures, 2) knowledge of very basic scientific principles, 3) abilities to develop scientific methodologies and study designs and 4) abilities to interpret data (*ABPI Report: Sustaining the Skills Pipeline in the Pharmaceutical and Biopharmaceutical Industries* http://www.abpi.org.uk/Details.asp?ProductID=285).

3. The future needs of pharmaceutical R&D

Given that the pharmaceutical industry is a major investor in the UK the consequences to "UK plc" of this skills gap being maintained or worsened over time are severe. This is further emphasised by gaining an understanding of the way in which the focus of pharmaceutical R&D is currently changing and will continue to change over the next decade or so.

Fundamentally this change is driven by the understanding of the human genome which facilitates the increased use of the "omics" technologies (e.g. genomics, transcriptomics, proteomics, metabonomics) and "molecular profiling" throughout the drug development process. The resulting focus on the "quantitative analysis of biological systems" and their inter-relationships will enable to discovery and development of more precise medicines i.e. medicines that are much better targeted towards the patients in whom they'll actually work and be better tolerated.

This new direction however, will demand increased emphasis on the following examples of specific skills sets.

The **"omics"** technologies require multidisciplinary approaches encompassing genetics, molecular biology, biochemistry, IT, mathematics and statistics.

New trends in **drug discovery** (chemistry and biology) to support the altered focus of pharmaceutical R&D will also require an altered emphasis on skills. These include the following disciplines:

- **Quantitative biology**
  - From description of the genome to understanding how each cellular component contributes to the "whole" (systems biology)
  - Needs 1) biologists with strong maths and physical science training and 2) computational scientists trained in advanced statistics to underpin systems modelling
- **Medicinal design chemistry**
  - Premium activity needing post-doc synthetic chemists with strong background in "what to make", "how to make it" and computational chemistry
    - > To exploit full range of *in silico* design tools
- ***In vivo* pharmacology**
  - Absolute requirement for translational pharmacology
    - > To understand the PK/PD relationship in a whole animal
  - Needs specialised skills in *in vivo* pharmacology
- ***In silico* modelling**
  - Hypothesis building for drug targets and potential safety profile via use of modelling software, literature, patent and public databases
  - Needs broad based biology discipline and full conversance with text mining and search engine applications
- **Molecular pharmacology**
  - Skills which range from designing and building *in vitro* screen cascades, to scale up of biological modalities (e.g. monoclonal abs), to developing novel differentiation protocols for stem cells
  - Needs biochemistry, molecular and cellular biology training
- **Structure based drug design** e.g. NMR measurement of protein interactions
  - Needs flow cell technologists with chemistry, biology and nanotechnology skills
- **Computational data analysis**
  - To enable large numbers of data points to be collected, analysed and databased quickly
  - To develop multi-parametric design optimisation tools
  - Needs computational and statistical scientists
- **Genetics**
  - Sub-population selection for more cost effective, early clinical read-out and better "tailored" medicines
  - Needs human geneticists with expert knowledge of genetic associations and linkages to identify novel drug target hypotheses.

Within **Clinical R&D** there is an urgent need to increase numbers of trained "clinician scientists" to undertake "translational research" i.e. the area of R&D that acts as a bridge between preclinical research and the later stages of clinical development. This needs clinicians with a specific understanding of how preclinical data can be interpreted and modelled to accurately predict future patient benefit. In turn this expertise drives the design of more efficient clinical trial programmes which includes the identification and development of new biomarkers.

Supporting many of the functions described here is **engineering**. It is therefore no surprise that the pharmaceutical R&D organisation of the future will also place increased demands on the provision of engineers with specific expertise in highly complex process control and instrumentation engineering.

4. A review of skills-related reasons for recruitment difficulties

As the previous section described the current pharmaceutical R&D skills gaps in the UK and highlighted the types of skills needed in the future, this section reviews the skills issues in a slightly more granular perspective i.e. for Pfizer in Sandwich, when the "rubber hits the road" during recruitment, what are the specific skills areas in which candidates are often noted to deficient? What is Pfizer doing to support the skills agenda? What recommendations can we make to education providers?

This is approached from the individual perspectives of a representative spread of R&D and Manufacturing disciplines, which are prefaced by a brief explanation of the role of the department and/or the individual.

The order in which these disciplines are presented approximates to the point in time where each department has its principal focus of emphasis in the overall R&D process. It will also be noticed that some of the language contained in the descriptions below is duplicated. This is because the Discovery section below was completed first and then used as a template for the contributions from other R&D disciplines. The instances of similarity/duplication therefore serve to emphasise the areas where concerns and issues are shared. It follows that these may help identify those areas of "low lying fruit" that could be most amenable for improvement.

4.1 Discovery (Chemistry and Biology)

What does a Discovery scientist do?

Discovery is a multidisciplinary department which aims to identify and validate new drug targets and then to design, synthesise and test new chemicals with activity against these targets and thus to identify potential new medicines to go into development. The main disciplines in discovery are organic, synthetic and medicinal chemistry, pharmacology, physiology, biochemistry and molecular/cell biology, analytical chemistry and related disciplines.

For chemistry and biology entrants to Pfizer, both would be laboratory-based (80-90% of time on lab-related work including data analysis). In chemistry, a new graduate would be part of a small team and their role would be synthesis of novel compounds (and as they become more experienced, route design). In biology, they would go on

rotation for the first 18 months to gain exposure to 2 or 3 different groups and techniques - depending on the role they could be running screens (cell based, tissue based or with isolated enzymes and proteins etc), carrying out exploratory work or learning and utilising *in vivo* models.

What are the skills-related difficulties with recruitment?

In Discovery at graduate level, if applicants fail interview on skills grounds these usually fall into a couple of technical categories – a **lack of knowledge and understanding of the basics** of their discipline (e.g. pharmacologists who cannot characterise a drug in terms of IC50, pA2s, Kds, agonism/antagonism etc, or chemists who cannot name reagents, mechanisms etc) **or lack of practical experience and application** (e.g. cannot describe practical work beyond following a protocol). For this reason most recruits into Discovery at graduate level have done an Industrial Trainee year or a practical research based masters or at least a summer placement. This not only improves skills, but also acts as a surrogate for motivation. It is possible that the key issue here is not that they haven't been taught these basic skills, but rather they haven't learnt them or don't understand them. Also, the modular basis of many degrees now means that they might study the basics early on but then do not go on to apply this is a meaningful way (to them) - answers like "we did that in the first year but I can't remember now" are frequently encountered.

It is clear that “on the job” training is hard to beat. For top-performing undergraduates, could universities look to increase their degree of integration into the day-to-day research infrastructure of the university department? Not only would this foster the development and application of skills, but would also be an important way to enhance communication skills and team working, which are both often lacking in graduate applicants.

What does Discovery do to support the skills agenda?

With regard to current training activities undertaken within the department, Discovery recruits a limited number of school leavers into a Trainee Research Assistant Scheme. This involves 4 days on-site and 1 day at University (Greenwich). The trainees work towards a HNC after 2 years and a BSc after 5 years. The scheme is highly successful and some trainees have been awarded Achievement Awards – the highest internal recognition of a colleague’s work in Pfizer. Applicants for the scheme are expected to be able to apply the chemistry and biology practical skills taught at A level. Trainees who have done an appropriate selection of A levels are usually able to meet the specification here. However, inappropriate A level selection e.g. biology and 2 non-science A levels can result in failure as the student does not have the necessary “quantitative” and/or overall scientific foundations to do the job. Similar issues can arise with students whose training is based on a GNVQ (General National Vocational Qualification) or AVCE (Advanced Vocational Certificate in Education), particularly if they also lack more advanced mathematical skills. We would therefore like to see more rounded “science-directed” guidance being given to students as they select their A levels.

Discovery also takes 20 to 30 industrial trainees per year thus supplementing their undergraduate training with real life practical training. Similarly, there are a number

of Masters students who again benefit from the provision of an industrial, practical component to their training.

Sponsorship is also provided for the MSc at Kings College London in Drug Discovery Skills. Support is given through input to a steering committee (advice on curriculum, standards etc), finance (sufficient to support approximately 10 students per year), provision of course speakers, visits to Sandwich and projects (currently a couple of 4-6 month projects). The course is highly relevant to drug discovery and includes a large *in vivo* training component which is incorporated into the projects hosted on-site wherever possible.

Once graduates are recruited they are placed on a rotation scheme in biology to further extend their training both scientifically, technically and in softer skills.

What skills sets could be shared with other R&D disciplines and organisations?

Within Pfizer and other pharmaceutical companies, PDM (Pharmacokinetics, Dynamics and Metabolism), DSRD (Drug Safety R&D), and Pharmaceutical Sciences would have similar needs for well trained laboratory biologists and chemists. However, these same types of skills are also needed in the Biotechnology sector, Contract Research Organisations, Academia (i.e. graduates going on to PhDs, Post Docs and academic careers) and Diagnostics, Chemicals and Assay Design companies.

What would Discovery ask of the education providers?

To encourage students to link topics and gain as much practical experience as possible (both inside and outside of the course*) - to learn from and understand the practical work they do at university and not just blindly follow protocols.

* The French system, with a heavy emphasis on placements (industrial and academic) produces very well regarded graduates in chemistry, for example, but this is probably something wider than the individual providers to implement and would need a sea change in how UK education is run.

4.2 Drug Safety R&D

4.2.1 Investigative toxicology

Background

Toxicology is a complex science that in its broadest sense defines the harmful interactions between chemicals and biological systems. Toxicology is a multidisciplinary subject requiring the application of chemical, biochemical, pathological and physiological knowledge to provide insight into potential toxic effects. An investigative toxicologist is interested in identifying and understanding the mechanisms of action of chemicals using *in silico, in vitro* and *in vivo* techniques.

What does an Investigative Toxicologist do?

An investigative toxicologist can support the various stages of drug development from early Discovery through to clinical studies. Focusing on Discovery support, an investigative toxicologist would look to provide increased confidence in safety of a new drug target and also chemicals within different series. Depending on the question, a screening cascade to provide concentration response relationships between chemicals may be appropriate or, endpoints providing an increased understanding at the cellular and molecular level of mechanism of action may be more appropriate.

There are very few undergraduate courses in the UK that focus specifically on toxicology. It is more usual to gain toxicology experience through a specific MSc course and/or a relevant PhD. For a graduate /MSc entrant to Pfizer, entering an investigative toxicology laboratory, there would an expectation for 70-80% of time to be focused on lab-related work (including data analysis). The graduate would be part of a small team and their role would include working on development of new cell based/molecular based screens for specific program(s) in Discovery, with the goal of ranking compounds according to confidence in safety (CIS), or to apply relevant expertise to further elucidate understanding of a mechanism of action by carrying out exploratory work utilising *in vitro* and *in vivo* models.

What are the skills-related difficulties with recruitment?

In Toxicology at graduate level, if applicants fail interview on skills grounds these usually fall into a couple of technical categories – a lack of knowledge and understanding of the basics of their discipline (e.g. IC50, ADME, common mechanisms of toxicity, e.g. acetaminophen) or lack of practical experience and application. For this reason, in most instances graduate recruits in investigative toxicology will have completed a minimum of an Industrial Trainee year, or a practical research based masters and / or at least a summer placement. This not only improves skills, but also acts as a surrogate for motivation. It is possible that the key issue here is not that they haven't been taught these basic skills, but rather they haven't learnt them or don't understand them. Also, the modular basis of many degrees now means that they might study the basics early on but then do not go on to apply this is a meaningful way (to them) - answers like "we did that in the first year but I can't remember now" are frequently encountered.

It is clear that “on the job” training is hard to beat. For top-performing undergraduates, could universities look to increase their degree of integration into the day-to-day research infrastructure of the university department? Not only would this foster the development and application of skills, but would also be an important way to enhance communication skills and team working, which are both often lacking in graduate applicants.

What does Investigative Toxicology (IT) do to support the skills agenda?

With regard to current training activities undertaken within the department, IT recruits 2 to 3 industrial trainees per year, thus supplementing their undergraduate training with real life practical training. Similarly, there are a number of Masters students who again benefit from the provision of an industrial, practical component to their training

and IT have partnered with The University of Surrey where sponsorship for an MSc student is provided each year. Several of the senior members of IT across the Pathology and Toxicology disciplines are actively involved in lecturing on the MSc Toxicology course at Surrey.

What would IT ask of the education providers?

To encourage students to link topics and gain as much practical experience as possible (both inside and outside of the course) - to learn from and understand the practical work they do at university and not just blindly follow protocols. To provide more emphasis and teaching for the discipline of Toxicology on certain specific undergraduate courses as this is currently extremely limited.

4.2.2 Global Safety Pharmacology (GSP)

Background

Pharmacology is the study of the effect of a compound (such as synthetic molecules e.g. drugs or natural molecules e.g. hormones) on biological systems and hence is a discipline central to drug discovery and development. The discovery of a new medicine requires the study of the "benefit" of the pharmacology which imparts therapeutic efficacy as well as the "safety" of the pharmacology which may bring unwanted effects. Since all medicines, and putative medicines, are potential poisons, safety pharmacology is essential to allow an understanding of the safety profile and safety margin (dose of a compound which brings benefit v dose which is unsafe) of a compound. As such the safety pharmacologist works at all stages in the drug discovery and development process performing non-clinical experiments. In the discovery phase the safety pharmacologist works with the discovery team to determine if the intended drug target and chemical series are sufficiently safe by law. Prior to testing potential new medicines in humans the safety pharmacologist must perform experiments to establish the safety of a compound on the physiological systems critical to life (cardiovascular, respiratory and central nervous system) and provide these to the governments regulatory authorities (e.g. MHRA, FDA). Once a compound has progressed into human testing the safety pharmacologist may be called upon to perform experiments to investigate any clinical side effects which have been observed.

What does a Safety Pharmacologist do?

As mentioned above, a safety pharmacologist works at all stages in the drug discovery and development process and as such works as part of a multi-disciplinary team which includes biologists, chemists, toxicologists, drug metabolism scientists, pharmaceutical scientists and clinicians. The safety pharmacologist uses knowledge and skills in physiology and pharmacology to investigate the safety of a compound in non-clinical experiments. These experiments may be in vitro utilising animal or human cells or tissue, as well as in vivo using laboratory animals. Since these studies characterise the safety of a compound prior to testing in humans they must be performed with high rigour and to the quality standard defined by the government termed "Good Laboratory Practice" (GLP). Hence 70 to 90% of a safety

pharmacologist's time is spent designing, performing, interpreting and reporting laboratory experiments. These experiments are used to make key business decisions regarding compound and drug target progression through discovery and development.

What are the skills-related difficulties with recruitment?

At the graduate level, if applicants fail interview on skills grounds these usually fall into two main technical categories. Firstly, there is often a lack of knowledge and understanding of the basics of their discipline (e.g. pharmacologists who cannot characterise a drug in terms of IC50, pA2s, Kds, agonism/antagonism etc. In addition, approximately 90% of experimentation involves in vivo studies (studies in animals) and hence requires a sound understanding of physiology as well as a desire to perform in vivo work. Secondly, there is also often a lack of practical experience and application (e.g. cannot describe practical work beyond following a protocol). For this reason it is desirable that recruits at graduate level have experience from a Industrial Trainee year or a practical research based masters or at least a summer placement. This not only improves skills, but also acts as a surrogate for motivation. It is possible that the key issue here is not that they haven't been taught these basic skills, but rather they haven't learnt them or don't understand them. Also, the modular basis of many degrees now means that they might study the basics early on but then do not go on to apply this is a meaningful way (to them) - answers like "we did that in the first year but I can't remember now" are frequently encountered.

It is clear that "on the job" training is hard to beat. For top-performing undergraduates, could universities look to increase their degree of integration into the day-to-day research infrastructure of the university department? Not only would this foster the development and application of skills, but would also be an important way to enhance communication skills and team working, which are both often lacking in graduate applicants.

Our recent experience, during 2006, where we attempted to recruit 10 people into GSP is that there is a general lack of appreciation of what is meant by "Safety Pharmacology". We believe that this is likely driven by three main factors i) Safety Pharmacology is an emerging science coming both from pharmacology and toxicology ii) it is not routinely taught as part of most pharmacology or toxicology degree courses ii) it is primarily a discipline found in industry rather than academia. The statistics of our 2006 campaign bear evidence to this; for 10 positions we received >200 applicants of which >50 received 1st round interviews, 20 second round and we have recruited 8. Of these 8 most require some specialist training to fulfil our basic job requirements.

To address the lack of recognition of Safety Pharmacology we are actively engaged with universities and societies and attended job fairs to promote the science. We have also written articles for scientific journals e.g. nature jobs.

What does Global Safety Pharmacology, Sandwich do to support the skills agenda?

Currently in a department of 28 full time employees we employ 2 Trainee Research Assistants. These are employees who joined post-A level and we support their higher education. This involves 4 days on-site and 1 day at University (Greenwich). The

trainees work towards a HNC after 2 years and a BSc after 5 years. The scheme is highly successful with several examples of individuals who have joined and followed this route having highly successful careers. We also have a good relationship with various universities and each year we run 1 BSc student placement, 4 PhD studentships (CASE awards which involve the students spending time at both University and in the dept.) and 1-2 summer students (A level and degree students) who work with us in the department. Often these trainees and students publish their data in scientific journals or present at scientific conferences and several trainees have been awarded Achievement Awards – the highest internal recognition of a colleague's work in Pfizer.

We also work hard to promote education by going out to universities to present lectures. One member of staff is an honorary lecturer at Imperial College London and others teach on various courses e.g. MSc in toxicology at university of Surrey. Further we work closely with learned societies such as the British Pharmacology Society and support and teach a diploma in drug discovery. Sponsorship is also provided for the MSc at Kings College London in Drug Discovery Skills. Support is given through input to a steering committee (advice on curriculum, standards etc), finance (sufficient to support approximately 10 students per year), provision of course speakers, visits to Sandwich and projects (currently a couple of 4-6 month projects). The course is highly relevant to drug discovery and includes a large *in vivo* training component which is incorporated into the projects hosted on-site wherever possible.

What skills sets could be shared with other R&D disciplines and organisations?

Within Pfizer and other pharmaceutical companies, discovery biology, PDM (Pharmacokinetics, Dynamics and Metabolism), and Pharmaceutical Sciences would have similar needs for well trained laboratory biologists. However, these same types of skills are also needed in the Biotechnology sector, Contract Research Organisations, Academia (i.e. graduates going on to PhDs, Post Docs and academic careers) and Diagnostics.

What would GSP ask of the education providers?
To encourage students to link topics and gain as much practical experience as possible (both inside and outside of the course) - to learn from and understand the practical work they do at university and not just blindly follow protocols.

4.3 Pharmacokinetics, Dynamics and Metabolism (PDM)

What does a PDM scientist do?

PDM is a multidisciplinary department whose work involves studying the fate of potential new medicines within the body. In broad terms, this entails characterising the absorption and excretion of novel drug molecules, their distribution into body tissues to elicit a pharmacological effect and how they are modified by enzymes to form metabolites. Within the drug discovery process, PDM scientists work closely with chemists, biologists and clinicians to design molecules with optimal pharmacokinetic and pharmacological properties for their intended medicinal use.

The main disciplines within PDM currently are biochemistry, biology, chemistry, pharmacology, analytical sciences and other related scientific disciplines.

Traditionally all graduate entrants within PDM are laboratory-based (80-90% of their time on lab-related work including data analysis) but it is progressively more possible to have a scientific career within PDM outside the laboratory. PDM increasingly uses modelling and simulation, or *in silico*, approaches to help us understand and eventually predict the likely timecourse of effect and excretion of a drug molecule in the body. Thus graduates with an interest in computing or mathematical / statistical modelling can learn to apply these techniques within a scientific research environment.

What are the skills-related difficulties with recruitment?

There is no degree course in "Pharmacokinetics, Dynamics and Metabolism". Graduate recruits usually have biology, chemistry or pharmacology backgrounds and in-house training is provided to fill in the knowledge gaps. Graduates from such degree courses usually have a rudimentary understanding of PDM based upon modules provided on their degree courses.

Key specific skills such as mathematics and/or computer modelling are required for recruitment into the *in silico* areas of PDM. However, it is not intuitively obvious to graduates with such skills that a career within a scientific research environment such as PDM is possible.

What does PDM do to support the skills agenda?

With regard to current training activities undertaken within the department, PDM recruits a limited number of school leavers into a Trainee Research Assistant Scheme. This involves 4 days on site and 1 day at University (Greenwich). The trainees work towards a HNC after 2 years and a BSc after 5 years. The scheme is highly successful and some trainees have been awarded Achievement Awards – the highest internal recognition of a colleague's work in Pfizer.

PDM also takes between 4 and 6 industrial trainees per year thus supplementing their undergraduate training with industrial practical and scientific training. Similarly, there are a number of Masters students who again benefit from the provision of an industrial, practical component to their training.

PDM co-funds a number BBSRC studentships each year for PhDs with UK academic centres and during its course, the student will conduct some of their research at the Pfizer laboratories.
PDM also runs an in-house scientific training program which is attended by all graduate recruits. This program consists of a mixture of seminars, workshops and secondments which aim to increase the trainees' knowledge of PDM science as well as the overall drug discovery and development process.

What skills sets could be shared with other R&D disciplines and organisations?

Within Pfizer and other pharmaceutical companies Discovery Biology / Chemistry, DSRD (Drug Safety R&D) and Pharmaceutical Sciences would have similar needs for well trained laboratory scientists. However, these same types of skills are also needed in the Biotechnology sector, Contract Research Organisations, Academia (i.e.

graduates going on to PhDs, Post Docs and academic careers) and Diagnostics, Chemicals and Assay Design companies.

It is more difficult to envisage a shared source for *in silico* candidates, other than other pharmaceutical companies and Contract Research Organisations. It is particularly difficult to recruit experienced Pharmacokinetic-Pharmacodynamic (PKPD) Modellers.

What would PDM ask of the education providers?

To embed PDM core disciplines and competencies into science teaching at universities across Europe. These include knowledge of metabolism and transporters, bioanalytical science and automation, *in silico* and computational modelling and biomarker analysis. For a laboratory-based career, encourage students to gain as much practical experience as possible. Ensure that students are made aware that it is possible to have a career in scientific research outside the laboratory if they wish, particularly if they have an interest in or aptitude for computer / mathematical modelling. Ensure that graduates with qualifications in computer / mathematical modelling are made aware that a career within scientific research in the pharmaceutical industry is an option that is open to them.

4.4 Pharmaceutical Sciences

What does a Pharmaceutical Scientist do?

Pharmaceutical Sciences is a multidisciplinary group which encompasses skills in support of four broad areas: synthetic organic chemistry, analytical chemistry, drug product formulation and drug delivery device development. These areas require skills in organic chemistry, mechanical engineering, material sciences, formulation science, pharmaceutical sciences, chemical engineering and associated life sciences. The role of Pharmaceutical Sciences is to enable the selection of drug molecules from Discovery and to design robust organic synthetic routes and drug product formulations and manufacturing processes, with supportive analytical testing, which are suitable for both clinical trials and commercial manufacture.

For almost all scientists entering Pfizer at BSc or PhD level involves hands on laboratory activity and scientific decision making. Usually entrants would be part of a small team and may be expected to work with other disciplines as part of a multidisciplinary team. Pharmaceutical Sciences recruitment looks for a mixture of flexible competent scientists and uniquely skilled recruits within each of the four broad disciplines. All recruits receive training as they enter Pfizer.

What are the skills-related difficulties with recruitment?

There are a number of challenges we are increasingly facing with recruitment and these are as follows. Firstly there appears to be a lack of basic scientific understanding existing in many graduate interviewees (e.g. lack of understanding of pH, pKa, basic mathematical concepts, enthalpy, entropy etc). Cited as common at interview is “time since learning” which in many cases is a possible causal factor.

More importantly, from our perspective, is a perceived lack of appreciation as to the relevance of these concepts to practical science within the industrial context. This would point to either inappropriate context setting or poor teaching methods. Secondly there is a shortage of quality post graduate particularly in the formulation sciences which in the latter case is following an alarming decline in the quality and quantity of skilled academic teachers practitioners within UK universities. Third and last is the rapidly changing development paradigm which increasingly requires predictive approaches based on molecular material science and crystallography allied to computational approaches. In particular the trend towards molecular material sciences in drug product design and chemical engineering skills allied to pharmaceutical unit processing are two key areas worth highlighting.

What does Pharmaceutical Sciences do to support the skills agenda?

With regard to current training activities Pharmaceutical Sciences recruits a limited number of school leavers into a Trainee Research Assistant Scheme. This involves 4 days on-site and 1 day at University (Greenwich). The trainees work towards a HNC after 2 years and a BSc after 5 years. The scheme is highly successful and has been running for a number of years. Applicants for the scheme are expected to be able to apply the basic chemistry and biosciences practical skills taught at A level.

Annually each of the four discipline areas within the Pharmaceutical Sciences will provide spaces for 10-15 industrial trainee placements from a variety of universities. (This is in addition to the 20-25 summer scholars we employ over the summer months from a wide variety of UK academic institutions across all of our skill areas.) These students work in Pfizer laboratories usually undertaking a general scientific project which they present to the relevant university as part of their coursework. In our experience this has been a successful scheme for all parties involved and many IT students (and summer scholars) have returned as full time employees on completion of their degree. Moreover, Pfizer provides fully funds up to six Pre-registration Pharmacy placements in collaboration with local NHS trusts where the students spend a year split between industry and hospital prior to the RPSGB pre-registration exam. This has provided a useful career path for pharmacists wishing to follow the industrial path and has been beneficial to in attracting pharmacy students into the industrial environment.

With the rapid advancement in the pharmaceutical sciences over the past decade one of the challenges academia and industry are increasingly facing in post graduate education is the imbalance in funding between the public and private sector. This has resulted in students having inappropriate access to the range of equipment routinely available in the industrial sector. To this end Pharmaceutical Sciences have forged links with universities (Greenwich in particular) to source post graduate students to work in Pfizer laboratories on state of the art equipment in areas of common scientific interest to the academic institution and industry. Typically this has involved up to 12 post-doctoral students from UK and mainland Europe working in Pfizer Laboratories at any one time. We believe this model should be examined further as a method of providing a skilled workforce in coming years. In addition to this we fund a range of academic institutions in the UK in both PhD and Post Doctoral programs where students are based primarily in academia.

What would Pharmaceutical Sciences ask of the education providers?

- To partner with industry to understand the emerging trends in the industrial arena to ensure an appropriate level of teachers and ultimately students available to meet demand of our emerging science.

- To look for innovative way to work with industry to bridge the gap between funding in the public and private sector.

- To recognise that quality of the student skills base must be balanced with quantity and that from our perspective there would appear to be either an inappropriate teaching of scientific principles or a fundamental in-ability on the part of many students that we see to comprehend.

- That the core of science (chemistry, bioscience and mathematics) are maintained to an appropriate level and not diluted by a trend towards "topical" applied courses.

- To ensure that academia remains a fertile ground first and foremost for "education" and that "training" is achieved by novel mechanisms without inappropriate imposition and imbalance on the indicative syllabus.

4.5 Comparative Medicine

What is Comparative Medicine?

Comparative Medicine is the discipline relating to laboratory animal science and ensures that high standards defined in law and Codes of Practice are met or exceeded. This is achieved through a combination of direct provision of husbandry and veterinary medical care for animals and an assurance that environmental parameters are consistently met. The discipline is also charged with the conduct of ethical review to ensure drug discovery and development is conducted to high ethical standards and all requirements for regulatory licensing and training are met.

What do technicians in Comparative Medicine do?

A technician in Comparative Medicine, or laboratory animal science, provides husbandry and care to ensure the welfare of animals and they must have an understanding of the ethical use of animals in drug discovery and development.

Animal technicians provide animal care on a daily basis ensuring all the fundamental welfare needs of an animal and its environment are met. The needs provided by a technician range from providing food, water and bedding to checking that the room temperature and light levels are appropriate against strict quality standards. Animal technicians may review procedures to suggest where the welfare of animals can be optimised. As animal technicians gain competency in the observation and handling of animals they may conduct routine technical procedures as part of the experimental protocols.

Animal technicians may develop their careers by managing the complex buildings and facilities which house the animals as well as supervising the staff who provide day-to-day care. Senior animal technicians may be responsible to assure compliance with strict welfare standards defined in Codes of Practice by performing the role of "Named Animal Care and Welfare Officer". All animal technicians are expected to gain additional academic, professional and vocational qualifications.

What do veterinarians in Comparative Medicine do?

The statutory role of "Named Veterinary Surgeon" and the associated responsibilities are outlined in Codes of Practice and professional guidance. The veterinarian will advise on animal health and welfare to assure that procedures which require the use of animals are fully consistent with the principles of humane experimentation known as the "3Rs" (refine, reduce, replace). The veterinarian is charged to provide a full programme of animal health monitoring and preventive medicine. Often veterinarians will advise scientists on techniques to minimise or obviate any pain, suffering or distress animals might experience.

What are the skills-related difficulties with recruitment?

For Comparative Medicine we recruit animal technicians (approximately 2-3 per year) and veterinarians (average less than 1 per year).

Our local strategy for animal technicians is to work closely with Canterbury Christchurch College, so we get students through their HND/HNC courses. We then provide vocational training, education through IAT* qualifications and through to BSc by support in the workplace (we've two BSc students right now and others enrolling this year/next year). In other words, we take raw people and grow them up. This absorbs resource. However, finding trained animal technicians with the required armoury of practical skills would be very difficult. This is a recognised issue throughout this sector in the UK.

For vets, this is more difficult – there is a short supply though the quality of more recent graduates has been extremely high i.e. well-rounded people with excellent interpersonal skills. Having said that, finding an experienced person who would fit well into the very complex, interdependent and highly matrixed workplace that is Pfizer, can still be a great challenge. Often the hurdle at interview is simply one of motivation and people lacking clarity about where they want to go in their career.

**What is the IAT?*

The IAT is the Institute of Animal Technology (www.iat.org.uk) and this organisation has provided qualifications in animal technology for over 50 years. Many of the animal technicians working in laboratory facilities are members of the IAT and possess its qualifications ranging from Certificates to Fellowships and Registrations. The IAT is phasing out the current qualification system over the next two years and will adopt a framework which is consistent with the new national system, having worked

closely with LANTRA. The IAT also offers career information in animal technology and promotes a positive understanding of the discipline.

What does Comparative Medicine do to support the promotion of relevant skills?

It is rare that we are able to recruit an animal technician or a veterinarian already possessing all the relevant technical skills to work in a biomedical research environment. Applicants tend to have qualifications ranging from GCSEs through to HNDs in animal care although these courses have no content directly relevant to biomedical research. Therefore for animal technicians we have a rigorous programme in place to train recruited colleagues on-the-job with various media including our own training modules. Moreover all animal technicians must embark on further education to gain the IAT qualification of Membership and we fund provision of this syllabus on site, the alternative being day release to a further education college which is more than 80 miles away. Many technicians continue on further education to IAT Fellowship level and even BSc, either of which requires significant investment from us an employer as well as time and energy from the candidate. One experienced senior technician is a moderator for the IAT examinations, an activity which takes up several working days annually. A senior manager makes career presentations to students on animal care courses at both the local further education college and university.

We fund an extramural studies scheme for veterinary students, which allows them to gain experience as undergraduates in laboratory animal facilities. If a veterinarian is recruited we would provide a customised training programme and make as much use as possible of training courses and CPD provided by external parties. We would expect a veterinarian to enrol with their professional body for the relevant certificate and then diploma for the discipline. We would fund this enrolment and provide the time taken during working hours for study activities and any training off-site.

What skills could be shared with other R&D organisations?

Both academia and the biotechnology sector have a requirement for the skills of animal technicians and veterinarians and experience difficulties recruiting.

What would Comparative Medicine ask of education providers?

It is very important that education providers deliver courses to educate animal technicians at the entry grades and upwards so that the employer does not carry this entire burden. The IAT is transitioning its qualifications to the national framework and it is very much hoped that there will be a level of further education provision that meets the current demands of both industry and the public sector. Ideally this provision would geographically cover all of the UK.

4.6 Clinical R&D

This department includes clinical statistics and clinical pharmacology, for which the skills issues are described below. This initial section therefore describes the skills situation as it applies to the (usually) medically qualified clinicians who work in Clinical R&D.

What does a R&D Clinician do?

Clinicians working in pharmaceutical R&D usually have a medical degree with a postgraduate qualification (e.g. MRCP, MD, PhD) or a biomedical PhD with experience in clinical research. Clinical experience may be broad or highly specialised within a specific disease area.

Within the Clinical R&D department of a large company conducting research into many therapeutic areas, a clinician will gain a broad range of professional and research experience. Working within large multidisciplinary drug development teams, the central role of these "clinical research" doctors is to bring their clinical perspective to all research and development activities.

Before human clinical studies commence, the clinician must work with other research colleagues (e.g. Discovery Biology) to ensure that an appropriate level of prospective scientific thinking goes into understanding the clinical development strategy for an investigational drug. For example, is the unmet medical need fully understood i.e. which patients will potentially benefit from this new medicine?; what does preclinical data suggest about the potential efficacy, tolerability and safety profiles in humans?; how will biomarkers be developed and validated?; how will theoretical, potential or actual risks be assessed and appropriately communicated? In essence, their role is to develop the clinical aspects of a "product profile" to ensure all feasible clinical uses for the new drug have been considered. This maximises the potential benefit of the medicine to patients and society.

What are the skills-related difficulties with recruitment?

There are very few suitable UK-based applicants. Basic requirements at entry level are a medical degree, therapeutic area expertise and research experience. The latter includes knowledge of research methodologies. It seems that because careers in research (and especially translational research) are seemingly not attractive or promoted pathways at medical school, it follows that the pool of candidates with the knowledge of how to design and conduct clinical research and then interpret its findings, is small.

These skills are routinely tested at an extended interview via three main routes. Firstly, candidates are asked a series of questions that test their basic understanding of pharmaceutical medicine and the principles of drug development. Secondly, they are given a short paper to read, review and critique to identify basic methodological and analytical flaws. Thirdly, they are asked to read a short summary of core data from a clinical development programme, following which they present their recommendations for the compound's further development, based on the key issues they've identified from the data summary.

Sadly however, it is often the case that clinicians do not demonstrate sufficient basic understandings or "analytical insights" to make the required grade for entrance here. This was illustrated by a recent clinician recruitment campaign during which over 60 applicants underwent an initial telephone screening. This resulted in just over 20 being brought to Sandwich for second interview, following which 4 job offers were made.

A significant contributing factor to this low level of "applied clinical research skills" is that the principles of drug development are not an integral part of medical student training (e.g. included in clinical pharmacology).

What does Clinical R&D do to support the promotion of relevant skills?

Clearly, while we expect them to have a basic knowledge of drug development principles, all clinicians recruited at entrant level from hospital or general practice require in-house "on the job" supervision to become fully functional and to progress to clinical team leadership positions. The latter not only depends on the individual building high levels of technical competence, but also on their proven ability to communicate and work efficiently with all members of the highly matrixed, multidisciplinary development team and within this, especially the clinical pharmacologist and the clinical statistician. These aspects, as with other lines at Pfizer, are actively developed through a performance management process.

Clinicians are also able, should they wish, to maintain a clinical appointment in the health service e.g. a half day per week outpatient clinic. Financial support is given to those who wish to study for the Diploma of Pharmaceutical Medicine (Dip Pharm Med). If successful, this would normally be anticipated to lead to membership of the Faculty of Pharmaceutical Medicine (MFPM). Additionally, now that pharmaceutical medicine is recognised as a specialty in its own right, clinicians are supported to pursue Higher Medical Training (HMT) in the discipline, following the completion of which they are "accredited" as "pharmaceutical physicians", much in the same way that physicians or surgeons need to gain accreditation in their respective disciplines before being eligible for a consultancy.

Direct collaborations with universities on medical education are somewhat in their infancy. However, a short modular course on aspects of pharmaceutical medicine has been developed with Brighton & Sussex Medical School (BSMS). This covers the general principles and objectives of 1) each phase of drug development and 2) safety and risk management. The course was designed and is delivered by Pfizer clinicians as part of students' training in clinical pharmacology. Preliminary feedback from the (approximately 10) students who've currently been on it is positive.

What skills sets could be shared with other R&D disciplines and organisations?

The most obvious synergy here would be in academic research which also requires clinicians and "clinician scientists" to design and conduct high quality clinical

research and be able to interpret complex datasets to determine or predict the benefit/risk to patients.

What would Clinical R&D ask of education providers?

To follow on the theme of the Pfizer/BSMS course, it would be good to see the principles of pharmaceutical medicine and drug development being incorporated routinely within the clinical pharmacology training of medical students. Core topics could include 1) awareness of the varied role of the pharmaceutical physician 2) the ABPI code of practice 3) the principles of drug discovery and development 4) clinical trials; objectives and design 5) principles of quantitative decision making 6) development and utility of disease models 7) quantitative approaches to synthesising knowledge and 8) pharmacovigilance.

4.6.1 Clinical Pharmacology

What does a clinical pharmacologist do?

Clinical pharmacology colleagues design, manage, analyse and interpret clinical studies and programs to understand the effects of drugs on the body (pharmacology) and the elimination of drugs from the body (pharmacokinetics) in order to provide appropriate advice to clinicians in how best to dose the drug (e.g. once a day or twice a day). Most of the studies designed are conducted in healthy volunteers rather than patients. Clinical pharmacology increasingly is involved in mathematical modelling of drug dosing, drug concentrations in blood, efficacy and safety which is designed to understand complexities of how best to dose patients and to simulate scenarios which may not have been studied. The main disciplines are pharmacology (or some relevant biological science such as physiology), pharmacy or medicine, biochemistry/chemistry (needed for assay specialists who develop drug assays and assays for biochemical changes that occur in response to drugs), statistics or mathematics or some numerical science (for modelling specialists). Colleagues are mostly office based and spend their time in scientific endeavours preparing documents outlining what clinical pharmacology studies and analyses are needed in a program, designing study protocols, undertaking data analysis, providing interpretation in reports and communicating the implications of the results to colleagues in other disciplines.

What are the skills-related difficulties with recruitment?

The main need is for colleagues with a high level of education (typically PhD or MD, occasionally MSc) with knowledge of drugs, the drug development process and skills in experimental design and advanced data analysis or mathematical modelling. If applicants fail interview on skills grounds these usually fall into a couple of technical categories – a lack of knowledge and understanding of the basics of their discipline (e.g. don't adequately understand pharmacokinetics or pharmacology) and lack of quantitative skills. Two other reasons for failure at interview are an inability to communicate complex scientific issues to other disciplines in an understandable way and in a way that facilitates drug development decision making and an inability to lead, which includes the potential to work well in a team.

What does Clinical Pharmacology do to support the skills agenda?

We provide funding to PhDs & post docs at major academic centres of excellence in clinical pharmacology (e.g. Uppsala University in Sweden for modelling, University of Manchester (general pharmacokinetics, drug metabolism & modelling), University of Sheffield (clinical pharmacology). We try to recruit PhDs & post docs from these programs.

What skills sets could be shared with other R&D disciplines and organisations?

Within Pfizer and other pharmaceutical companies Pharmacokinetics, Dynamics and Metabolism would have similar needs for well trained clinical pharmacologists and modellers. Other departments could use the general skills including clinical and Outcomes Research. These same types of skills are also needed in the Biotechnology sector, Contract Research Organisations and mathematical modellers are used in multiple industries e.g. aircraft design, household appliance design!

What would Clinical Pharmacology ask of the education providers?

To encourage students to think, write and communicate science. Develop problem based work rather than memory tests of established knowledge.

We are not aware of any advanced courses in the UK that provide the mix of disciplines that we are in need of (pharmacology-biology, clinical use of drugs (medicine or pharmacy), mathematics and/or statistics and biochemistry).

4.6.2 Clinical and non-clinical Statistics

What does a statistician do in Pharmaceutical R&D?

Statisticians are integral members of scientific teams that span all phases of R&D activity from the earliest assay development through to post-marketing programmes for commercially available medicines. They therefore collaborate with all the scientific disciplines from chemistry and biology in Discovery, to clinicians and clinical pharmacologists in Development through to process and analytical chemists and pharmacists in product formulation and manufacturing. Statisticians work on study designs, analysis of data-sets, reporting and interpretation of results and increasingly are involved in the synthesis of relevant information prior to clinical study design. They will contribute to individual studies but also at the programme design level.

Virtually all statisticians will have a mathematics undergraduate degree with a Master's degree in Statistics and some will have a PhD. A new entrant joins a small team of statisticians where they will be exposed to the work of that team and will benefit from close supervision to help them make the considerable step up from education to practical R&D statistical work.

What are the skills-related difficulties with recruitment?

Increasingly a more quantitative, model-based approach is being used in pharmaceutical R&D and there is therefore a high demand for capable statistical students. However it is our belief that there is a shortage of good students entering Masters courses in Statistics and indeed it is our perception that the mathematical skills of entrants to Mathematics BSc courses has declined. This is perhaps in accord with the concerns expressed in Prof A Smith's report for the Governments' Post-14 Mathematics Inquiry. When we reject an MSc applicant on skill grounds it is typically for their inability to demonstrate their grasp of the discipline fundamentals or for their inability to apply these to practical scientific situations. We do not recruit at the BSc level because a student typically has insufficient technical knowledge at this stage. We recognize that a new entrant has a great deal of learning still to do in the job however we do require the fundamentals of the subject to be securely in place. We view the fundamentals as: *statistical design*, i.e. how do you collect the information needed to answer defined questions, this links the scientific area to a mathematical model; *statistical modelling* which requires a high level of mathematical capability; *statistical inference* that links the observed data to potential models and in particular today Bayesian methods are becoming far more frequently used; *statistical programming*, i.e. capability using software to turn methods into practice.

From comments made to us we perceive that some of the difficulties in statistical education currently are: modular courses which allow for students to miss out on key components, e.g. statistical design; insufficient time on courses for the key ideas "to settle" for some students; and a rather too theoretical or mathematical introduction to topics which are less effective for many students than using practical examples to introduce, motivate and illustrate ideas.

What does Statistics do to support the skills agenda?

Statistics employ 4 Industrial Trainee students each year who spend their 3rd year of a 4-year "sandwich" undergraduate course at Pfizer working as part of a small team and learning how to apply statistical method in the scientific setting. Additionally we offer summer placements to interested and qualified students. Each year we sponsor 4 students to study for their MSc in Statistics and currently we are collaborating in 3 PhD Case awards with UK universities. Each year we run statistical consulting workshops for MSc students and we offer "Pfizer prizes" to encourage and reward excellent student performance at selected BSc/MSc courses. The "Pfizer prize" includes an invitation to Sandwich to see something of our work.

What skill sets could be shared with other R&D disciplines and organisations?

Skills in statistical design, modelling, inference and programming are the core skills that will be required by any R&D organisation recruiting applied statisticians. Furthermore these are the skills that will be required of a student who wishes to pursue postgraduate research with a view to an academic career. The Government would also require this type of skills-set for recruitment into their statistical service.

What would Statistics ask of education providers?

Three requests:

1. Focus on the fundamental aspects of our discipline, ensure that these are well taught and that a student is not confused by a plethora of more peripheral courses.
2. Help students to make the connections between these core aspects of the discipline and to have appreciation of how they fit together into a coherent whole, and at the same time to motivate why ideas or methods that may seem abstract at first can have great practical value in R&D.
3. See Statistics as a discipline in its own right that finds natural partnership with science (and beyond) and do not see it as (just another) branch of mathematics only.

4.7 Clinical Study and Data Management (CSDM)

What does CSDM do?

Within the area of clinical trials, CSDM is the group who are responsible for the operational set-up and conduct of clinical studies and the delivery of high quality clinical data. In essence they operationalise a clinical study protocol. Within the group and on a *per study* basis, the key individual is the Study Manager.

The Study Manager works with a network of other groups and suppliers to orchestrate delivery of the clinical trial activities from delivery of a protocol synopsis to final locked database. At entrant level, individuals would work with an experienced study manager to deliver a subset of activities in the areas of study set up (recruitment planning, delivery of drug supplies, country and centre selection, co-ordination and production of study documentation, definition and production of data collection tools), study conduct (managing data and query flow, tracking recruitment, ensuring appropriate quality) and close out (close out of centres, finalisation of the database, hand-off to the reporting group). Amongst it all project management, communication and problem solving skills are key.

What are the skills-related difficulties with recruitment?

Although many entrants to study management have a BSc in a relevant scientific discipline, CSDM will also consider junior posts for motivated candidates with basic (A-level) backgrounds in science. This is because it is often "softer skills" that are needed to do this job successfully, rather than skills in "hard science". However, it is sadly also the "softer skills" of communication and team working that are most often found to be lacking. Applicants frequently show no or little ability to interact or influence positively when tested on these skills at interview.

What would CSDM ask of the education providers?

Promote effective communication, influencing and team-working skills. One activity that has been deployed successfully in Sandwich is to work with a group of actors who play out scenarios. The audience is asked to suggest responses, courses of action etc. The actors then play out the potential results. This can be a real eye opener and a useful way to teach some of the basic soft skills.

4.8 Engineering

What does the Engineering department at Pfizer do?

Engineering disciplines within a pharmaceutical environment are widely needed at Pfizer across a range of specialties, including Manufacturing [cGMP], Pharmaceutical Science, Analytical R&D and those associated with other aspects of Good Laboratory Practice (GLP). The breadth and scale of the engineering need can be illustrated by the fact that Sandwich employs chemical, mechanical, electrical, instrumentation and control engineers to design, operate and maintain the equipment and systems that enable science and drug manufacture to take place. An example of this diverse engineering requirement can be seen in the range of engineering activities required from operating the sites own power station which generates up to 20MW of electrical power and sufficient steam production for all operating processes. Additionally, over 2000 containment systems such as fume hoods require upwards of 6MW of power to operate whilst pilot plant process equipment and other R&D systems utilise the "balance of plant" (i.e. the difference between what is being used for an operation and what is left over for other operations).

Ongoing studies [de-bottle-necking], to improve operational performance generate projects that require project engineering skill sets to implement, whilst the engineering systems and equipment need to be operated and maintained to meet regulatory compliance standards (e.g. FDA, MHRA) to the safety of pressure systems and explosive atmospheres compliance regulated by the HSE.

What are the key issues in the recruitment of engineers into Pfizer?

Despite the diversity of the engineering need at a site such as Pfizer Sandwich, engineering as a career in a pharmaceutical R&D company is not an immediately obvious choice for a suitably qualified graduate. Neither within the pharmaceutical industry is engineering seen as being at the "competitive edge". Could this therefore be one area where increasing the internal and Industry-specific visibility of the specialty (e.g. through the establishment of an Engineering "Centre of Emphasis") could promote external awareness that pharmaceutical companies have engineering as extremely viable career options?

The Engineering Dept. at Sandwich recruits and educates engineers via 3 routes, but none of these can currently be considered to be wholly optimal.

Firstly through an Apprenticeship Training Programme, approximately 2 apprentices aged 16-19 years old are taken on each year. The training runs for 4 years during which time the apprentice works towards an NVQ level 4 and HNC. At the end of this time he/she may be permanently employed if a suitable vacancy exists as a craftsperson or technician. Some of these qualified apprentices go on to become degree qualified through the part-time degree route and support the business in the capacity of an engineer. Sandwich has also occasionally taken on Industrial Trainees in Engineering, but historically this has been somewhat sporadic.

A second route is via the recruitment of graduate engineers. However, no graduate entrant scheme for engineers appears to exist within the Pharmaceutical Industry and

whilst an attempt to initiate such a scheme at Sandwich was started, the need to provide upwards of 2 years training before an entrant has assimilated the necessary amount of "applied" knowledge and skills to be fully functional and the lack of a recognised career path for engineering graduates has currently left this process stalled.

Whilst there is an ongoing need for high quality process, mechanical, chemical, electrical (etc) engineers, the Pharmaceutical Industry does not specifically develop them. Therefore, it is perhaps not that surprising that the remaining route for the recruitment of engineers is often from other sources outside the industry e.g. the petrochemical industry.

Perhaps more so than in many other R&D lines and specialties, is engineering an example where more could be done to help skills needs at an Industry (employer) level?

What skills sets could be shared with other R&D disciplines and organisations?

Asset management; This may be defined as the optimisation of the lifecycle costs of a (engineering) system and as such requires an in depth understanding of all aspects of that system's purchasing, operation and maintenance strategy. Its principles are effectively applicable to all R&D companies, if not in fact to all companies *per se*. Some industries are more mature than others in adopting an asset management strategy. For example, this is a relatively new programme for most pharmaceutical companies, whereas other industries have been using asset management strategies for over 25 years.

What would Engineering ask of the education providers?

Include an understanding of the need for and optimising the response to regulation, [cGMP, etc]. This is a significant cost burden in the Pharma industry in that it appears without exception to be poorly understood and applied.

Include asset management strategies; see above comment.

Identify possibilities for the convergence of disciplines and therefore for shared learnings and synergies e.g. between chemistry, biology, physics and engineering. This is increasingly pertinent in our business where different disciplines share and collaborate on projects. Examples would include nanotechnology (encompassing mechanical engineering and drug delivery systems) and similarities between engineering specialists in fluid dynamics and research in to the human circulation. This may help reduce siloism as well as increase the profile of engineering in pharmaceutical R&D.

4.9 Quality Operations (Manufacturing Laboratories)

What does a Quality Operations scientist do?

Quality Operations carries out a wide variety of analytical testing from the Raw Materials through to the Active Pharmaceutical Ingredients (API's) using a range of analytical techniques including HPLC, GC and FTIR. The laboratories are also involved in process and cleaning validation, product stability testing, microbiological testing and safety and environmental monitoring. There is also a Technical Services group that carries out method improvement and development.

Chemistry entrants to Pfizer would be laboratory-based (80-90% of time on lab-related work including data analysis) and be part of a team.

What are the skills-related difficulties with recruitment?

In Quality Operations at graduate level, if applicants fail interview on skills grounds these usually fall into a couple of technical categories – a **lack of knowledge and understanding of the basics** of Analytical Chemistry (e.g. HPLC, do not understand the principles of the technique, for chemicals do not understand basic reactions). The degrees tend to be combined degrees that reduce the Chemistry content of the course. The candidates also **lack practical experience and application** (e.g. cannot describe practical work beyond following a protocol). For this reason most recruits into Quality Operations at graduate level have done an Industrial Trainee year or at least a summer placement. This not only improves skills, but also gives them valuable experience of the working environment. It is possible that the key issue here is not that they haven't been taught these basic skills, but rather they haven't learnt them or don't understand them. Also, the modular basis of many degrees now means that they might study the basics early on but then do not go on to apply this is a meaningful way (to them) - answers like "we did that in the first year but I can't remember now" are frequently encountered.

It is clear that "on the job" training is hard to beat. Graduates typically have difficulty performing basic analytical techniques including weighing and pipetting. For top-performing undergraduates, could universities look to increase their degree of integration into the day-to-day research infrastructure of the university department? Not only would this foster the development and application of skills, but would also be an important way to enhance communication skills and team working, which are both often lacking in graduate applicants.

There is also a difficulty in recruiting school leavers with appropriate skills. The majority of scientific school leavers tend to go onto further education, to study degrees which do not give them the skills that they require to work in an analytical environment. It would be useful for schools to be more aware of the opportunities available for scientific school leavers.

What does Quality Operations do to support the skills agenda?

With regard to current training activities undertaken within the department, Quality Operations supports the following further education courses:-

HNC (Chemistry) University of Greenwich – day release program
BSC (Analytical Chemistry) University of Greenwich – day release program
OU Degree.

Once graduates are recruited they gain experience of the different laboratories within Quality Operations, to further extend their training both scientifically, technically and in softer skills.

What would Quality Operations (Manufacturing) ask of the education providers?

To encourage students to link topics and gain as much practical experience as possible (both inside and outside of the course*) - to learn from and understand the practical work they do at university and not just blindly follow protocols. To carry out practical work using real examples that can be linked back to the theory.
To review the degrees currently available and reduce the number of combined degrees so that more emphasis is placed on the practical Chemistry content.

* The French system, with a heavy emphasis on placements (industrial and academic) produces very well regarded graduates in chemistry, for example, but this is probably something wider than the individual providers to implement and would need a sea change in how UK education is run.

5. Discussion and points for consideration

The research and development of new medicines is a long, complex and expensive process that carries an inherently high rate of compound attrition. It follows that the Pharmaceutical Industry needs multi-disciplinary R&D teams of high calibre skilled life science graduates to prosecute its work. Its multi-disciplinary nature is emphasised by the above descriptions of the departments and roles of individuals who are involved throughout R&D.

5.1 Career awareness

However, in many cases both undergraduate and postgraduate students and post-docs may not be immediately aware that interesting and rewarding careers could await them in pharmaceutical R&D. Although this is a "general awareness" issue it particularly applies to "pharmacokinetics, dynamics and metabolism", pharmaceutical sciences and manufacturing. Interestingly these are examples of disciplines that may heavily rely on chemistry graduates to fill posts, but are not "chemistry" departments *per se*, i.e. in the same way that "Discovery Chemistry" is. Additionally, departments such as engineering, that provide critical "functional support" to ensure the successful continuance of the overall operation are other clear examples where pharmaceutical career opportunities may be "non-intuitive".

Therefore as well as encouraging the inclusion of relevant course content for pharmaceutical R&D (see below), it is certainly the case that the Industry needs to play a much more visible role in explaining "what it is, what it does and what it needs" to both education providers and life science students as a means to raise awareness of career opportunities. In turn, we invite education providers to identify suitable forums for our participation.

5.2 Optimising course content to deliver the required level of skills

Having identified the types of career opportunities available to life scientists within pharmaceutical R&D, it is then vital to ensure that their education and training provides the requisite skills base. From the deficiencies described above, it is clear that this is currently often not the case. There are several commonly shared areas of concern across disciplines; 1) a lack of knowledge of the basics e.g. chemists who cannot describe what a mole of compound is, or clinicians with little knowledge of the principles of clinical trial design, 2) a lack of knowledge as to how to apply theory to actual practice e.g. graduates who can only follow a prescribed protocol and do not have the skills to develop new methodologies independently and 3) a lack of practical skills e.g. *in vivo* biology and toxicology or the awareness of the types, uses and applications of complex technologies.

Using the suggestions for course content described above, we therefore ask education providers, where possible, to include these ideas in student teaching. This may be achieved through the development of specific modules pertinent to pharmaceutical R&D and/or additional emphasis on key course components that have potential application.

Pfizer would be keen to offer support where possible to help achieve these objectives, either via the provision of subject matter expert advice, or active involvement "in kind". However, it must also be understood that we have very restricted resource that can be deployed for these sorts of activities. We cannot ourselves function as a university. What resource does exist is often already being used for "on the job" training or to support the significant amount of work currently being done in-house to directly support the skills agenda.

Indeed it may not have been immediately obvious to the external onlooker as to the degree to which Pfizer currently supports the science skills agenda. The number and types of educational activities identified in the various research lines in this report should dispel any myth that employers do not play their part. It is also the case that similar efforts are being made by other R&D organisations.

We also recognise however, that universities cannot be asked to produce, for example, specifically trained "pharmaceutical R&D statisticians". This would not be possible after a 3 year course, neither would it be desirable for the individual graduate if in reality a career in the pharmaceutical industry didn't work out; what else could he/she do? This is not what we're asking for. Rather, we ask that education providers take real note of what we need to prosecute pharmaceutical R&D now and most importantly in the future and adjust course content appropriately to better reflect these needs.

To address this further, the identification of potential areas of shared skills needs between various R&D organisations is an attempt to help education providers focus on those subjects that could benefit the widest range of employers in the R&D sector and thus optimally equip graduates with the skills needed for a range of R&D career opportunities. Many of the disciplines have perhaps predictable synergies with academia itself, the biotechnology sector, contract research organisations and assay

design companies. However, potential "non-obvious" synergies also exist between pharmaceutical R&D and 1) aircraft design and household appliance design companies (mathematical modelling), 2) government departments (statistics) and 3) the need in many companies for graduates skilled in asset management (represented here by engineering).

One additional suggestion would therefore be for education providers in selected skills sectors where overlaps and synergies in skills needs have been identified between different types of organisations, to organise workshops with relevant potential employer groups in order to collectively shape future course content.

6. Conclusions

The gap in the provision of science-based skills to meet the needs of UK-based R&D has long been recognised and within the pharmaceutical industry has been highlighted by the ABPI. What this report does is to show the granularity of the problem from the perspective of Pfizer *per se* and by so doing provide some detail with regard to how course contents need to change to deliver appropriately skilled life science graduates.

Failure to close this gap, taken together with other environmental disincentives to continue investment in "UK plc", will inevitably persuade the pharmaceutical industry to increasingly relocate its R&D elsewhere e.g. to the emerging territories in the Far East. Given the historical size of the investment by this industry to the UK, this would clearly have a detrimental impact on the economy.