DISCUSSION ON EMERGING SKILLS AND EMPLOYABILITY IN LIFE SCIENCES SECTOR

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I. TRENDS AND DRIVERS OF CHANGE IN LIFE SCIENCES SECTOR

In recent years, a number of variables have changed the global and European scenario as we used to know it, influencing also the health-related life sciences sector. The most relevant trends are detailed below [1, 2, 3, 4, 5, 6, 7, 8, 9].

Cost Competitiveness: Companies in the biopharma-pharmachem sector are facing growing pressures on reducing costs and maximising returns on investment in an environment characterised by stringent regulation, loss of patent protection and increasing R&D costs, while maintaining high standards and managing risk. Increased competition from with a lower cost base and the cost containment strategies of health services globally, highlight the importance of addressing competitiveness.

Regulation: In an environment where biopharma-pharmachem companies are facing pressures to reduce costs and time to market, they must also comply with regulatory processes and requirements for sufficient clinical data to illustrate a product's safety and effectiveness for approval. The blurring of the distinction between medical devices and medicinal products creates a challenge for regulators (and industry) to identify an appropriate regulatory approach to handling products based on convergent technologies. In a skills context, companies must ensure that their employees are fully conversant with the regulatory environment. Developments such as the use of Process Analytical Technology (PAT) and Quality by Design (QBD) require the development of specialised technical skills in this area.

Increased M&A Activity: Large biopharma-pharmachem companies are increasingly looking to start-ups and biotechnology companies as a source of new IP acquired through licensing, collaboration or M&A to bolster their product pipeline and future revenue growth. 15-20 % of sales revenue of the top 20 pharmaceutical companies now comes from licensed products and about 40 % of their pipelines are composed of externally sourced compounds. It has long been recognised that the 'go it alone' approach to innovation and development is no longer viable. Today the complexity of problems and the need for multidisciplinary approaches requires the flow of ideas and knowledge exchange. Collaborating and partnering enables innovation and new industry creation. M&A activity requires skills in areas such as intellectual property management, legal, tax and investment skills.

[1] The present document has been realized in the context of BIOTECH-MA PROJECT, Teaching Biotechnology for human health: from the bench to the market Funded by the Erasmus+ programme of the European Union, 2015

Loss of Patent Protection and the Rise of Generics: It is estimated that US$115 billion of branded drugs from the top 50 pharmaceutical companies will lose patent protection by 2012 and will be open to competition from generics. The main challenge facing companies is the fact that products come off patent at a relatively early stage, which demands ongoing investment in innovation and successful delivery of new higher value products to market within a relatively short time frame From a skills perspective, this will require an increased emphasis on innovation, entrepreneurship and specialised technical skills.

Shrinking Research Pipelines: The costs of drug development are increasing while at the same time the drug pipeline, particularly in the pharmaceuticals sector, is thinning. The typical net cost of bringing a drug to market is US$800 million. R&D makes up a major portion of this cost with approximately 25 % of all R&D expenditure going on clinical trials. The average time to market for a new pharmaceutical product can be anywhere between 5 to 15 years depending on the type of drug and its status. Only one in twenty drugs entering clinical testing successfully completes the clinical trial process and the FDA approved only 19 new drugs in 2007, the fewest in 24 years. In many cases the failure of a drug to gain approval does not happen until late in the process at which time considerable investment has been committed to large scale clinical trials. Skills that help increase efficiency and speed to market, along with innovation and business acumen to identify alternative products and markets, will be necessary to address this phenomenon

Biotechnology: Developments in biotechnology are enabling the creation of new biopharmaceuticals, improvements in manufacturing processes and in the greater application of the predictive sciences. A recent OECD report envisages that biotechnological knowledge will play a role in the development of all therapies by 2015, both small molecule pharmaceuticals and large molecule biopharmaceuticals, and that advances in biotechnologies will be instrumental for realising the potential for personalised healthcare There are considerable challenges if the potential is to be fully realised, however, not least the enormity of the logistical demands in undertaking large-scale population genotyping and the design of the genoprofiling diagnostics tests, intellectual property (IP) considerations, computing infrastructures and ethical issues.

Ageing and chronic diseases: The world population over sixty years old will double in percentage terms, rising from 7.76% in 2010, to 15.9% in 2020 while, at the European level, the phenomenon is even more pronounced, with a clear trend that can already be seen: the percentage of people over seventy has already reached 20%, and the percentage of octogenarians will probably double in the next 15 years. Statistical studies show that 75% of the population over sixty years old is suffering from at least one chronic disease (heart disease, hypertension, diabetes, Alzheimer's, obesity, etc.), while 50% is affected by two or more pathologies.

Social inclusion: With the rising of life expectancy, more people now reach an age where declining physical and mental health make them dependent on help from others. While most of this social care is currently provided by relatives, in future the availability of this kind of informal social care by family members is expected to decline, as people are having fewer children, who may also live further away from their elderly parents and be unable to provide care. With the ageing

phenomenon and the linked increase in chronic diseases, social inclusion shall be reorganised by public authorities in order to face these challenges.

Health cost pressure: In general, health cost pressure is a more and more difficult problem to manage: nowadays the healthcare approach is focused on illness treatment based on hospitalization as the most important element. This approach causes, in addition to much inefficiency, a general increase in costs that is not manageable by the governments anymore. Furthermore, the ageing phenomenon will inevitably lead to an increase in chronic diseases with a consequential rise in healthcare expenditure: statistical studies show in fact that the population over sixty years old uses three to five times more healthcare system services and that spending on chronic diseases accounts for 60% of the total healthcare costs.

The growth of the Bioeconomy: in the last year the industrial biotechnology sector has shower incredible growth rates. Agro-food, Chemical processes, new materials and management of energies are at the core of such approach. So the trend will affect different markets and products with probably a wider impact that the “pure” health focused approach. Clear advantages are outlined: Lower cost of production, possibility to develop really Innovative products and lower environmental impact. The approach require state of the art skills in biotechnology but also a clear application vision.

Economic growth rate: The 2008 economic world crisis led Europe to stagnation and experts predict first improvements only from 2014 onwards: the recent economic reports of the European Commission (DG ECFIN), with short term economic forecasts, expected another year of recession in the EU in 2013, with -0.1% of real GDP growth rate, and a return of the economic growth only in 2014, with +1.5%. The last economic forecast of the OECD provides similar figures for real GDP growth of European Union countries, with a GDP growth rate of about -0.1% in 2013 and +1.3% in 2014 for the Eurozone.

Globalization: In their way out of the crisis, European economies are moving to increase their trade with global emerging economies. Companies located in different European countries and economic sectors are taking advantage of the growth of emerging markets differently. On the other hand, many companies, and in particular SMEs (that represent over the 90% of all European enterprises), are suffering from the competition of the new emerging countries. For the life sciences sector, globalisation is seen both as an opportunity and as a challenge to be faced, with new markets but also with new competitors to consider. As consequence global demographic, socio-economic and consumption trends are having a major impact on the markets for biopharma-pharmachem products and services. The United Nations projects that the world’s population will increase from 6.6 billion in 2005 to 7.7 billion by 2020. Ageing populations in developed economies will drive demand for a wide range of treatments to address age related ailments. At the same time, ageing populations and the growth of chronic and lifestyle related conditions are putting significant pressures on healthcare systems globally. Thee rise of emerging economies as locations of production and markets will also alter the life sciences landscape over the coming decade. Enterprises now invest in emerging economies to undertake a range of activities, including R&D and clinical trials. That said, for now, many senior executives cite infrastructural deficiencies, shortages of relevant PhDs and regulatory bureaucracy, as potential risks to such

investments. In the developed world, for many people, increased wealth and free time has resulted in a focus on a healthier lifestyle. This increased focus on overall 'wellness' has led to a growing demand for lifestyle related treatments and products. Patients are increasingly well-informed, both because of the fact that health issues are reported on in the media to a greater extent and the fact that the Internet has played a significant role in expanding health awareness and providing extensive information on health related issues. This trend has seen consumers taking a more active role in managing their health; demanding choices for treatment options and alternatives. From a skills perspective, these trends emphasise the need for excellent business skills, particularly, business development, sales, marketing and health economics, for a continually upskilled, flexible workforce, capable of reacting to and anticipating consumer demand. Intercultiural skills are also becoming one of the key variables in hiring personnel from such point of view.

Structural changes in our economic systems: In the last decade the global business environment has changed radically, with new economic power actors in place. This results in both challenges and opportunities for European industry: now European companies have to compete with China, Brazil, India and other emerging economies also on high-value products. Technology, ICT and professional skills are becoming increasingly important for international competitiveness. To address these challenges and to remain competitive on the global market, the European Commission's Europe2020 strategy draws a new master plan that is intended to support the European way out from the current situation of crisis by investing in education, research and innovation.

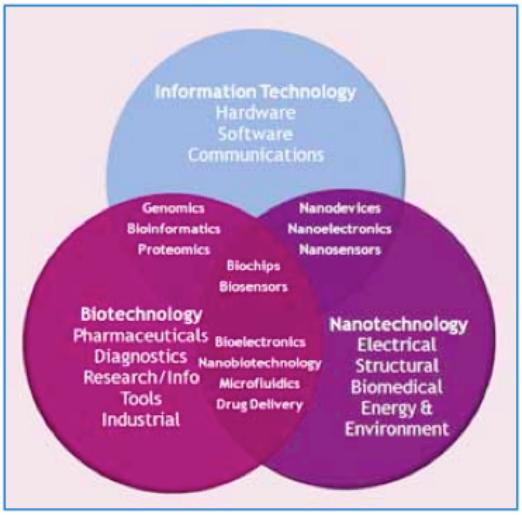
Brain drain: As a consequence of the economic crisis, many Europeans, and in particular young people with a high level of education and of professional skills, decide to emigrate outside of Europe looking for job opportunities. This is true in particular for the research field, where many highly educated researchers decide to leave Europe looking for countries that are investing more in research.

General Advances in Technology and Science: The pace and degree of technological advances have unfolded a series of new, predictive sciences which are opening the possibility of new approaches to drug development, more effective diagnosis, therapeutics, and patient care. These predictive sciences include genomics, pharmacogenomics, and proteomics, which effectively enable the development of drugs and treatments that are tailored to an individuals' genetic makeup, and enable early 'signalling' of an individuals' propensity to a specific disease. In this context, molecular diagnostics is now the fastest growing field in diagnostics and coupled with advances in laboratory equipment will play an increasing role in early diagnosis, monitoring and targeted pharmaceutical intervention. This takes on particular relevance given the reduced product pipelines in pharmaceuticals, such that existing compounds can be modified and/or targeted for sub-populations to increase overall efficacy. Other technological advances, such as those in wireless, sensors, nanotechnologies, microelectronics and 'wearable' technologies that collect and transmit data from patient to clinician will have an impact on future healthcare diagnostics and delivery. Optoelectronic or photonic technologies have enabled advances particularly in relation to the evolution of 'labs-on-a-chip,' which are devices that integrate one or several laboratory functions on a single chip of only millimetres to a few square centimetres in size. These

technological advances will require a highly-skilled labour force in new and emerging processes across a variety of disciplines, including nanotechnology, engineering, information technology and others.

Converging technologies and “convergence”: The term "converging technologies" refers to the synergetic convergence of different fields of science and technology that are all progressing rapidly, like nanotechnology, new materials, ICT and biotechnology, and that can join forces for creating radically new solutions for the health market (Figure 1). If managed appropriately, they can play an important role in the European economic and social development, creating at the same time new innovative products and services, and consequently new market opportunities for European companies.
Convergence is defined as the intersection and combination of more than one technology platform, for example, nanotechnology, biotechnology, ICT, & cognitive sciences. Although the concept of convergence is not new, the pace at which it is enabling the development of leading-edge innovative new products and solutions has accelerated. Convergence stretches across pharmaceuticals, biotechnology, medical devices and diagnostics, and has already resulted in the creation of many convergent products.

Figure 1: converging technologies



Source: “Future Skills requirements of the biopharma-pharmachem sector”, 2010 [10]

The impact on industry has resulted in a blurring of the lines between formerly discrete sectors. Product development and marketing now, more often than not, involves alliances or M&As between companies from different sectors and the development of new revenue sharing and business models. For example, the introduction of drug eluting stents (DESs) - the most successful combination product so far with a market size of US$5.5 billion worldwide - stimulated both of the sectors to collaborate and create a whole new line of products.

According to PRTM Management Consultants, the market for convergent products is currently estimated to be around US$40-50 billion and growing at 14% annually. However, this area is still in its early stages, and several challenges need to be addressed. These include risks associated with the technological components and interfaces needed for integration, the challenges of partnering with other firms, often from other industry sectors, and uncertainties about the size and receptiveness of prospective markets. From an investor perspective, convergent technologies combine the risks of drug development with the quite different risks of device development, without decreasing overall risk. There is also a matter of regulatory issues - as products get smaller in size and are implanted in the patient's body to reach the targeted area, their safety will be of utmost importance. That said, there are many successful convergent products already in the market, with the number of applications for convergent products with the US Food and Drug Administration (FDA) increased from less than 100 in 2003 to 333 by 2007. Although these advances in science and technologies are enabling the realisation of personalised healthcare, there are many different views as to when and to what extent it will become a reality. Factors such as the economic viability of production, costs and infrastructures, individual risk and insurance and data protection need to be taken into consideration. Having said that, evidence points to products and solutions being developed that are tailored for groupings of patients with similar genetic dispositions (as opposed to being tailored specifically to the individual). Convergent products in the market today include:

- Drug-eluting stent that opens and inhibits restenosis in coronary and peripheral arteries;
- Bone grafting scaffold coated with a growth protein that promotes bone regeneration;
- Implantable, programmable pump that delivers a drug or biologic in small, timely doses;
- Implantable polymer wafer that releases a chemotherapy agent to a specific site;
- Implantable neuromodulator that enables the targeted, regulated delivery of a drug or electrical stimulation;
- Transdermal patch that transports drugs locally and systematically through the skin;
- Pre-filled, metered dose syringe, injector pen, or inhaler;
- Screening test for the presence of a specific gene or protein coupled with targeted drug therapy;
- Use of passive pharmaceuticals and radiopharmaceutical tracers as contrast agents for positron emission tomography (PET) scanner.

From a skills perspective, technological convergence will impact on skills requirements in a number of ways:

It will broaden the range of disciplines that are core to the biopharma-pharmachem sector to include not only chemistry, the biological sciences and chemical engineering but also encompass mechanical, biomedical and materials engineering, nanotechnology and information technology.

While the main requirement will be for people with a deep knowledge of their core discipline who can work in a multi-disciplinary environment, there will also be requirement for people with blended skills or skills that span different disciplines.
There will be a requirement for skills in business acumen, risk analysis and management, intellectual property management, legal, tax and finance skills.

The life sciences industry and particularly the healthcare sub-sector, is one of the world's largest and fastest growing industries, and in Europe it represents a significant part of national economies, with implications for economic growth, employment and public health. In this scenario, we believe that the demographic changes (characterised by a shift of the population towards the elderly and by the increased incidence of many chronic degenerative diseases), together with the new opportunities coming from converging technologies, can be a big opportunity for the development of the European life sciences and healthcare sector, with relevant positive consequences for Europe's society and economy. However, the current challenges require a change in the approach, model and the solutions that are used now and at all levels of the healthcare value chain. Consequences could be appreciated also from a company and human resources point of view.

To cope with changes in the global and European scenario of health-related life sciences sector, the development of a work force presenting a new set of skills is required. Countries like Scotland are studying such issue and are developing "Skill investment plan" for the future (Figure 2)[11].

Figure 2: An example of drivers of change and skills implication

Driver	Description	Skills implication
Ageing population and pressures on healthcare	Increased demand for providers to develop new, innovative and cost-effective healthcare solutions and products to treat the rise in chronic old age diseases such as cancer, diabetes and dementia.	Constant change in skills requirements of the workforce. Education system needs to be agile in order to respond to the changing needs and expectations of businesses.
Rise of the middle class in emerging markets	Significant opportunities due to the growth in demand for medical products in countries such as China, Brazil, India, Russia, Turkey and Mexico.	Demand for a high quality skilled workforce becomes critical if Scotland is to take advantage of increased global opportunities.
Patent expiration	Companies are under increasing pressure with blockbuster drugs coming off patent. Greater competition, an increase in generic drugs and a long lead-time to develop new drugs. Regulatory requirements prior to product launch are considered to be more onerous leading to longer lead times of drug development.	Further development of the talent pool needs to be aligned with the changing expectations and business opportunities, as well as a requirement for specialist regulatory skills. This can act as a catalyst for growth and job creation.
Limited access to venture capital finance for early-stage companies	Life sciences companies, like those in many other sectors, are now facing reduced access to financial products, including venture capital.	Demand for the right blend of business and commercial skills.
Emergence of stratified/ personalised medicine	Not all drugs are equally effective in all patients. It is estimated that only 30-70% of patients respond positively to any particular drug. Cost-effective solutions to deliver the right treatment to the right patient at the right time will need to be created. This will generate a large volume of data that will require seamless and secure medical records and data recording systems.	Opportunity for Scottish life sciences companies to specialise in health informatics and bioinformatics. A requirement for increased IT and data recording and analysis skills (including analysis of huge and complex datasets, clinical informatics, patient administration and health records).
Converging technologies for managing patient health	The merger of life, physical, and engineering sciences is creating new technologies and products such as Telehealth where electronic sensors/ equipment monitor vital health signs remotely such as in the home or on the move.	Demand for a higher level of skills of an interdisciplinary nature. A trained person who can monitor and make decisions about potential interventions in real time, without the patient needing to attend a clinic.
Industry restructure	Challenging market conditions have led to increased consolidation within the industry, particularly in the pharmaceutical industry where merger & acquisition activity has continued and driven the move towards more outsourcing and partnering.	Outsourcing will present opportunities for Scotland's life sciences sector and its researchers. CROs and consultancies will have the opportunity to take advantage of the need to submit complex data submission packages in a highly regulated environment.

Source: Skills Investment Plan For Scotland's life sciences sector, 2014 [11].

As discussed below the workforce-related skill needs may be divided in three groups [12] :

(1) Skills in life sciences disciplines, such as chemistry and biology;

(2) Orientation towards the life sciences industry, with a clear understanding of industry-specific ways of working, such as compliance with US Food and Drug Administration regulations,

sixsigma and zero-defect quality systems and assurance in product development and manufacturing, and the design and execution of rigorous clinical studies;

(3) Soft skills and the ability to work effectively across disciplines.

II. Technical skills and multi-competencies

Biotechnology is a multidisciplinary and industrialized field that faces many challenges. Biotechnology encompasses a wide range of products and processes, from drugs and medical devices to biofuels and agricultural products [13].

The three major industry groups of the biotechnology sector include:

- Biotechnology – firms that are engaged in manufacturing ethyl alcohol, fibers, soap and detergents, polish and other sanitation products;
- Medical devices, equipment and supplies – firms that are engaged in manufacturing, electromedical and electrotherapeutic apparatus, analytical laboratory instruments, irradiation, surgical and medical instruments;
- Pharmaceuticals and related manufacturing – firms that are engaged in medicinal and botanical manufacturing, phramaceutical preparation manufacturing, in-vitro diagnostic substance, and biological product manufacturing [14].

Biotech industry has diverse job opportunities that span multiple classification.

One of the main hurdles in biotechnology development and application lies in its workforce or human resource development as there is a need not only for the relevant knowledge education at various levels and for various target groups but also for the capacity building in bio-safety measures. The biotechnology industry is anchored firmly in the abilities of scientifically trained people at all levels, from the laboratory bench to the capital providers, who understand both science and business.[15].

Hence, biotech industries demand a talent pool with a strong knowledge base, with all of the components necessary to translate scientific discovery effectively and efficiently into commercial products. For this purpose, they are continuing to experience job growth with an evolving and strong need for knowledge workers. There is a substantial need of:

- Employees with baccalaureate and advanced degrees in chemistry or biology/biotechnology or engineering;
- Employees with high school-only graduates who can receive industry-specific training;
- Employees with industry-based work experience and industry-specific job skills in disciplines ranging from clinical, validation and biochemical analysis, to regulatory and quality systems;
- Employees with advanced or specialized degrees, such as biostatisticians with the ability to address needs in bioinformatics and computational biology, as well as engineers with the ability to manage complex biological process scale-up, are in exceptional demand [12].

Figure 3: Life sciences skills most frequently requested (in 64,334 job postings) [12]

Technical skills

Industry views on future skill needs were very consistent at all three sites where the main future skill needs were defined as follows:

Good basics

The preference is for graduates that are smart, well equipped with the basics of science, technology and engineering, their core specialisation, and ready to learn. Loading the graduate with a lot of specialisations is widely regarded as a mistake.

Understanding of the drug chain

Graduates need to understand the drug process from discovery to market and the different profession all inputs at each stage. Team-working is considered essential, and a cross-disciplinary understanding of other team members' needs and viewpoints. Working in such a system requires a mixture of hard skills and soft skills, including communication, team-building and project management skills (Figure 4).

Informatics and Bioinformatics

There is a widespread view in these three locations that all involved in the drug industry will be increasingly involved in, and often dependent on, analysis and interpretation of large data sets. It is therefore important that industry staff have the ability to understand the basics of data management processes and equipment as a grounding for usage of whatever systems will be used within industry. A good understanding of the statistical principles which undergo the data is also considered an essential requirement

Said that, there is a need of solid scientific background which includes also:

- Laboratory experience (practical/project work components in cell culture, molecular biology, etc);

- Research skills (experimental design, critical interpretation of results, scientific writing and communication);
- Expertise in specific cutting edge technologies (e.g. sequence data generation, data mining, systems biology) [16].

Multicompetiences

There is a shift in the industry's demand for talent away from the senior scientist positions that tend to be more highly specialized and narrowly focused, to a talent pool consisting of individuals who have interdisciplinary academic training with the ability to work broadly across multiple areas and in project teams where not everyone has to be an expert in everything[12]. Requested capabilities include strong communications skills that facilitate the translation of the science effectively to stakeholders, a commercial market-based mindset versus an academic mindset, the ability to apply skills to real world problems, comfort with big data management, the capacity to be creative and the willingness to push boundaries.

Several themes emerged among hiring managers and industry leaders from all sectors who participated in the interviews, including the need for:

• Individuals with strong science skills combined with multidisciplinary academic training and experience (*"professional hybrids"*).

• Regulatory professionals who can help bridge the gap between regulatory functions and business activities.

• Scientists, engineers and clinicians who possess cross-functional skills that promote strong communication and the ability to interface well with both internal and external partners.

• People with policy acumen who can help navigate health economics and the Affordable Care Act as well as influence legislators.

• Strong and informed partnerships between academia and industry to provide tailored and relevant training to effectively meet industry needs.

- Marketing, entrepreneurial and technology transfer skills (IP, licences, know-how, confidentiality, market survey, etc.) [8].
- Foreign language knowledge (English) is a pre-requisite. A second foreign language is a plus.

The skills needed today and in the near future still require a strong STEM (Science, Technology, Engineering, and Math) background, yet also an evolving need for their use in combination with other disciplines. Having a basic science degree appears no longer enough to be successful. The findings suggest that there is an absolute need for *"professional hybrids"* – individuals who have the skill sets necessary to link scientific knowledge with business acumen to advance a product or technology through its life cycle [8].

In particular:

Regulatory knowledge

In recent years, the regulatory landscape has shifted dramatically, resulting in a demand for candidates who understand current regulatory policies both within and outside of the United States. Company leaders and hiring managers emphasized the need for employees who possess a stronger understanding of industry-specific ways of working, such as compliance with FDA/EMA

regulations, as well as with quality assurance in product development and regulations. There is a need across subsectors for regulatory professionals who can provide strategic direction at all stages of development [8].

Policy acumen

The importance of understanding health economics, reimbursement and the impact of the Affordable Care Act on the life sciences industry is also required. Knowledge of government affairs, particularly the need to educate and build relationships with legislators both locally and nationally to support industry growth, was also viewed as important [8].

Industry-academic partnerships

The need for collaborative partnerships between industry and academic institutions was strongly emphasized across the subsectors. This included a particular emphasis on new approaches that incorporate experiential learning models or a learn-by-doing approach, as in internships with biotech companies.

Interviewees also expressed concerns over lag times in getting new hires up to speed, citing the hires' inability to understand the business aspects of the company environment.

Many of them indicated the importance of working with academic institutions to build curricula that are relevant and applicable to industry, and of producing graduates prepared for direct entry into the workplace [8, 17].

Considerations related to company's peculiarities

It is clear that only scientific skills are not enough. Business and Personal skills are needed. Among the most important:

Business skills: project management, market knowledge, product commercialisation, innovation management, intellectual property rights.

Soft skills: communication skills, team work and creative thinking.

Actually a distinction has to be made considering SME and large companies' needs are not the same, since large companies have the ability to allocate resources for in-house training. Regardless of this, companies need well trained and skilled employees.

Specific consideration can be made taking into account that the sector is highly polarized in two types of businesses: large and small.

Very small enterprises need business skills, knowledge of intellectual property, finance, strategic planning and internationalization.

An ideal person for SMEs would have to show proactive attitude, capacity to cover different roles in the company and doesn't hesitate to take responsibility when needed.

Actually, a mix of technical and managerial background together with socio-economic skills is really welcomed, as most SMEs cannot afford to hire in both areas [18].

Large companies, as well as in other sectors, need updating, managers need MBAs (Master in Business Administration), in general as any other professional sectors. In example Big pharma clinical executives need people with "big organization" skills, such as strong communication, political savvy, patience, and a "big picture" understanding of their role in the company's efforts.

Strategic vision, an understanding of the therapeutic market, and strong presentation skills are absolute necessities for success in this environment.
Moreover, one of the main demands of businesses is to find good directors and senior scientists with experience. Such profiles in many cases come from pharmaceutical companies, in particular:
- CFOs are also required to manage businesses with losses during the first years of life, - good business development managers who are able to negotiate licensing agreements with pharmaceutical companies,
- intellectual property experts who know how to defend patents against big companies in the pharmaceutical market [18].

CROs (Contract Research Organizations), whose main function is to deliver pharmaceutical services, are often perceived as the "boot camp" of the industry. Candidates being sourced for CROs may bring a certain clinical research skillset to their new organization; several years later they possess a broader spectrum of experience, having been exposed during that time to a variety of therapeutics, indications, and geographies.
They become far more valuable as candidates because of the far-reaching experience provided by working for a CRO versus the more "siloed" approach typical of large pharmaceutical companies.
Progressive CROs, while proposing and bidding on multiple drug studies simultaneously, keep talent acquisition at the forefront of their focus, especially since their staffs are a prime target for search firms. CROs without the resources for multiple office locations are moving toward employing regional, home office–based clinical research professionals with solid experience and maturity. This trend allows greater latitude for search firms, as shortages in certain clinical disciplines continue. CROs benefit by being able to move talent easily from one study to another as studies come to an end. One of the more recent trends within CROs is the growth of the functional outsourcing model, which is a variation
from full-service delivery that allows pharmaceutical companies to engage the CRO for only a segment or portion of a study.
At the technical level it is also very difficult to recruit staff because it requires people with experience in each particular field [19].

Ph.D. means attractive competence
By some estimates, no more than 20% of Ph.D. life scientists land tenure-track faculty jobs within 6 years of earning their terminal degrees [20].
Moreover as recently described in a recent paper [21] there is a growing number of postdocs and few places both in academia and in companies.
Companies are no longer willing to hire Ph.D.s who don't bring additional skill sets to the table. Ph.D.s students are trained to identify scientific questions, carry out experiments to answer those questions, and present the data in a clear manner to other scientists. The hiring managers in industry are looking for those fundamental skills when they set out to hire a scientist, and peer-reviewed publications are the best way to demonstrate that you have what it takes [22].

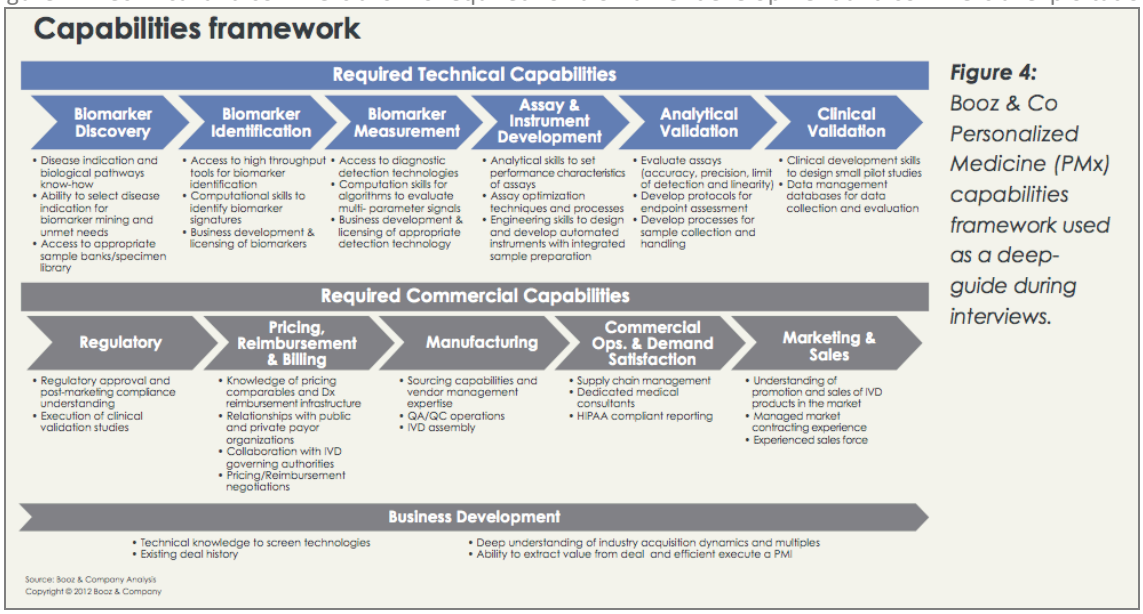
Since nearly all industrial projects are carried out by multidisciplinary teams PhD.s without an additional industrial life sciences training is not appealing for job seekers. Training programs, including short-term certificate programs and specialized degree programs, can provide at least

some of the additional knowledge and skills scientists straight out of academia need to impress industrial hiring mangers and display their commitment to industrial employment.
In additional other kinds of experience are strongly requested: Postdoctoral fellows in industry, Internships I industry, attended regulatory affairs meetings, follow Ph.D. programs that emphasize industrial training.
Participation in small seminars identifying the problems at the cutting edge of the application of biotechnology to medical, industrial, and environmental problems program requires students to take courses on legal and business best practices and bioethics, seminar series with industry professionals, and internships at regional biotechnology companies are strongly requested.
Ph.D.s students with a smattering of leadership, business, and project management skills that they will need to succeed in the biotechnology industry, their industry internships were among the most important aspects of their training may have more opportunities.
High level education, such as Masters, is the preferred way to move towards the desired skills and continuous professional development should be perceived in order to keep updated and to gain a useful cross disciplinary education, including non-technical expertise.
Master of science, master of biotechnology and master of agriculture/forestry are examples of desirable qualifications.

Limitations in existing education/training programs

Nowadays in the post 2008 financial crisis, a reduction of budget in education/training program both in academy and in enterprises has been observing. This is particularly problematic in science and technology courses that require a strong training component to pass on practical skills only acquired through "hands-on" experience, but require however a much higher budget than theoretical courses. As a consequence there is a lack of enough practical training components in graduates. In addition, in many countries a lack of training opportunities within companies is declared. This aspect strongly reduces interactions between universities and SMEs while it should be useful to ensure that the undergraduate programs developed match the needs of SMEs [16].

Figure 4: Technical and commercial skills required for biomarker development and commercial exploitation



Source: Demand for talent: Current & Projected Workforce Trends in the Life Sciences Industry, Coalition of State Biosciences institute and Booz & Company [23]

III. Transferable skills and soft skills importance

1- Definitions and future needs [24, 25, 26, 27].

More than different technical areas including scientific and/or business ones, other kind of skills are growingly requested from labour market, the so-called transferable skills and associated soft-skills.
Transversal skills encompass aptitude and knowledge acquired and developed through a person's life via formal courses, informal education, personal reading, social activities, professional activities and life in general, and are relevant and helpful in a wide variety of situations and workplaces [27].

Transferable skills can be organized under different categories including [27]:

- Analytical skills: skills that enable to identify and analyse problems and find creative, innovative and feasible solutions (research skills, data gathering skills, data analysis skills, creativity, risk analysis)
- Technical skills: practical hands-on skills like computer proficiency, ability to work with specific machinery, software, hardware, and ability to build or repair (C++ Programming, HTML coding, SQL knowledge, Flash, Photoshop, Illustrator proficiency)
- Organisational skills: skills that allow to sort data, plan, arrange projects or resources, maintain accurate, effective and user-friendly records and coordinate multiple resources or tasks (prioritizing, time management, task management, resource management, coordination.
- Personal skills: set of skills to do with workplace character (integrity, reliability, punctuality, diligence, decision-making ability

Another category of skills that is sometimes found assimilated or included into transferable skills are the soft skills, also known as interpersonal skills, intangible skills or people skills. It entails the set of skills of an individual related to personal knowledge, abilities, and attitudes. It encompasses the character traits that characterize a person's relationships with other people, skills that allow people to positively relate to, communicate with, influence and inspire others [27].
Sometimes the term "soft skills" is used to describe a person's "EQ" or "Emotional Intelligence Quotient" (as opposed to "IQ"), that is the cluster of personality traits, social graces, communication, language, personal habits, friendliness, and other abilities and attitudes characterizing relationships with other people[25].
In the workplace, soft skills contrast to hard skills, which are generally easily quantifiable and measurable. Moreover hard skills can be learned and perfected over time, while soft skills are more difficult to acquire and change. Soft skills could be considered at the third level of skills after technical non-transferable and transferable skills.

Soft skills can be found divided in 4 main areas (Figure 5) [24, 26]:

- Cognitive area: skills related to how one individual is able to reason. It includes analysis, synthesis, problem solving and critical thinking skills.
- Implementation capability skills: skills related to how one individual translate plans into actions. It includes organization, result oriented, time management skills.
- Social area: skills related to how a person relationship with others. It includes communication, team work, negotiation, leadership skills
- Emotional area: it includes self-awareness, empathy, stress tolerance.

Figure 5: Soft skills classification

	OPERATIONAL OR ENTRY LEVEL	MANAGER	EXECUTIVE
Cognitive area	Analysis Synthesis Openmind	Problem solving Decision making Flexibility	Strategic vision Critical thinking Innovation
Implementation capability skills	Initiative Precision Dynamism Result oriented	Global overview Perseverance Planification	Risk management Control Resilience Organization
Social area	Communication Support Collaboration	Persuasion Implication Awareness of networks/communities	Negotiation Talent management Leadership
Emotional are	Self-awereness Stability Self-esteem	Self-efficacy Proactivity Empathy	Resourcefulness Stress tolerance Emotional Intelligence

Source: Adapted from Soft Skills for Talent, ManpowerGroup, 2014 [24]

According to Manpower Group, a set of soft skills can be defined for the three fundamental levels of an organization: operational or entry level, manager and executive.

A set of new skills that need to be developed in the next future to cope effectively with changes in the socio-economic context has been identified [24]:

- **Intercultural skills:** ability to work in multicultural contexts, integrating and exploiting differences in various social and organizational systems. Ability to learn quickly new languages and to communicate effectively in both written and oral in multinational contexts.
- **Creative thinking and problem solving:** ability to think and find unconventional solutions to new problems, beyond imposed rules and patterns.
- **Project management skills:** ability to represent, organize and develop work activities and processes to achieve desired results and goals. Ability to perform and carry out more tasks and activities at the same time, ensuring accuracy and attention**.**
- **Team-working:** ability to work in team and ability to expand in different areas, to understand concepts and work through multiple disciplines. Ability to work in a productive manner, motivate and manage participation as a virtual or remote member of a team.
- **Abilitity to manage information flow and network:** Ability to discriminate and filter important information. Ability to translate data and statistics in concepts and, conversely, to extract data from arguments. Ability to critically evaluate and develop content using new technologies and forms of media. Ability to quickly identificate appropriate internal and external references, in

order to create networks and/or exchange information. Ability to communicate and connect with others in a fast and direct way, in order to facilitate and stimulate communication and interactions.

2- Importance for employability [28, 8, 29]

Transferable skills and soft skills are recognized as key to effective performance across all job categories. Employers do not simply look at academic credentials and past work experience; they seek candidates with the right combination of transferable and soft skills. For scientists, soft skills are nearly as important as bench skills. Ability for presenting data to different audiences, communicating across disciplines and understanding the language of finance and marketing are added value for employability.

The most requested skills by life science labour market are **communications skills** and **interpersonal skills**. Employers look for people able to pass information in a clear and concise manner with solid writing and oral skills and the ability to make effective presentations. Communicate in more than one language is also very important. People able to work well in teams, diplomatic, resourceful and able to build networks among their peers are highly sought. Moreover, negotiation is a skill that employers value highly.
Other soft-skills are often requested and among them:

- **Time management:** ability to juggle multiple priorities and responsibilities; meeting deadlines and deliver projects on time and budget.
- **Motivation and commitment:** hire candidates who put a great deal of pride and personal efforts into their work – high personal standards and drive to succeed; ability to bring out these qualities in others; leadership skills are always in high demand, especially as companies rely more and more on self-directed teams and project-oriented work organization
- **Personal image and self-awareness:** image employees present to co-workers and clients; understanding how people perceive you is important in a variety of areas such as negotiations, managing workplace relationships, and selling your company to prospective business partners.

Today there is a need for greater skills, particularly in terms of communication and team working. The ability to **work across disciplines and functions** are added-value skills for candidates [23, 2, 8].
Due to the growing development of converging technologies, industry requires professionals with a deep knowledge of their core discipline who can work in a multi-disciplinary environment, contributing to a multi-disciplinary team. Scientists not only need to patronize a technological field and to communicate well with peers but they also have to work at the interface with other technological disciplines. In the life science sector, the ability to work internally in multi-functional teams and to interface well with external partners is a key requirement for employees. Strong communication skills are required to communicate effectively with marketing, business or legal departments and to translate science into effective communications to multiple internal and external stakeholders or funders [23]. Moreover, to juggle with colleagues or partners in multiple geographical areas simultaneously excellent communication, interpersonal and **intercultural** skills are needed. The agility to **manage change** and to generate **creative solutions** will be more and more requested all levels of responsibilities and not only for managers or executives.

3- Skills development plan [29]

Soft skills requested by life science labour market and able to enhance candidates' employability should be developed during education at school, university and professional experiences. However skills gaps remain at all levels of formation.

Communication is highlighted as a particular skills gap. It is described that many science and engineering graduates enter the workforce without technical writing skills, which negatively impacts on their performance. Influencing skills are also a key part of communications and need to be improved. Graduates need to be able to confidently state their professional views and to convince others that their views should be taken into account in decision-making processes. In a general way, new graduates need to build their soft skills including team work, attitudes to deadlines, work ethic and communication.

During doctoral studies and post-doctoral positions young scientists develop valuable skills that can be translated into new career in many areas. Skills needed for academic careers are the same for non-academic careers: strengths in analytical thinking, problem solving, written and oral communication, and collaboration. Young scientists develop and acquire such skills leading research projects, working in teams, mentoring students, teaching, writing grants and communicating complex ideas. Writing clearly and concisely is an invaluable skill that postdocs must possess to succeed in almost any future jobs. There are a lot of careers that employ scientific writing skills including science communications and journalism, medical writing, regulatory affairs, and intellectual property [29]. But young scientists should make sure to collect soft skills as well as research data to enhance employability potential. The main skill gap described for post-doctoral students is the lack of time management.

Soft skills can be developed during personal and professional experiences but it exists also specific courses and workshops to implement these skills. Based on career stage and goals, it is possible to assess soft-skills and more generally transferable skills to determine the program and level of training that is needed.

CONCLUSIONS

- A new skilled workforce is needed to cope with current and future changes in life sciences industry.
- Strong technical and scientific knowledge and skills are the pre-requisite toghether with ICT skills and knowledge of foreign languages
- Employees with knowledge in different technological fields are highly requested.
- A multidisciplinary education is recommended. For example, marketing, Intellectual property, business development…
- Excellent communications, team-work across disciplines and functions are essential skills requested.

REFERENCES

[1] AA.VV bioXclusters - Joint Action Strategy (JAS), 2013.
[2] Future Skills requirements of the biopharma-pharmachem sector, 2010.
[3] AA.VV Health at a glance –Europe 2012, OECD, 2012.
[4] AA.VV The future of health care in Europe", Economist Intelligent Unit, 2011.
[5] AA.VV ALISEI – Advanced Life science In Italy strategic development plan 2013 – 2017, 2012.
[6] J. Tooke The future of healthcare in Europe, UCL, 2013.
[7] 2015 - Global life sciences outlook – adapting in an era of transformation, Deloitte, 2014.
[8] Kathy L Nugent & Lori Lindburg Life sciences workforce trends evolve with the industry, Nature Biotechnology 33: 107–109, 2015.
[9] Accenture technology vision 2014 for life sciences, Accenture, 2014.
[10]Future Skills requirements of the biopharma-pharmachem sector", Expert Group on Future Skills Needs, 2010.
[11] Skills Investment Plan For Scotland's life sciences sector, 2014.
[12] Kathy L Nugent & Avi Kulkarni An interdisciplinary shift in demand for talent within the biotech industry, Nature Biotechnology 31 (9): 853-855, 2013.
[13] Employment Developmen Department EDD 4/13, p3.
[14] Northern California Center of Excellence, 2010.
[15] B.Panduranga Narasimharao* Need for New Trends in Biotechnology Education and Training Asian Biotechnology and Development Review Vol. 11 No. 2, 89-114, 2009.
[16] Life sciences Workforce Trends Report, Coalition of State Bioscience Institutes, 2014.
[17] Deliverable 2.4 "Needs assessment for research, training and skills of emerging professionals in the bio-based product sector" October 2010 Europe Innova Eco-innovation Biochem.
[18] Souza and Carrell, An Executive Recruiter's Perspective on Hiring for CRO, pharmaceutical, and Biotechnology Companies, Clinical Research Career, 2007.
[19] http://sciencecareers.sciencemag.org/career_magazine/previous Biotech training programs expand employment options, 2012.
[20] The future of the Post-Doc, Kendall Powell, Nature, 520: 144-147, 2015.
[21] Lisa Belmont So, what's really like to work in biotech? MboC Perspective, 24: 61-62, 2013.
[22] Biotechnology education. Training offer & needs in the Atlantic Area, Share Biotech, 2013.
[23] Demand for talent: Current & Projected Workforce Trends in the Life Sciences Industry, Coalition of State Bioscience Institutes and Booz & Company, 2015.
[24] Future skills needs, 2010.
[25] Soft Skills for Talent, ManpowerGroup, 2014
[26] http://en.wikipedia.org/wiki/Soft_skills
[27] http://studentslife.it/soft-skills-colloquio-lavoro/
[28] http://www.bayt.com/en/career-article-2721/
[29] Paul Watson, Transferable skills for a competitive edge, Nature Biotechnology, 21: 211, 2003.
[30] The importance of soft skills, Coalition of State Bioscience Institutes, 2013.
[31] Developing Iowa's Bioscience Workforce, The Role of the Community Colleges of Iowa In Creating Skilled Workers for the Emerging Bioscience/Biotechnology Sector Iowa Department of Education Division of Community Colleges & Workforce Preparation, 2006.
[32] Global Human Capital Trends 2014 Engaging the 21st-century workforce, Deloitte University Press, 2014.
[33] Syed Imtiaz Haider and Anika Ashtok, Biotechnology: A Comprehensive Training Guide for the Biotechnology Industry, Journal of Commercial Biotechnology 16: 272 – 274, 2010.
[34] Michael Francisco First-quarter biotech job picture Nature Biotechnology (31): 2013.
[35] Larry E. Gundersen, Training needs in regulatory science for the biopharmaceutical industry. Nature Biotechnology, 19: 1187-1188: 2001.
[36] New chemistry: Getting the biopharmaceutical talent formula right, PwC Health Research Institute, 2013.
[37] http://www.cogentskills.com/about-cogent-skills/news/research-search.
[38] Mary Pat Huxley, Thoughts about the Twenty-First Century Biotechnology Workforce. Agricultural Biotechnology: Economic Growth Through New Products, Partnerships and Workforce Development. Training and Personnel Needs in Biotechnology Chapter 8.

[39] Michael F. Easley, Jr. Tar Heel Biotech: the policies, trends and investment that continue to promote growth in north Carolina's Biotechnology Sector.
[40] Godelieve Gheysen, Training and education in biotechnology and biosafety Ghent University, IPBO. Biotechnology, ABDC-10 , Guadalajara, Mexico, 1-4 march 2010.
[41] Human Capital Needs Analysis (A SAASTA INITIATED PROJECT), Centre for Research on Science and Technology CREST) at Stellenbosch University, 2010.
[42] R. C. Kennedy Thomson‡ and John Porter, Biotechnology Education, The Scottish Perspective on Biotechnology Education and Training, Biochemistry and Molecular Biology Education, 31: 59-61, 2003.
[43] Gus A. Koehler, PhD. Bioindustry: A Description of California's Bioindustry and Summary of the Public Issues Affecting Its Development. http://www.library.ca.gov/crb/96/07/BIOT_CH5.html
[44] The Transferrable Postdoc FOCUS ON CAREERS POSTDOC, Science/AAAS Custom Publishing Office.
[45] David Haselberger, Petra Oberhuemer, L'introduzione delle soft skill nelle istituzioni di istruzione superiore. Linee guida per la progettazione di contesti di apprendimento volti a favorire l'acquisizione delle soft skill. Versione 1.0. 2010.
[46] Getting better at biotechhttp://www.nature.com/naturejobs/science/articles/10.1038/nj...
[47] New Economy Strategies, LLC and The Leonard Resource Group, Inc. for The U.S. Department of Labor Employment and Training Administration Business Relations Group. The Biotechnology Industry Identifying and Addressing Workforce Challenges in an Emerging Industry, 2004.
[48] The Supply and Demand for Skills in the Biotechnology Sector A study for the Expert Group on Future Skills Needs by Peter Bacon & Associates Economic Consultants, 2003.
[49] Future Skills Requirements of the Biopharma-Pharmachem Sector, 2010.Expert group on Future Skills Needs.
[50] LEEM Les enterprises du Medicament ÉTUDE PROSPECTIVE SUR LES FACTEURS D'ÉVOLUTION DE L'INDUSTRIE DU MÉDICAMENT & LEUR IMPACT à 10 ANS SUR L'EMPLOI. 2012.
[51] Paul Watson Transferable skills for a competitive edge. Mastering the 'soft' skills can convince prospective employers of your potential. Nature Biotechnology, 21: 211. 2003.
[52] Soft Skills for Talent, Indagine ManpowerGroup sulle competenze trasversali più richieste dal mercato del lavoro, 2014.
[53] Le biotech fanno posto ai laureati. Il Sole 24 Ore, 2015.
[54] Polo Biotecnologie Piemonte. Analisi fabbisogni formativi imprese del territorio per il settore biotecnologie e scienze della vita, Allegati 1, 2 e 3, 2008.