

SKILLS AUDIT REPORT

Report Reference no.:	BI011019
Customer:	BioPharmaChem Skillnet
Audit date(s):	September 2019
Assessor(s):	Stan O'Neill , The Compliance Group

Introduction:

BioPharmaChem Skillnet had appointed The Compliance Group to conduct a skills audit on the BioPharmaChem sector with the following expectations;

- 1) Review all existing skills reports for the sector and collate the relevant information
- 2) Meet with some member companies (either 1:1 or in workshops) to discuss skills gaps and requirements within the sector and emerging/future trends

Brief report of the assessment activities undertaken:

Scope of Assessment:

The skills audit was performed via face to face and phone interviews with a variety of companies.

Companies / organisations met/interviewed during the assessment:

BioPharmaChem Skillnet
BioPharmaChem Skillnet Steering Committee
Alexion
Gilead
Pfizer Ringaskiddy
Pfizer Citywest
DuPuy Synthes
BMS Cruiserath
Fannin Healthcare

Assessors findings and observations.

1 Review of current reports

There are a number of reports relating to the Sector. These reports were reviewed taking into account the perspective of themes and topics related to the offering of BPCSN over the coming years. The items identified were as follows;

Future Skills Needs of the BioPharma Industry in Ireland, Expert Group on Future Skills Needs

Takeaway messages relevant to this assessment included

- The sourcing of experienced staff especially for Process Engineering and Quality Assurance / Validation roles
- “Soft skills” including communications, teamworking, problem solving and influencing skills.
- Knowledge in contamination, sterile processing and cleanroom operations.
- Data Analytics
- Development of BioPharma Apprenticeship and BioPharma Career Traineeship.

BioPharma Ambition 2018 – Conference Report

Takeaway messages relevant to this assessment included

- the necessity to be prepared for Industry 4.0
- more innovative manufacturing environments
- continuous manufacturing
- data analytics
- Regulatory Science

Ireland – the Global BioPharmaChem Location of Choice A Strategy for the BioPharmaChem Manufacturing Sector in Ireland 2019-2023, BioPharmaChem Ireland.

Takeaway messages relevant to this assessment included

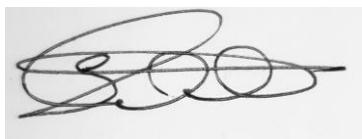
- the vision that Ireland will be the globally recognised centre of excellence for innovation and development in biopharmaceutical, pharmaceutical and chemical manufacture and supply; and the location of choice for the launch of new products.
- The imperative to continue to stay innovative;
- The importance of expanding and integrating the entire cluster
- Advanced Therapeutics are coming to the fore but manufacturing these in a cost effective and reliable way remains a challenge to be addressed.
- Alignment of academia with cluster industry needs
- Apprenticeships
- Make Ireland a global leader in ATMP (cell and gene) characterisation, manufacturing and supply
- Enhanced data analytics of manufacturing, supply chain and the patient
- Biopharma 4.0
- The Biopharmachem Skillnet encourages companies with shared training needs to collaborate and achieve their training goals in a cost effective manner

Note – the topics in green recurred as existing requirements during the subsequent interviews.

2 Interviews with companies

The interviews with companies identified the following skills needs for the future

- “Soft skills”
 - This was the most commonly referenced skills gap and appears to be important for all levels from operators to Senior Leadership in areas of communications, teamworking, problem solving, error management, and influencing skills.
- Benchmarking events to look at best practice in other industries.
 - A number of companies expressed specific interest in benchmarking events. This would either be in the form of benchmarking in sites in the pharmaceutical industry and/or in sites from different technologies. For example, the medical device industry is known to use human behavioural training such as picture formatting use in SOPs and this would be of significant interest to the pharmaceutical industry.
 - In addition, benchmarking for Training Managers was also mentioned on a number of occasions. It was stated that the Skillnet Committee was of significant benefit, but there was no training directed specifically at Training Managers. In particular, early morning, breakfast one hour meetings were suggested as a potential format.
- Best in class practices.
 - Alongside the benchmarking discussion, there was an interest in the development of white papers where SMEs would be identified within the pharmaceutical industry to act as “go-to” individuals or opinion leaders on a specific subject.
- The development of courses which were transferrable across companies or even across industries.
 - It was suggested that courses would be developed which would be accredited somehow, for example, knowledge management, engineering skills, fundamentals of GMP etc.
 - The format of the courses would allow for graduates of the courses to move across different industries such as medical device and electronics industries.
 - This could be in the form of apprenticeships or courses accredited from a third level institute such as a University
- Data analytics
 - Data analytics needs range from the basic and advanced use of Microsoft Excel, the use of Microsoft Note, to the more advanced use of statistics for collection and processing of automation outputs. In particular, with the evolving of areas such as continuous manufacture, the area was considered to be important
- Knowledge management.
 - This topic was raised to address single points of failure i.e. where knowledge was held by a single individual and the aging workforce in more established facilities. For the latter, the concern was expressed that “Tacit Knowledge” contained within the older workforce may be lost with upcoming retirements.
- Commercial activities were discussed with divisions of pharmaceutical organisations who do not have a manufacturing presence but who do have a Sales and Marketing presence. Areas of interest include
 - Commercial skills around understanding finance
 - Making business cases.
 - Communication
 - Selling skills, and the evolution of selling skills across different media
- Foundation Skills in the Pharmaceutical Industry
 - There are a number of basic skillsets within the industry which are ongoing needs which are struggling to be met due to competition within the Sector. Specifically Regulatory Science, Quality Assurance and Validation roles



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