



Life Science Industry

# User Guide for Companies

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# Registration guide for Companies

## Purpose of this guide

This document provides an outline for life science companies who have employees who regularly engage with the NHS, and who require guidance on the registration process to the Life Science Industry (LSI) Accredited Credentialing Register.

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## Who needs to be on the LSI credentialing register

Staff from the Life Science industry engage with NHS staff and patients on a daily basis. It is important that these interactions take place within a professional, ethical and safe framework.

The Life Science Industry in collaboration with the NHS and the Academy for Healthcare Science have joined forces to develop a high-quality, accredited credentialing register for Life Sciences staff who interact routinely and directly with NHS front-line staff and/ or patients, to ensure that industry personnel are appropriately trained to enter primary and secondary healthcare settings.

Any industry employee could be asked to provide evidence that they are on a register on entry to an NHS premises, or when moving between areas within the premises. Hence if you have an NHS-facing employee who regularly enters these settings, they may need to be on the register.

## Registration process in outline

The proposed credentialing register, and information about it, can be accessed from the LSI website <https://lifescienceindustry.co.uk/>. The register and website are managed by the Academy for Healthcare Science (AHCS).

Individuals on the LSI credentialing register will be acting as company representatives and therefore applications to the register will require company involvement during the registration process and, where applicable, in the complaints process, should a complaint ever arise.

## Pre-Steps

### Education & Training

Before any applications to the Register can be made, companies must provide the course titles of all internal and external training courses offered to their employees and send this to the LSI Administrator at [lsiaadmin@ahcs.ac.uk](mailto:lsiaadmin@ahcs.ac.uk). You can either provide this information on an Excel spreadsheet (taken from the Company's HR Department records), or on company letterhead.

**Without this information, employees will not be able to complete this Section of the application and therefore will not be accepted onto the Register.**

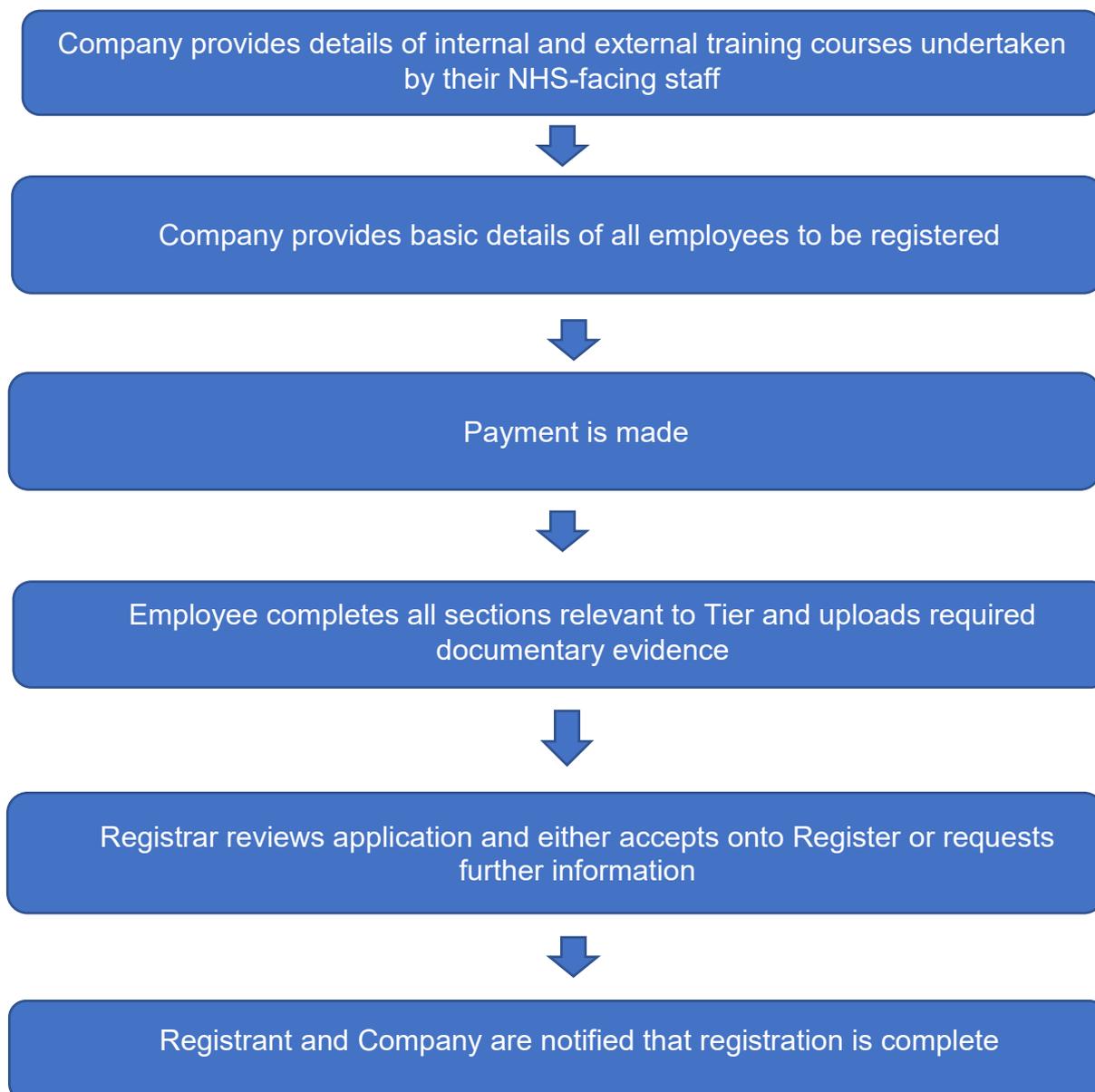
### Tiers

As a company, you will need to decide which Tier your employees will be registered at, as this determines which sections of the application form to complete. The Tier also determines the level of access given within a primary or secondary healthcare setting.

Our helpful Guidance – Tier Clarification document [link to doc] will explain the differences in the tiers and also contains useful examples of which job roles may apply to each tier.

Once you have provided training course details and understood the tier criteria, you are ready to begin.

The registration process can be summarised as follows:



## Registration process (in full)

Company provides details of internal and external training courses undertaken by their NHS-facing staff

All employees should have received training appropriate to their role, and a record of the dates of the training provided should be held on file by the company. Training may have been delivered in-house, face to face or online, or through an external training supplier. The only training that must be delivered face to face through an appropriate course is the additional training for high risk settings required for entry onto Tier 3 of the register.

Refresher courses should be offered as part of employees' Continued Personal and Professional Development (CPPD). As a company, you should also note the dates that these courses were completed. It is particularly important to give refresher training when guidance changes and, for example, to take account of product updates and new product introductions.

Companies will have provided training course information to the LSI Administrator as a pre-step to the Registration process.

Employer provides basic details of all employees to be registered

There are two ways a company can provide information to start the registration process:

### 1. Basic Data Sheet

Provide the following details, either on an Excel spreadsheet or Company letterhead, of all employees you wish to register:

- Title
- First Name
- Last Name
- Email Address
- Company Name
- Tier

**NB: If you prefer to submit an Excel spreadsheet, please request this from the LSI Administrator at [lsiadmin@ahcs.ac.uk](mailto:lsiadmin@ahcs.ac.uk)**

### 2. Full Data Sheet

There is a more comprehensive Excel spreadsheet that can be used by larger companies with HR departments, which hold extensive employee records, including all personal information and details of every training course, or refresher course, undertaken along with

dates of that training. The Full Data sheet can also be requested from the LSI Administrator at [lsiadmin@ahcs.ac.uk](mailto:lsiadmin@ahcs.ac.uk)

On receipt of the Basic or Full Data Sheet, the LSI Administrator will upload the information onto the system. Employees will receive a welcome email with instructions on how to log in to their own application and create a unique password. Employees will now need to complete each section, as shown in the following screens:

Search Account Sign Out

### Life Science Industry Credentialing Register Application

To join the LSI Credentialing Register you must complete the sections below. In each selection you can select SAVE to come back to the page at a later date. Once you are satisfied the section has been completed, select the COMPLETE SECTION. Once ALL sections have been completed and you are happy that the information in each section is correct, please press the 'submit application' button at the bottom of this page. Once you have submitted your application your data will be read-only, other than your personal details, unless you contact the Registrations Administrator via [registration@lifescienceindustry.co.uk](mailto:registration@lifescienceindustry.co.uk)

**0%**  
Complete

 Personal Details	 Monitoring Information
 Education and Training	 Payment
 Document Storage System	 Registrant Card
 Declarations	

Submit Application

Payment is made

On receipt of the basic data, or full data, the company will be invoiced @ £38 per employee. The fee breakdown is £30 registration and £8 barcoding badge.

Employee completes all sections relevant to Tier and uploads required documentary evidence

In all sections, the fields marked with a \* are mandatory.

Guidelines for each section have been segregated as follows:



## Personal Details

The Company will have provided some of these personal details, and the employee will be directed to check, and complete outstanding information.

Employees will have to upload a photo in accordance with the criteria set out in the [LSI Photo Guidance document](#) [link to doc] which has been made available to them. They will also be required to upload photo evidence, ie passport or driving licence.



## Education and Training

The Education and Training section is split into Tiers 1, 2 and 3. Employees will need to complete all sections relevant to the Tier which has been determined by the Company.

For example, if the Company requires an employee to attain Tier 2, then Tier 1 and Tier 2 sections will both need to be completed; likewise, if the Company requires an employee to attain Tier level 3, then Tier 1, Tier 2 and Tier 3 sections will all need to be completed.

For further guidance on tiers please read the [Guidance – Tier Clarification](#) document [link to doc].

A Company should keep records of all training courses undertaken by employees, whether in-house or external, in the following areas:

- Product training
- NHS Values and Behaviours
- Codes of Business Practice – company, trade association and NHS
- Health and Safety including infection prevention and control
- Information Governance
- Competition and Procurement

Training course details will have previously been provided in the pre-steps to registration. Employees will now complete the sections, shown below:

## Education and Training:

[Back](#) [Menu](#) [Next](#)

Life Science Industry Credentialed Register application

You can find further information on which tier is appropriate for your education and training [here](#). You will need to complete all tier 1 education and training fields below to be eligible for tier 2. You will need to complete all tier 1 and 2 education and training fields below to be eligible for tier 3.

### Tier 1

Here are the requirements for Tier 1. Please fill them in.

#### Product Training appropriate to role:

To understand and apply appropriate knowledge of your area/product its function and application.

How it is delivered:

Name of Training / Course Attended:

Please save before you can add extra courses.

Have you completed this training?  Yes  No  In Progress  N/A

Training Date:

Have you completed recent refresher training?  Yes  No  In Progress  N/A

Refresher Date:

#### NHS Values & Behaviours:

To understand and comply with NHS values and behaviours including the NHS constitution - the NHS 7 key principles, values, rights and responsibilities.

How it is delivered:

Name of Training / Course Attended:

Have you completed this training?  Yes  No  In Progress  N/A

Training Date:

Have you completed recent refresher training?  Yes  No  In Progress  N/A

Refresher Date:



### Document Storage System

This section has been provided to give your employee an easily accessible storage facility for all documents relevant to their continuing personal and professional development.

The mandatory component of this section is that for Tiers 2 and 3 the employee must upload a current DBS Certificate. If neither the Company or employee has a current DBS certificate, this can be obtained from the government's website:

<https://www.gov.uk/request-copy-criminal-record>



### Declarations

If the Company has registered employees as part of a group, in this section the employee will be asked to confirm that the information provided by the company is correct. The employee will have to make a declaration concerning their good character, any previous registrations (including any sanctions applied by another register), their fitness to practise and their compliance with the expected standards of this Register.



## Monitoring Information

This section of the application form will not be used as part of the assessment process. The information collected is only used for monitoring purposes in an anonymised format to assist the organisation in analysing the profile and make up of individuals who apply. With the exception of “Date of Birth”, which requires information entering, all other questions are mandatory, even if selecting the option “I do not wish to disclose”.

Further details of what is required in this section is provided in Appendix 1, below.

Registrar reviews application and either accepts onto Register or requests further information

Once all sections have been completed, the employee selects “Submit Application” from the main menu, as below:

### Life Science Industry Credentialing Register Application

To join the LSI Credentialing Register you must complete the sections below. In each selection you can select SAVE to come back to the page at a later date. Once you are satisfied the section has been completed, select the COMPLETE SECTION. Once ALL sections have been completed and you are happy that the information in each section is correct, please press the 'submit application' button at the bottom of this page. Once you have submitted your application your data will be read-only, other than your personal details, unless you contact the Registrations Administrator via [registration@lifescienceindustry.co.uk](mailto:registration@lifescienceindustry.co.uk)

**0%**  
Complete



Personal Details



Monitoring Information



Education and Training



Payment



Document Storage System



Registrant Card



Declarations

Submit Application

The Registrar will review the application, and either confirm entry onto the Register, or request that further information is submitted, if for instance certain parts of the application form have not been fully completed or the required documents have not been uploaded.

The Company will receive regular updates on the progress of all applications.

### **Procedure if employees leave your company**

Individuals on the LSI credentialing register act as company representatives and therefore it is essential that employer details are kept up to date. As a Company, you are responsible for notifying the Registrar when employees leave the employment. Registration will be deactivated until such time as the leaving employee takes up a post with a new employer.

The Company will also be contacted if a complaint is received against a Registrant.

### **Annual re-registration**

There are standards of Continuing Professional and Personal Development (CPPD) that an employee must meet to remain fit to practise and stay registered.

If a registrant, who is an employee of yours is selected for audit by the AHCS, they will need to submit a written record of their CPPD activities (see Appendix 2 below) and any supporting evidence which outlines how they have met the Standards of Proficiency CPPD standards.

## Standards of Proficiency

The Standards of proficiency underpin the training required to be registered

### **Standard 1 - Adhere to industry ethical and professional standards**

- 1.1 Understand and comply with the LSI registrants Standards of Conduct
- 1.2 Understand and comply with the Codes of Business Practice relevant to your sector and function relevant to your employment

**Standards of Conduct** set out the minimum requirements expected of an employee in their everyday professional life. An employee, is personally responsible for the way they behave.

The Standards of Conduct are laid out in the [LSI Credentialing Standards](#) [link to doc] and are closely related to the standards of proficiency. They cover the following areas:

- Adhere to industry ethical and professional standards
- Maintain up to date knowledge to undertake their role
- Work within their area(s) of competence and remit
- Understand, respect and comply with the values and behaviours of the NHS
- Protect the safety, health and wellbeing of self, staff, patients, carers and others
- Comply with the legal, ethical and policy requirements relevant to the healthcare sector appropriate to the role being undertaken
- Communicate appropriately and effectively

**Code of Business Practice.** The Company should ensure that all employees receive appropriate training to aid their understanding of the company code of business practice (if appropriate). Employees who work in a customer-facing role should also be aware of, and fully compliant with, the current Code of Practice for your industry sector (eg the ABPI, ABHI or BIVDA codes of practice).

The NHS also has policies relating to standards of business conduct for NHS England employees and for CCGs. These contain guidance on a number of areas including gifts and hospitality, sponsored events and management of conflicts of interest. The company should make employees aware of these through appropriate training they have provided.

### **How do employees demonstrate that they have met this standard?**

**Standards of Conduct.** Companies should keep records of when employees completed this training.

**Code of Practice.** Companies should have trained employees on the code of practice for their industry sector during induction into their role. Employees should receive regular update training when the code changes, or at regular intervals.

Employees should also have received training on the company code of business practice and NHS policies during their induction training and regular refresher training. The Company should keep records of when employees completed this training.

**Standard 2 - Understand the knowledge base relevant to your role, and be appropriately qualified and up to date to undertake your role.**

- 2.1 Know and understand your specialty area/product, its use/application, and where appropriate can impart knowledge of this use/application.
- 2.2 Know and understand infection control risks and processes appropriate to your role.
- The following Standard of Proficiency relate to Tiers 2 & 3*
- 2.3 *Know and understand the risks and processes relevant to your role, including information governance and patient safety.*
- The following Standard of Proficiency relates to Tier 3*
- 2.4 *Know and understand risks, roles and responsibilities, etiquette, protocols and processes for high risk settings, e.g. theatre, cardiac labs, critical care and paediatric wards.*

**Standard 3 - Work within the area(s) of competence and legal and ethical boundaries of your remit**

- 3.1 Know and work within your professional remit as an employee of a life sciences company working within your agreed scope of practice for lawful, safe and effective practice.
- 3.2 Know and work within the limits of your personal competence and only enter discussions or undertake tasks and roles for which you are competent, even if asked to do otherwise.
- 3.3 Know the limits of your role and when to refer to another professional.

Within an employees' role/area of responsibility, they need to be able to understand and apply appropriate knowledge regarding any products the Company promotes or supports, their functions and their application.

Where appropriate, an employee needs to be an effective communicator/trainer of the functions and safe use of the product.

An employee should have the knowledge to carry out their role safely and effectively and know when to seek help.

**How does an employee demonstrate that they have met these standards?**

Companies should offer high quality initial and regular refresher training. Records should be kept of training in these areas.

#### **Standard 4 - Understand, respect and comply with the values and behaviours of the NHS**

- 4.1 Understand the key principles, values and behaviours of working with the NHS.
- 4.2 Understand patient confidentiality and do not disclose information without relevant consent, except where such disclosure is required by law.
- 4.3 Understand the need to respect and uphold the rights, dignity and confidentiality of patients and professionals.
- 4.4 Understand and respect the impact of culture, equality and diversity when interacting with others

The NHS is founded on a common set of principles and values that bind together the communities and people it serves – patients and public – and the staff who work for it. These are underpinned by core NHS values, which have been derived from extensive discussions with staff, patients and the public. NHS values are set out in the NHS Constitution.

Companies should ensure that their employees are aware of the Standards of Business Conduct Policy applicable to NHS England staff and of the standards set out in the related Clinical Commissioning Groups Statutory Guidance on Conflicts of Interest.

#### **How do employees demonstrate that they have met this standard?**

Companies should offer training during induction and when changes occur, or at regular intervals. The Company should keep records of all training completed.

#### **Standard 5 - Protect the safety, health and wellbeing of self, staff, patients, carers and others**

- 5.1 Understand the relevant policies and processes to protect safety, health and wellbeing, for example infection prevention & control.
- 5.2 Understand the importance of maintaining your own health (including relevant immunisations).
- 5.3 Understand the need to maintain a safe working environment.

An understanding of relevant local and national policies and processes to protect safety, health and wellbeing, including infection control risks and complying with the principles of good hand hygiene, is required.

As required by regulatory agencies, all pharmaceutical company employees have a responsibility to understand and comply with the procedures for reporting adverse events to the appropriate authorities. Companies should ensure employees are aware of the processes for reporting safety information, so that they know what to do if they become aware of an adverse event or adverse drug reaction.

In addition to national policies, Companies should ensure their employees are aware of the local policies of the hospitals that they visit, to ensure that they also comply with their requirements. Local policies may include restrictions on entering the premises if employees are suffering from, or may be incubating, any infectious disease, are suffering from mild infections such as colds or flu or have recently experienced symptoms of diarrhoea and vomiting.

Whilst no immunisations are required for registration on the LSI Credentialing Register at Tiers 1 and 2, employees should be aware of, and should comply with, national and local NHS requirements. Immunisation has a role in protecting the employee and their family as well as protecting patients and the NHS staff caring from them. Local policies may include an expectation that employees are up to date with their routine immunisations (eg tetanus, diphtheria, polio and MMR). If employees need to be registered for Tier 3, they may also be required to have Hepatitis B vaccination.

For entry onto Tier 2 or Tier 3, aspects of Standard 2 are also relevant to this Standard.

To register for Tier 3 employees are required to have gained a thorough understanding of the additional risks of working in areas where especially vulnerable patients may be encountered.

### **How do employees demonstrate that they have met this standard?**

Companies should ensure that employees have knowledge of appropriate policies, imparted through training. Training records should be kept.

A DBS check is not normally required for registration on Tier 1 as employees will not be in contact with vulnerable adults or young people. However, a standard DBS check is required for entry onto Tiers 2 and 3 of the LSI Credentialing Register.

Tier 3 registrants are expected to have completed a Theatre Access training course.

## **6. Compliance with legal requirements relevant to the healthcare sector**

- 6.1 Know the legal requirements that apply specifically to your professional activities, such as the Bribery act, Competition Law and Procurement Regulations
- 6.2 Understand Data Protection legislation and Caldecott Principles relevant to your role

To safeguard the patient, healthcare professional and the industry employee, knowledge of the following legal aspects is required for registration:

- Bribery Act 2010
- Competition Law
- Data Protection Act 1998 and, from May 2018, General Data Protection Regulation (GDPR) legislation
- Caldicott Principles
- Other legal aspects where appropriate, for example procurement regulations

### **How do employees demonstrate that they have met this standard?**

Companies should deliver training covering these legal requirements and records must be kept.

## **7. Can communicate effectively**

7.1 Understand and apply appropriate and effective written and verbal communication skills.

Companies should ensure that employees are given appropriate training to enable them to communicate with healthcare professionals and, where relevant, patients and members of the public.

The Company industry sector code of practice may cover appropriate communication with these groups. Employees are required to know, understand and adhere to your company, industry and trade association codes of business practice.

### **How do employees demonstrate that they have met this standard?**

Companies will need to provide training, and keep records, of all training employees have undertaken on appropriate communication with healthcare professionals, patients and the public.

## Appendix 2

### **Standards of CPPD required for re-registration of employees**

These set out the CPPD required for annual re-registration:

1. Undertake CPPD activities relevant to role and organisation

CPPD activities could include in-service training and development, appraisal, mentoring, or reading.

2. Undertake company mandatory training as required

This could include company values, and industry and company codes of practice/conduct and relevant legislation.

3. Participate in appraisal

Employees must actively participate in their own appraisal/review as prescribed by the company.

4. Refresh knowledge of the register's Standards of Conduct

This includes Anti-bribery and Corruption policies, NHS values and behaviours, Health and Safety and relevant immunisations.

5. Carry out product knowledge training when required

Employees must carry out training for any new developments in agreement with the company.

6. Employees must maintain a written record of CPPD activities