



Life Science Industry

# User Guide for Individuals

Submitted for Registration by a Company

30 May 2018

Version 1.1

Review date: 30 May 2021

Doc ref: #LSI013

# Registration guide for individual registrants who are submitted for Registration by a Company

## Purpose of this guide

This document provides an outline for employees of life science companies who regularly engage with the NHS, on the procedure for registration on the Life Science Industry (LSI) Credentialing Register which has been accredited by the Professional Standards Authority.

<b>Contents</b>	<b>Page</b>
Who needs to be on the LSI credentialing register	2
Registration process in outline	2
Registration process	3
Procedure if you leave your company	7
Annual re-registration	8
Appendix 1	9
How a company demonstrates that employees have met the Standards for registration	
Appendix 2	14
Standards of CPPD required for re-registration	

## 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 an accredited register on entry to an NHS premises, or when moving between areas within the premises. Hence if you are an NHS-facing employee who regularly enters these settings you 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 application to the register will require involvement of your employer during the registration process and, where applicable, in the complaints process.

You can register through the above site, or your employer can provide details of a group of registrants direct to the LSI Administrator at [lsadmin@ahcs.ac.uk](mailto:lsadmin@ahcs.ac.uk)

In either instance, the first step is for the employer to provide information on the training courses that their NHS-facing staff undertake, either internally or externally.

The process can be summarised as follows:



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



Registrant and employer are notified that registration is complete

### Registration process (in full)

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

You should have received training appropriate to your role, and a record of the dates of the training provided should be held on file by you and/or your employer. Training may have been delivered by the employer, 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.

Your employer must have provided details of the training course employees have undertaken before you can register.

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

Employer provides basic details of all employees to be registered

Your employer will be asked to provide title, name and email information of employees to be registered, which will be uploaded onto the system by the LSI Administrator. Individuals will then receive a welcome email with instructions on how to log in to your application and create a unique password. You will now need to complete each section, as shown in the following screens:

## 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](#)

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

In all sections, the fields marked with a \* are mandatory. Please ensure that you finish each section by selecting "Save and Complete Section". If at any stage you need to source information, documentation or photos, please select "Save Personal Details for Later" and re-visit the section at a later date.

Guidelines for each section have been segregated as follows:

 Personal Details
--

Some of these details may have been supplied by your employer; please check them and make any necessary amendments.

You will need to upload a recent photo which is:

- not older than 2 years old
- of yourself, and not with other people and objects
- a shoulder and head shot with you looking forward
- a photo which takes up 80% of the screen
- free of any obstructions (ie. hats, scarves, masks)

Confirmation of ID – you will need to upload a copy of your passport or driving licence.

For further guidance please read the [LSI Photo Guidance document](#) [link to doc]



The Education and Training section is split into Tiers 1, 2 and 3 and you will need to complete all sections relevant to your Tier.

For example, if you are at Tier level 2 you will need to complete both Tier 1 and 2 sections; likewise, if you are at Tier 3 your will need to complete all Tier 1, Tier 2 and Tier 3 sections.

You can find out more information about Tiers by reading the [Guidance – Tier Clarification](#) document [link to doc]

Your employer should have on record the details of the course you have completed, whether external or internal and you will need to enter the course titles and the dates you completed courses 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

If you have any queries, please refer to your employer or email [lsiaadmin@ahcs.ac.uk](mailto:lsiaadmin@ahcs.ac.uk) for help.

If you need to add more than one course in any section, click on the “Save” button at the end of each entry and this will save the current course details and allow you to add a new one:

### Education and Training:

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

Life Science Industry Credentialing 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:

Once all the Education and Training fields have been populated ensure you click the “Complete Section” at the bottom of the page.

### Document Storage System

This section will help you save time by giving you a storage facility for all documents relevant to your continuing personal and professional development.

The mandatory component of this section is that for Tiers 2 and 3 you must upload a current DBS Certificate. If neither you or your employer have a DBS certificate, this can be obtained from the government’s website:

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

### Declarations

If your employer has registered you as part of a group, you will be asked to confirm that the information provided by your company is correct. You will have to make a declaration concerning your good character, any previous registrations (including any sanctions applied by another register), your fitness to practise and your compliance with the expected standards. Please read, then click the “Accept Declarations” and then “Save and Complete Section

### 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 you are selecting the option “I do not wish to disclose”.

Please ensure you “Save for Later” or, if complete, select “Save and Complete Section”

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

**Payment is made**

Your employer has registered you as a group of employees and the Company will pay directly by invoice.

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

Once you have completed all sections and selected “Save and Complete Section” in each, you will now be able to click the “Submit Application” from the main menu:

### 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 your application, and either confirm your entry onto the Register, or request that you submit further information, if for instance parts of the application form have not been fully completed or the required documents have not been uploaded.

Your employer will receive regular updates on the progress of applications.

### Procedure if you 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. Your employer is responsible for notifying the Registrar if you leave employment, at which time your registration will be deactivated. Should you take up a post with a new employer, and complete any additional training, your registration can be re-activated.

The employer will also be contacted if a complaint is received against you.

## **Annual re-registration**

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

If you, as a registrant, are selected for audit by the AHCS, you will need to submit a written record of your CPPD activities (see Appendix 2 below) and any supporting evidence which will outline how you have met the Standards of Proficiency CPPD standards.

## Appendix 1

### 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 you in your everyday professional life. As a registrant, you are personally responsible for the way you behave.

The Standards of Conduct are laid out in the LSI Credentialing Standards document 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 your role
- Work within your 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.** You should receive appropriate training to aid your understanding of the company code of business practice (if appropriate). If you are working 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. You should also be made aware of these through appropriate training provided by your company.

#### **How do I demonstrate that I have met this standard?**

**Standards of Conduct.** You should keep records of when you completed this training.

**Code of Practice.** You should have been trained on the code of practice for your industry sector during induction for your role. You should receive regular update training when the code changes, or at regular intervals.

You should also have received training on the company code of business practice and NHS policies during your induction training and regular refresher training. You should keep records of when you 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 your role/area of responsibility, you need to be able to understand and apply appropriate knowledge regarding any products you promote or support, their functions and their application.

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

You should have the knowledge to carry out your role safely and effectively and know when to seek help.

**How do I demonstrate that I have met these standards?**

You should be offered high quality initial and regular refresher training. Records should be kept of your 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.

You should also be 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 I demonstrate that I have met this standard?**

Training should be provided by your company during induction and when changes occur, or at regular intervals. Records of training completed must be kept.

#### **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. You should be aware of the processes for reporting safety information, so that you know what to do if you become aware of an adverse event or adverse drug reaction.

In addition to national policies, you must ensure that you are aware of the local policies of the hospitals that you visit to ensure that you also comply with their requirements. Local policies may include restrictions on entering the premises if you 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 Credentiaing Register at

Tiers 1 and 2, you should be aware of, and should comply with, national and local NHS requirements. Immunisation has a role in protecting you and your family as well as protecting patients and the NHS staff caring from them. Local policies may include an expectation that you are up to date with your routine immunisations (eg tetanus, diphtheria, polio and MMR). If you need to be registered for Tier 3 you may 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 you 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 I demonstrate that I have met this standard?**

Knowledge of appropriate policies needs to be imparted through training. Training records should be kept.

A DBS check is not normally required for registration on Tier 1 as you 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 I demonstrate that I have met this standard?**

Training should be delivered 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.

You should be given appropriate training to enable to you to communicate with healthcare professionals and, where relevant, patients and members of the public.

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

### **How do I demonstrate that I have met this standard?**

Training will need to be provided, and records kept, of all training you have undertaken on appropriate communication with healthcare professionals, patients and the public.

## Appendix 2

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

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

1. Undertake CPPD activities relevant to your 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 your company values, and industry and company codes of practice/conduct and relevant legislation.

3. Participate in appraisal

You must actively participate in your own appraisal/review as prescribed by your company.

4. Refresh your 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

You must carry out training for any new developments in agreement with your employer.

6. Maintain a written record of your CPPD activities