



Life Science Industry National Credentialing Register

Registration User Guide

6 December 2021

Version 1.4

Review date: 6 December 2022

Doc ref: #LSI013

This document is one of a suite of policies and procedures which are part of the Academy for Healthcare Science



Registration Guide for Individual Registrants and Companies

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) National Credentialing Register which has been accredited by the Professional Standards Authority.

Contents	Page
Who needs to be on the LSI credentialing register	3
Registration process in outline	3
What does it mean for existing LSI registrants?	3
New Register applications – the process	4
Tier levels	4
Education & Training – what is required?	4
Documentation required	7
Appendix 1	9
How a company demonstrates that employees have met the Standards for registration – Standards of Proficiency	
Appendix 2	11
Standards of CPPD required for re-registration	

Who needs to be on the LSI National 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 need to be on the register. This applies to all UK-based employees as well as those based outside the UK who need to make visits to NHS premises in the UK.

Registration process in outline

The governance and administration of the LSI National Credentialing Register is undertaken by the Academy for Healthcare Science.

MIA facilitate a gateway to the register for their members.

The LSI National Credentialing Register, and information about it, can be accessed from <https://www.ahcs.ac.uk/our-registers/life-science-industry/>

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, or your, employer can start the registration process by contacting the Medical Industry administration team on 01732 920900 or miahelp@medicalindustry.co.uk

NEW ENQUIRIES/APPLICATIONS

Contact the MIA administration team on 01732 920900 or miahelp@medicalindustry.co.uk

Or,

Register for an account here <https://www.medicalindustry.co.uk/>

What information will you need to provide?

1. Personal Details

Some of these details can be supplied by your employer. Alternatively, you will need to provide:

- Full Name (including middle names)
- Email
- Date of Birth
- Job Title
- Company
- Photo

The photo you upload will need to be:

- 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 (i.e. hats, scarves, masks)

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

2. Tiers

What Tier level do I need to Register at?

The Education and Training section is split into Tiers 1, 2 and 3 and the employer will need to decide which Tier an employee is registered at. The agreed Tier level determines the training that will need to have been completed.

An explanation of the Tiers, can be found below:

Information about tiers

	PSA Accredited	PSA Accredited	PSA Accredited
Tier X	Tier 1	Tier 2	Tier 3
Temporary Tier level for MIA Registrants to reach Register Standards <ul style="list-style-type: none"> • No additional training required • Temporary status lasting for no more than 12 months 	Interaction with Healthcare Professionals but no contact with patients or relatives other than incidentally in areas open to the general public <ul style="list-style-type: none"> • Product (it is up to company training managers – or equivalents – to deem what is appropriate product training) • Information Governance • Competition and Procurement • NHS Values and Behaviours • Code of Business Practice 	Interaction with Healthcare Professionals and with patients or relatives in areas where no invasive procedures are taking place. <ul style="list-style-type: none"> • Tier 1 training <p style="text-align: center;">+</p> <ul style="list-style-type: none"> • Self, public and patient safety (<i>enhanced</i>) 	Interaction with Healthcare Professionals and with patients or relatives in areas where invasive procedures are taking place <ul style="list-style-type: none"> • Tier 1 & 2 training <p style="text-align: center;">+</p> <ul style="list-style-type: none"> • Training for high-risk settings

3. Education & Training

What training should be completed?

The Tier level will determine the training needed to have been completed.

An employer can provide MIA with details of the training courses its employees have completed, or individuals may complete this information themselves. In the case of product training, a 'letter of competency' from the company is sufficient. Letters of competency should be uploaded by the employee.

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.

Tier 3 employees are expected to have comprehensive and detailed knowledge in relation to their attendance in specialist areas such as the operating theatre. Ideally this would be via training delivered face-to-face or through other teaching methods such as video seminars, interactive on-line teaching etc. This comprehensive training may be supplemented by periodic online 'refresher' courses, but full training should be repeated on a regular basis (every 5 years is recommended).

Tier 3 personnel who are new to the role should always receive comprehensive and detailed training before attendance in applicable treatment settings; those who are new company starters, but who are already experienced, should receive periodic refresher training and full training should be repeated on a regular basis (every 5 years) to ensure compliance with any changes in best practice.

Refresher courses should be offered as part of an employees Continued Personal and Professional Development (CPPD). It is particularly important that employees receive refresher training when guidance changes and, for example, to take account of product updates and new product introductions.

Employers should have on record the details and dates of courses employees have completed, whether external or internal.

Training course titles and dates the training was completed will be required in the following areas:

TIER 1	
Training	How this training may be offered
<p>Product Training: Understand and apply appropriate knowledge of your area/product, its function and application.</p> <p>Have the knowledge to carry out your role safely and effectively and when to seek help.</p>	<p>Training specific to role</p> <p>Trade Association Code/exam (if offering a service, i.e. manager, IT staff)</p>
<p>NHS Values and Behaviours: To understand and comply with NHS values and Behaviours, including the NHS constitution - the NHS 7 key principles, values, rights and responsibilities.</p>	<p>Latest published version of the NHS Values & Behaviours</p> <p>External training provider</p> <p>In-house, by PowerPoint or online</p>
<p>Code of Business Practice: Know and understand your company / industry / trade association code of business practice and the standards of conduct of the Register</p>	<p>Code of Business Practice</p> <p>Code of Business Ethics</p> <p>Code of Practice</p> <p>Induction procedures</p> <p>Trade Association Code/Exam</p>
<p>Information Governance: Understand and comply with:</p> <ol style="list-style-type: none"> 1. Data Protection Act 1998 2. Caldecott principles relevant to your role. 	<p>GDPR principles</p> <p>Caldecott principles</p> <p>Trade Association Code/Exam</p>
<p>Competition and Procurement: To understand and comply with</p> <ol style="list-style-type: none"> 1. The Bribery Act 2010 2. Competition Law 3. Public Contracts Regulation. 	<p>Anti-bribery policies</p> <p>Code of Business Practice</p> <p>Trade Association Code/Exam</p>

TIER 2 - Self, Public and Patient Safety	
Training	How this training may be offered
<p>Environmental Health & Safety Understand relevant policies and processes to protect safety, health and wellbeing, for example infection prevention & control</p>	<p>Theatre Access course – face to face or online through an external training provider</p> <p>In-house training</p>

TIER 2 - Self, Public and Patient Safety	
Training	How this training may be offered
Infection Prevention & Control Understand the importance of maintaining your own health (including relevant immunisations)	Theatre Access course – face to face or online through an external training provider In-house training
Adverse Event Management Understand the need to maintain a safe working environment	Theatre Access course – face to face or online through an external training provider In-house training
Immunisations Understand the importance of maintaining your own health (including relevant immunisations)	Refer to the 'Recommended Immunisations' table in the Tier Clarification document

TIER 3 - Self, Public and Patient Safety	
Training	How this training may be offered
Theatre Access Training 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	Theatre Access course – face to face or online through an external training provider
Handwashing Training Know and understand infection control risks and processes appropriate to your role	Handwashing training (not Scrubbing) – face to face or online through an external training provider In house
Training for High Risk Settings 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	Theatre Access course – face to face or online through an external training provider

4. What documents will I need to provide?

It is mandatory at Tier 2 and 3 registration to provide a Basic DBS Certificate dated within the last 3 years

The arrangements for visits and appointments are made between MIA and individual NHS Trusts, some of which may specify a higher-level DBS check is required to access some or all of a Trust's facilities. These checks are acceptable for registration and specific Trust requirements are available on the MIA website

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>

If you have recently moved to the UK or are ordinarily resident or have spent a long time living outside the UK, you or your employer should also obtain a criminal record check from where you have been living. This process will differ depending on the country concerned, but you can find out how to get these checks through the following link <https://www.gov.uk/government/publications/criminal-records-checks-for-overseas-applicants>.

5. What other sections will I need to complete?

Declaration

Applicants will be asked to confirm that the information provided by the company, or by individuals, is correct. A declaration concerning an applicant's good character, any previous registrations (including any sanctions applied by another register), fitness to practise and compliance with the expected standards has to be made.

Monitoring Information

This section of the application form is not 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.

6. What is the cost of registration?

For current MIA members, the annual fee is £95 + vat (plus £20 non-vatable LSI National Credentialing Register fee).

7. Annual re-registration

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

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

Appendix 1

Standards of Proficiency

To be registered you must demonstrate that you:

1. Adhere to industry ethical and professional standards

- 1.1. Understand and comply with the LSI registrant's Standards of Conduct.
- 1.2. Understand and comply with the codes of business practice relevant to your sector and function relevant to your employment.

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

An appendix attached to this Standards Consultation document provides a brief description of each Tier

All Registrants

- 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.

Tier 2 & 3 These are terms used to relate to high risk areas.

- 2.3. Know and understand the risks and processes relevant to your role, including information governance and patient safety.

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.

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.

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.

5. Protect the safety, health and wellbeing of self, staff, patients, carers and others

- 5.1. Understand 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.

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.

7. Can communicate effectively

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

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 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