



Life Science Industry Credentialing Register

Standards expected of a Registrant on the Life Science Industry Credentialing Register

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National Credentialing Register for Life Science Industry

INTRODUCTION

Staff from the Life Science industry engage with NHS staff and patients, daily, in the capacity of representatives of those Life Science industries who trade and provide services to the NHS National Health Service. It is important that these interactions take place within a professional, ethical and safe framework.

Trusts are looking to confirm the identity, credentials and training status of individuals that visit their sites. The responsibility for this lies with each individual Trust and they have sought a variety of means to address this challenge. This variety has led to variable practices in the standards and processes used within the NHS to check status of industry staff on site.

PROPOSAL

It is proposed that an accredited credentialing register for Life Sciences sector staff who interact routinely and directly with NHS front-line staff, and/or patients, is established. This provides an opportunity, through the process of credentialing, of establishing the qualifications of employees from organisations within the Life Science Industry.

The register will:

- establish, minimum acceptable standards for registrants and training provision;
- set out the required standards of conduct, education, training and health & safety criteria;
- check that registrants and education providers meet these standards;
- provide a single point for NHS staff, any employer, or members of the public to verify an individual's status and eligibility to engage with the NHS;
- support NHS Trusts regarding credentialing;
- support the establishment of standards necessary for regulation (see above) without restricting access to the NHS.

To demonstrate the highest standards of governance, it is intended that the register will be accredited by the Professional Standards Authority (PSA).

It is important to note that the individuals on the register are also acting as company representatives, not just as individual professionals. This will therefore require a degree of integration and involvement of employers in the registration process and any complaints process.

Credentialing Register Standards

The Life Science Industries register allows NHS staff to interact with an individual confidently, knowing that that individual meets the professional standards required by the NHS.

To be registered and to remain on the register a registrant must be able to demonstrate that they are 'fit to practise'. By fitness to practise, we mean that someone has the skills, knowledge, character and capacity to carry out their role safely and effectively, both on their first day of registration and throughout their career interacting with the NHS and where appropriate the wider healthcare system. To demonstrate fitness to practise, registrants must meet certain standards. These include:

Standards of Proficiency - the basic education and training outcomes that someone must achieve before they can be registered with us;

Standards of Conduct - the minimum standards registrants must meet in their professional lives;

Standards of Continuing Personal and Professional Development - how you ensure your knowledge, skills and behaviours to carry out your role, are up to date.

These Standards were developed in partnership with the NHS, Industry Associations and regulation experts to create a coherent system for regulation. The Standards are written in a way that enables them to be appropriate for the many occupations and roles across the Life Science Industry and they should be read in the context of the role and scope of practice.

The Standards were produced by identifying:

- the potential risks posed by registrants to customers, NHS staff, patients and the public;
- the professional standards as required by the NHS;
- the key learning outcomes and the body of knowledge necessary for safe and effective practice by those newly registered;
- the minimum standards required to remain fit to practise.

About the Standards of Proficiency

Standards of Proficiency set out the minimum standards that you must meet at the time you first register with us. They are the standards that you must demonstrate through your education and training. These standards set out expectations and are used to quality assure education programmes, ensuring that someone who successfully completes a training programme can meet these standards.

The proposed 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.

About the Standards of Conduct

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, including those times you are not at work. The following Standards of Conduct give you, your employer, customers, NHS staff, patients and the public confidence and reassurance that you are providing a safe and professional service. These Standards are based upon the principle that your conduct, values and behaviours ensure that you treat patients, colleagues, healthcare professionals, and the public with respect, dignity and compassion at all times.

The proposed Standards of Conduct

To be registered you must:

1. Adhere to industry ethical and professional standards
 - 1.1. Comply with the codes of business practice/conduct relevant to your sector and function relevant to your employment.
2. Maintain up to date knowledge to undertake your role
 - 2.1. Ensure your knowledge, understanding, skills and abilities for your role are fully up to date.
3. Work within your area(s) of competence and remit
 - 3.1. Work within your remit for lawful, safe and effective practice.
 - 3.2. Work within the limits of your personal knowledge and competence.
4. Understand, respect and comply with the values and behaviours of the NHS
 - 4.1. Maintain patient confidentiality and do not disclose information without relevant consent, except where such disclosure is required by law.
 - 4.2. Never discriminate against an individual.
 - 4.3. Work in a collaborative and respectful manner with healthcare professionals and patients.
 - 4.4. Be open, honest and act with integrity at all times.
 - 4.5. Protect patients from risk or harm presented by another person's conduct, performance or health; following whistleblowing processes where these are available.
 - 4.6. Uphold the duty of candour you owe to customers, NHS staff, patients and the public and act accordingly.

- 4.7. Treat everyone as an individual, respect their dignity, confidentiality, rights and values.
- 4.8. Maintain professional relationships with customers, NHS staff, patients and the public.
- 5. **Protect the safety, health and wellbeing of self, staff, patients, carers and others**
 - 5.1. Identify and employ safe working practices and ensure compliance with legislation and NHS policies such as infection control and health and safety.
 - 5.2. Ensure your own personal health and safety and make appropriate changes to how you practise if your physical or mental health may affect your performance (including relevant immunisations).
- 6. **Comply with the legal, ethical and policy requirements relevant to the healthcare sector appropriate to the role being undertaken**
 - 6.1. Adhere to the Bribery Act/Conflict of Interest rules, Competition law, Procurement regulations and any related local requirements.
 - 6.2. Comply with Data protection legislation and Caldecott Principles.
- 7. **Communicate appropriately and effectively**
 - 7.1 Apply effective and appropriate skills in communicating information, advice and instruction. Listen to customers, NHS staff, patients and the public and communicate in a way they can understand.
 - 7.2 Communicate the Standards that you work within, such as the Standards of Conduct, clarifying your role and boundaries of that role.
 - 7.3 Where appropriate, keep accurate comprehensive records in accordance with legislation, protocols and guidelines.

About the Standards of Continuing Professional and Personal Development (CPPD)

Standards of Continuing Professional and Personal Development (CPPD) set out the minimum standards that you must meet to remain fit to practise and stay registered with us. The scheme is flexible, enabling you to maintain and develop your knowledge and skills by embedding and building upon your company's current structures for training and appraisal.

The proposed Standards of CPPD:

As a registrant, you must ensure that you continue to maintain and develop your knowledge to demonstrate your continued fitness to practise. You must:

- 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**
If you are audited by us, as part of our systems to check you remain fit to practise and so be registered, you will need to submit this record and any supporting evidence which will outline how you have met the Standards of proficiency and CPPD standards.

Future development of these standards

Registration and regulation are not static entities; they develop as professional practice, technology and our understanding of human health changes and as professions mature. They develop as new risks of practice are identified that require standards to mitigate those risks.

We will work with the AHCS Regulation Board, relevant stakeholders, including registrants, to ensure that these standards are, and continue to be fit for purpose.

Appendix - Tier Description

Tier 1 No contact with patients or relatives.

Tier 2 Possible contact with patients or relatives in areas where no invasive procedures are taking place.

Tier 3 Possible contact with patients or relatives in areas where invasive procedures are taking place.