



Life Science Industry Credentialing Register

# Quality Assurance Framework

**20 March 2017**

Version 2.0

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## Introduction

### Patients Public and Registrants

There are many ways in which Patients and the Public can be protected from harm, this can be in direct care situations and from a general health and safety perspective.

NHS Trusts need to be able to confirm the identity, credentials and training status of individuals who visit their sites. The responsibility for this lies with each Trust and they have sought a variety of means to address this challenge, leading to variable practices in the standards and processes used within the NHS to check the status of industry staff on site.

The purpose of this Quality Assurance Framework is to outline the agreed mechanism for oversight and maintenance of new training and education standards to address this problem. These standards are aimed at protecting both patient and registrant safety. Organisations that meet these standards will be recognised by the Life Science Industry (LSI) Educational Advisory Group (LSIEAG) and the relevant courses will be detailed in an LSIEAG directory.

Individuals who have successfully completed a recognised course will be eligible to apply to join the accredited credentialing register for Life Sciences staff who interact with NHS front-line staff and/or patients (once established, the register in accordance with the governance arrangements proposed by Academy for Healthcare Science (AHCS) will have a newly established LSI Registration Council, overseen by the AHCS Regulation Board).

The Education and Training Advisory Group's role is to:

- Ensure that Life Science Industry Standards of Training and Education are fit for purpose
- Have oversight and ownership of the Life Science Industry Quality Assurance Framework
- Maintain the Directory of LSI courses.
- Advise the Registrar of any changes to this which may impact upon registrants

Initially it will meet monthly.

## Professional Registration of Industry Personnel (Credentialing):

### The Mission

NHS England is working closely with industry partners to develop a single national professional registration scheme for industry personnel that will ensure the workforce are appropriately educated and trained in NHS values and support patient safety without adding undue burden or cost onto the NHS system or industry. Further to the communications that went out to all Trusts in August 2014, an initial consultation and 'call for evidence' was undertaken, the findings of which were considered by a Review Steering Group and directly informed the development of agreed national standards (see Appendix 1).

## Quality Assurance Roles and Responsibilities

In Life Science Industry (LSI) training and education there are three levels of quality assurance:

**Level 1: Quality Assurance** of the UK system, carried out by the Academy for Healthcare Science using a 'right touch' proportionate approach that is fit for purpose. The AHCS Regulation Board will produce annual reports for the Professional Standards Authority (PSA).

**Level 2: Quality Management** carried out by the Employer

**Level 3: Quality Control** carried out in-house by the Employer or sub-contracted by the Employer to a third party.

## AHCS Approach to setting Standards and QA processes

There are six principles in the development of both standards and quality assurance processes. These are:

- Proportionality
- Accountability
- Consistency
- Transparency
- Targeting
- Agility.

The table in the Appendix 2 summarises how these principles are applied to setting standards and quality assurance processes.

## Registration, Regulation and Fitness to Practise

All the standards described in Appendix 1 are required for the Registration Council to make judgements on individuals for entry to and removal from the accredited register. Appeals will be managed by the AHCS Regulation Board. Registration is important for the protection of patients and is increasingly viewed as essential by employers, providers, commissioners and patients themselves.

## The Academy for Healthcare Science AHCS commitment to driving up the quality of education and training

### The Academy for Healthcare Science will continue to:

- Work closely with patients and public and registrants to maintain focus in what we do
- Value stakeholder feedback evaluation from the service. This evaluation will inform decisions on the further targeting of quality assurance activities and on the further development of standards.
- Drive forward scientific excellence and strong leadership through fulfilment of its quality assurance role.
- Be committed to working closely with professional and other relevant bodies and to playing a pro-active role in national networks.
- Support the integration of new knowledge into practice.
- Analyse information from a wide variety of sources to learn from experience, improve performance and drive up standards.
- Carry out regular monitoring against performance indicators to measure progress in achieving quality improvement aims and objectives.
- Share information on best practice with a range of organisations, including employers and the Professional Standards Authority. We are all working towards better standards across the board. Feedback provides us with good intelligence on areas that need to be improved. By critically assessing evidence of what works and what does not work, we can focus our communications on specific approaches that are most likely to have a positive impact on raising standards.

Appendix 1



Life Science Industry Credentialing Register

# Education and Training Framework Matrix

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## Life Science Industry Register - Education & Training Framework Matrix

Training element	Outcome	Related Standard of Proficiency	Responsible for delivery	Example delivery options	Validation of delivery	Tier
Product	<p>To understand and apply appropriate knowledge of your area/product its function and application.</p> <p>Where appropriate be an effective communicator/trainer of the functions and safe use of the product.</p> <p>Know, understand and work within your remit.</p> <p>Have the knowledge to carry out your role safely and effectively and when to seek help.</p>	<p>2.1 3.1</p> <p>3.2</p> <p>3.3</p>	Employer	<p>In House</p> <p>3<sup>rd</sup>. party</p>	Declaration by employer	1
NHS values and behaviours	<p>To understand and comply with NHS values and behaviours including the NHS constitution - the NHS 7 key principles, values, rights and responsibilities.</p> <p>Understand and adopt appropriate and effective written and verbal communication skills relevant to your role.</p>	<p>4.1</p> <p>4.3</p> <p>4.4</p> <p>7.1</p>	Employer	<p>In House</p> <p>3rd party</p>	Declaration by employer	1



Training element	Outcome	Related Standard of Proficiency	Responsible for delivery	Example delivery options	Validation of delivery	Tier
Code of Business Practice	Know and understand your company/industry/trade association code of business practice and the standards of conduct of the Register.	1.1 1.2	Employer	In House 3rd party	Declaration by employer	1
Information Governance	Understand and comply with the Data Protection Act 1998 and Caldecott principles relevant to your role.	4.2 6.2	Employer	In House 3rd party	Declaration by employer	1
Competition and Procurement	To understand and comply with The Bribery Act 2010, competition law and public contracts regulation.	6.1	Employer	In House 3rd party	Declaration by employer	1
Self, Public and Patient Safety	<b>Tier 1</b> Understand 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.	2.2 5.1 5.3	Employer	In House 3rd party	Declaration by employer	1
	<b>Tier 2 &amp; 3</b> To understand and apply a duty of care regarding environmental health and safety	2.3 5.2	Employer	In House 3rd party	Declaration by employer	2

Training element	Outcome	Related Standard of Proficiency	Responsible for delivery	Example delivery options	Validation of delivery	Tier
	including infection prevention and control, adverse event management and maintaining one's own health through immunisation.					
High risk settings	<p><b>Tier 3</b></p> <p>In settings, such as theatre, cardiac labs, critical care and paediatric wards understand the high risks: use personal protective equipment appropriate to the setting; understand the etiquette, roles, responsibilities and protocols in high risk settings; carry out risk assessment including hazards, decontamination requirements, precautions etc. relevant to the setting; communicate effectively with all members of the team.</p>	2.4	Employer	In House 3rd party	Declaration by Employer and relevant certificate.	3

**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.

## Appendix 2 Academy principles in the development of Standards and Quality Assurance processes

**Summary table showing how we apply these principles**

Principle	Standards	Quality Assurance processes
<b>Proportionality</b> ( <b>'Right touch'</b> )	The burden created to comply with standards should be proportionate to the risks presented.  Standards are normally expressed as outcome statements, to allow a diversity of approaches to meeting them. As far as possible, standards will be applicable across the disciplines and roles of the healthcare science workforce.	It is a requirement that organisations and individuals undertake activities that help to mitigate risk.  Processes must call on evidence that already exists as much as possible.
<b>Accountability</b>	In producing and revising standards, there will always be appropriate public consultation.  Standards will be reviewed periodically to ensure that they remain fit for purpose.	The Academy is accountable to the regulator, the PSA.
<b>Consistency</b>	Adherence to standards must be measurable.	It is a requirement that individuals involved in QA are trained and developed, to ensure consistency. QA decisions will be evidence-based.
<b>Transparency</b>	The purpose of standards will be transparent and they will be available on the Academy's website.	QA processes will be transparent to all organisations and the individuals who must use them, including members of the public. The outcomes from QA activities will be publicly accessible via the AHCS web site.
<b>Targeting</b>	Standards are targeted at areas of risk.  When standards are reviewed, the creation of new standards or revisions to existing standards will be based in part on the evidence of risk.	QA processes will identify risk and prioritise areas of high risk over areas of low risk.  Where other bodies operate QA processes in the same setting, targeting will be used to prevent the duplication of evidence collection.
<b>Agility</b>	Standards will not inhibit the development of a profession or service, provided all risks have been reasonably mitigated.  Standards will be reviewed periodically to mitigate new and emerging risks, and amended where evidence suggests that existing standards require it or removed if they lack continued relevance.	Wherever possible QA will be pro-active and with an emphasis on risk prevention.