Visitors' report

Name of education provider	Institute of Biomedical Science
Programme name	Clinical Scientist Certificate of Attainment (Experiential Route)
Mode of delivery	Flexible
Relevant part of the HCPC Register	Clinical scientist
Date of visit	28 – 29 June 2017

Contents

Executive summary

The Health and Care Professions Council (HCPC) approve educational programmes in the UK which health and care professionals must complete before they can apply to be registered with us. We are a statutory regulator and our main aim is to protect the public. We currently regulate 16 professions. All of these professions have at least one professional title which is protected by law. This means that anyone using the title ‘clinical Scientist' must be registered with us. The HCPC keep a register of health and care professionals who meet our standards for their training, professional skills, behaviour and health.

The visitors’ report which follows outlines the recommended outcome made by the visitors on the approval of the programme at the education provider. This recommended outcome was accepted by the Education and Training Committee (Committee) on 07/12/2017. At this meeting, the Committee approved the programme. This means that the programme meets our standards of education and training (SETs) and ensures that those who complete it meet our standards of proficiency (SOPs) for their part of the Register. The programme is now granted open ended approval, subject to satisfactory monitoring.

Introduction

The HCPC visited the programme at the education provider as it was a new programme which was seeking HCPC approval for the first time. This visit assessed the programme against the standards of education and training (SETs) and considered whether those who complete the programme meet the standards of proficiency (SOPs) for their part of the Register.

Although they are regulated as a single profession, clinical scientists practise within discrete disciplines known as "modalities" and some requirements in the SOPs are modality-specific. For this programme, we assessed whether the clinical scientist SOPs are delivered relevant to the following modalities:

- Clinical Biochemistry
- Haematology
- Clinical Immunology

The approval process was formed of two stages. Outcomes from both stages of the process are contained within this report.

Stage 1 allowed modality expert clinical scientist visitors to review documentation relating to how the SOPs for clinical scientists are contained in the programme's curriculum, for the modalities listed above. This was a paper based exercise undertaken at the HCPC's offices on 1 June 2017. Due to the modality specific nature of the conditions relating to SETs 4.1, 4.2 and 6.1, the visitors from stage 1 (or appropriately qualified alternative visitors) will need to consider the conditions response from the education provider.

Stage 2 took the form of an approval visit to meet with the stakeholders involved with the delivery of the programme. Stage 2 reviewed how the programme meets the SETs.

The education provider has developed and proposed a new route to registration as a clinical scientist: the IBMS Clinical Scientist Certificate of Attainment (Experiential Route), which is based on prior learning and training.

This programme is designed to assess 'candidates' prior experience through their formal education and career to date. Candidates will provide a portfolio of evidence which details how their previous education and work experience meets the learning outcomes for the programme, which are intended to ensure those assessed through the programme meet the HCPC standards of proficiency (SOPs) for clinical scientists. Using a panel of experts, who will assess the portfolio of evidence and the candidate through a verbal examination, the education provider will determine if the learning outcomes are met or not. There is no opportunity for candidates to make up experience after being assessed and there is no formal learning or teaching on the programme. There is also no opportunity for candidates to undertake practice placement experience. The programme itself consists entirely of the assessment of a candidate's experience, skills and knowledge.

As part of the visit to the IBMS, the stage 2 visitors assessed whether the programme can be exempted from SET 5 (practice placements), as proposed by the education provider. After scrutiny of the programme via documentation and at the visit, the visitors concluded that the programme could be exempted from SET 5 as:

- the education provider demonstrated through the approval process that this not a taught programme;
- no additional training can be undertaken once the student has been admitted onto the programme, and no advice or guidance will be provided by the education provider which could constitute a learning plan
- the assessment of the candidate is completely retrospective; and
- applicants to the programme must have worked in an appropriate clinical environment, and have had contact with service users, which will be demonstrated through the admissions process.

However, in order for the programme to be exempted from SET 5 and approved, all of the conditions in this report must also be met.

This visit was an HCPC only visit. The education provider supplied an independent chair and secretary for the visit.

Visit details

Name and role of HCPC visitors	Stage one: Heather Barbour (Clinical biochemistry) David Stirling (Haematology) Graeme Wild (Clinical immunology)
	Stage two: Melvyn Myers (Clinical scientist) Pradeep Agrawal (Biomedical scientist)
HCPC executive officers (in attendance)	Rebecca Stent Jamie Hunt
Proposed student numbers	10 per cohort, 1 cohort per year
Proposed start date of programme approval	January 2018
Chair	Derek Bishop (Independent)
Secretary	Christian Burt (Institute of Biomedical Science)

Sources of evidence

Prior to the visit the HCPC reviewed the documentation detailed below, sent by the education provider:

	Yes	No	N/A
Programme specification	☒	☐	☐
Descriptions of the modules	☒	☐	☐
Mapping document providing evidence of how the education provider has met the SETs	☒	☐	☐
Mapping document providing evidence of how the education provider has met the SOPs	☒	☐	☐
Practice placement handbook	☐	☐	☒
Student handbook	☒	☐	☐
Curriculum vitae for relevant staff	☒	☐	☐
External examiners' reports from the last two years	☐	☐	☒

The HCPC did not review external examiners' reports prior to the visit as there is currently no external examiner as the programme is new. The HCPC did not review a practice placement handbook as this documentation does not exist due to there being no practice placement component of the programme.

During the visit the HCPC saw the following groups or facilities:

	Yes	No	N/A
Senior managers of the education provider with responsibility for resources for the programme	☒	☐	☐
Programme team	☒	☐	☐
Placements providers and educators / mentors	☐	☐	☒
Students	☒	☐	☐
Service users and carers	☒	☐	☐
Learning resources	☐	☐	☒
Specialist teaching accommodation (eg specialist laboratories and teaching rooms)	☐	☐	☒

The HCPC met with prospective applicants as the programme seeking approval currently does not have any students enrolled on it.

The HCPC did not meet with placement providers and educators as there are no practice placements for this programme.

The HCPC did not see the learning resources and specialist teaching accommodation as the proposed programme model does not require learning resources or any specialist teaching or laboratories at the education provider.

Recommended outcome

To recommend a programme for approval, the visitors must be satisfied that the programme meets all of the required standards of education and training (SETs), in this case exempting SET 5, and that those who complete the programme meet our standards of proficiency (SOPs) for the relevant part of the Register.

The visitors agreed to recommend to the Education and Training Committee that a number of conditions are set on the programme, all of which must be met before the programme can be approved.

The visitors agreed that 28 of the other SETs have been met and that conditions should be set on the remaining 17 SETs. The visitors also recommended that all of the standards in SET 5 are exempted for this programme.

Conditions are requirements that the education provider must meet before the programme can be approved. Conditions are set when certain standards of education and training have not been met or there is insufficient evidence of the standard being met.

The visitors did not make any recommendations for the programme.

Recommendations are observations on the programme or education provider which do not need to be met before the programme can be approved. Recommendations are made to encourage further enhancements to the programme, normally when it is felt that the particular standard of education and training has been met at, or just above the threshold level.

Conditions

2.1 The admissions procedures must give both the applicant and the education provider the information they require to make an informed choice about whether to take up or make an offer of a place on a programme.

Condition: The education provider must ensure applicants understand that only learning and experience from before the point of application can be used to evidence competence, and that no learning or experience undertaken following application can form part of the portfolio or further evidence submission.

Reason: From a review of the documentation provided, the visitors noted that the application form and 'Guidance to Candidates' provides the applicant with some information on the application process and the programme. At the visit, the programme team clarified that this is not a taught programme and that the assessment of a candidate is completely retrospective, with no advice or guidance provided by the education provider which would constitute a learning plan once a candidate is admitted onto the programme. From the documentation provided, the visitors could not see how applicants would be clear that all of their experiential learning must have taken place before the point of application and that they cannot undertake further education or training once admitted onto the programme, as this is not currently clearly articulated in the documentation. The visitors noted that this is particularly important in ensuring that applicants are able to make an informed choice about whether to take up a place on the programme, with an understanding that there is not the opportunity to undertake further training when admitted to the programme. As such, the visitors require further evidence to demonstrate that applicants are given the information that experiential learning applies before the point of application only and that no training aspect can be undertaken once admitted to the programme.

2.1 The admissions procedures must give both the applicant and the education provider the information they require to make an informed choice about whether to take up or make an offer of a place on a programme.

Condition: The education provider must demonstrate that the admissions procedures gives the applicant and mentor the information they require in relation to the role of the mentor in the application process.

Reason: The visitors noted from the documentation provided that the application form and Guidance to Candidates provides the applicant with some information on the application process and the programme, including that candidates must have access to a named mentor who is an HCPC registered clinical scientist. At the visit, the visitors learnt that the mentor would usually be sourced by the applicant, but could also be provided by the IBMS if the applicant was unable to identify a suitable mentor. The visitors also learned that the mentor would be expected to assist the applicant with the application process, in terms of putting together the description of the applicant's role and the environment in which they have gained experience. However, the visitors could not see from the documentation provided how applicants or mentors would be clear about the role of the mentor in assisting applicants with this. As such, the visitors require further evidence that the admissions procedures give the applicant and mentor the information they require in relation to the role of the mentor in the application process.

2.1 The admissions procedures must give both the applicant and the education provider the information they require to make an informed choice about whether to take up or make an offer of a place on a programme.

Condition: The education provider must demonstrates that the criteria used to assess the information provided in an application allows the education provider to make an informed choice to make an offer of a place on the programme, and how applicants are supported to provide all relevant information through the application process.

Reason: The visitors noted from the documentation provided that the application form and Guidance to Candidates provides the applicant with some information on the application process and the programme. The visitors noted in the Guidance to Candidates that applicants should include a description of their role in their application and confirm that the environment in which they developed their practice prior to application "had resources sufficient, appropriate and available to support their development and scope of practice to the threshold level of clinical scientist registration." At the visit, the education provider emphasised that there would be a "whole range of indicators" which would inform them as to whether the candidate had experience in an "appropriate environment" in the candidate's application statement. Furthermore, the programme team stated that it is likely that candidates would be registered HCPC biomedical scientists (although there may be exceptions), but it was not clear how registration status as a biomedical scientist would impact on an applicant's suitability for the programme. The programme team stated that the screening process would decide whether a candidate could be accepted and that their "scope of practice" would decide this. However, the visitors could not see from the documentation provided how applicants would be clear about what to include in this application statement. Furthermore, from the documentation provided, the visitors could not see whether the education provider had a criteria for assessing an applicant's current role, and whether the environment in which they gained experience was appropriate, to be able to make a decision about whether to make an offer of a place on the programme. As such, the visitors require information that demonstrates that the criteria used to assess the information provided in an application allows the education provider to make an informed choice to make an offer of a place on the programme, and how applicants are supported to provide all relevant information through the application process.

3.5 There must be an adequate number of appropriately qualified and experienced staff in place to deliver an effective programme.

Condition: The education provider must demonstrate that there will be an adequate number of appropriately qualified and experienced staff to carry out assessment of the proposed number of candidates for this programme.

Reason: The visitors noted from the documentation that there will be external assessors who will assess candidates' evidence of their prior experiential learning submitted in the Experiential Portfolio, and through a "viva voce" exam. The education provider explained that this exam would be to explore candidates' portfolios in more detail, but would not have a formal set of assessment criteria. The visitors also noted from the documentation that the panel of assessors would be made up of one clinical scientist and one "speciality-specific" biomedical scientist. At the visit, the education provider stated that they have access to a "sufficient pool of assessors" for the proposed number of candidates on this programme and the visitors heard where the

education provider would source these assessors from. Furthermore, the senior team stated that the clinical scientist assessor would not necessarily be modality-specific, as the biomedical scientist would be required to have modality-specific knowledge. However, the visitors were not clear from these discussions as to how many assessors will be available to assess candidates on this programme in order to make a judgement as to whether there will be an adequate number. The visitors were also unable to determine from these discussions how the panel as a whole is able to make clinical scientist modality-specific judgements when the specialist in the modality is from a different part of the Register and, therefore, how the education provider will ensure that the panel as a whole has the level of knowledge required. As such, the education provider must provide further evidence to demonstrate that there will be an adequate number of assessors for the programme to utilise and that they will have the appropriate qualifications and experience to be able to assess candidates practising in a specific modality at the level of a clinical scientist.

3.7 A programme for staff development must be in place to ensure continuing professional and research development.

Condition: The education provider must demonstrate that there is an appropriate programme for staff development in place for assessors.

Reason: The visitors noted from the documentation that there will be external assessors who will assess candidates' evidence of their prior experiential learning submitted in the Experiential Portfolio, and through a "viva voce" exam. From the documentation provided and discussions at the visit, the visitors learnt that these assessors receive initial training and refresher training related to the programme. However, the visitors did not see specific details of the content of the refresher training, and were therefore unable to make a judgement about whether this training is appropriate to support assessors in their continued understanding of the programme. Therefore, the visitors were not clear as to how there is a continuing programme for staff development in place for these assessors. Consequently, the visitors could not see how the education provider would ensure that the skills relevant to their profession would be up to date in order to assess whether candidates have met the standards of proficiency for clinical scientists, and to ensure that they understand the requirements of the programme. As such, the visitors require further evidence that this standard is met.

3.8 The resources to support student learning in all settings must be effectively used.

Condition: The education provider must demonstrate how they will be assured that the resources to support prior learning in environment(s) referenced in candidates' portfolios were effectively used.

Reason: From documentation provided prior to the visit, the visitors noted in the Guidance to Candidates that applicants should confirm that the environment in which they developed their practice prior to application "had resources sufficient, appropriate and available to support their development and scope of practice to the threshold level of clinical scientist registration." At the visit, the programme team stated that an applicant would describe the environment in their personal statement at the application stage and that this would confirm whether they have been in an Institute of Biomedical Science (IBMS) approved or Clinical Pathology Accreditation (CPA) / ISO15189 accredited laboratory and, if not, they would query it. The education provider

emphasised that there would be a “whole range of indicators” which would inform them as to whether the applicant had gained experience in an “appropriate environment” and that they would expect mentors to assist candidates with providing this information. However, the visitors could not see from the documentation provided how applicants or mentors would be clear about what to include in this application, or how the education provider would assess whether this environment had sufficient, appropriate, and available resources. As such, the visitors require further evidence to demonstrate how the education provider will be assured through the application process that the resources to support prior learning in environment(s) referenced in candidates’ portfolios were effectively used.

3.8 The resources to support student learning in all settings must be effectively used.

Condition: The education provider must demonstrate how mentors will have all of the information and guidance they require in order to fulfil their role and responsibilities in supporting candidates on this programme.

Reason: From a review of the documentation, the visitors noted that candidates must have access to a named mentor who is an HCPC registered clinical scientist. The visitors also read the following requirements of the mentor role in the Programme handbook: “The mentor is to provide professional support and advice for the applicant’s submission of evidence” and they must have “read and understood the information available on the IBMS website related to the IBMS Clinical Scientist Certificate of Attainment (Experiential Route) award.” Furthermore, other responsibilities of the mentor are stated in the documentation, such as reporting any issues relating to the candidate’s profession-related conduct. At the visit, the visitors learnt that the mentor would also be expected to assist the candidate with the application process. As part of the application process, the visitors noted that the mentor is required to sign a declaration that they have read and understood the programme information. However, the visitors could not see, from the documentation provided, how mentors would be able to access all of the information required to understand their role, and all of their responsibilities on this programme. Therefore, the visitors were unclear as to how the education provider can be assured that mentors are making an informed declaration at the admissions stage. As such, the visitors require further evidence to demonstrate that the resources for mentors will be effectively used so that they have all of the information and guidance they require in order to fulfil their role and responsibilities in supporting candidates on this programme.

3.9 The resources to support student learning in all settings must effectively support the required learning and teaching activities of the programme.

Condition: The education provider must demonstrate how they will be assured that the resources to support prior learning in environment(s) referenced in candidates’ portfolios effectively supported their ability to demonstrate competence through the portfolio.

Reason: From documentation provided prior to the visit, the visitors noted in the Guidance to Candidates that applicants should confirm that the environment in which they developed their practice prior to application “had resources sufficient, appropriate and available to support their development and scope of practice to the threshold level of clinical scientist registration.” At the visit, the programme team stated that an

applicant would describe the environment in their personal statement at the application stage and that this would confirm whether they have been in an Institute of Biomedical Science (IBMS) approved or Clinical Pathology Accreditation (CPA) / ISO15189 accredited laboratory and, if not, they would query it with the applicant. The education provider emphasised that there would be a “whole range of indicators” which would inform them as to whether the candidate had gained experience in an “appropriate environment” and that they would expect mentors to assist candidates with providing this information. However, the visitors could not see from the documentation provided how applicants or mentors would be clear about what to include in this application, or how the education provider would assess whether this environment had sufficient, appropriate, and available resources. As such, the visitors require further evidence to demonstrate how the education provider will be assured through the application process that the resources to support prior learning in environment(s) referenced in candidates’ portfolios effectively supported their ability to demonstrate competence through the portfolio.

3.10 The learning resources, including IT facilities, must be appropriate to the curriculum and must be readily available to students and staff.

Condition: The education provider must demonstrate how they will be assured that resources, including IT facilities, were appropriate to the curriculum and accessible to candidates in environment(s) referenced by candidates in their portfolio.

Reason: From documentation provided prior to the visit, the visitors noted in the Guidance to Candidates that applicants should confirm that the environment in which they developed their practice prior to application “had resources sufficient, appropriate and available to support their development and scope of practice to the threshold level of clinical scientist registration.” At the visit, the programme team stated that an applicant would describe the environment in their personal statement at the application stage and that this would confirm whether they have been in an Institute of Biomedical Science (IBMS) approved or Clinical Pathology Accreditation (CPA) / ISO15189 accredited laboratory and, if not, they would query it with the applicant. The education provider emphasised that there would be a “whole range of indicators” which would inform them as to whether the candidate had gained experience in an “appropriate environment” and that they would expect mentors to assist candidates with providing this information. However, the visitors could not see from the documentation provided how applicants or mentors would be clear about what to include in this application, or how the education provider would be assess whether this environment had sufficient, appropriate, and available resources. As such, the visitors require further evidence to demonstrate how the education provider will be assured through the application process that resources, including IT facilities, were appropriate to the curriculum and accessible to candidates in environment(s) referenced by candidates in their portfolio.

3.11 There must be adequate and accessible facilities to support the welfare and wellbeing of students in all settings.

Condition: The education provider must demonstrate that it provides adequate and accessible facilities to support the welfare and wellbeing of candidates once they have been admitted to the programme.

Reason: From documentation provided prior to the visit, the visitors noted in the Guidance to Candidates that applicants should confirm that the environment in which

they developed their practice prior to application “had resources sufficient, appropriate and available to support their development and scope of practice to the threshold level of clinical scientist registration.” However, from the documentation and discussions at the visit, it was unclear whether there are adequate and accessible facilities at the education provider to support the welfare and wellbeing of all candidates once they have been admitted onto the programme. Although this is not a taught programme, the visitors considered that there will be circumstances where candidates require welfare and wellbeing support from the education provider, but could not see how the education provider would provide this support. Examples of these facilities could include a counselling service, or support available for candidates during periods of sick leave. As such, the visitors require further evidence that the education provider has adequate and accessible facilities to support the welfare and wellbeing of candidates once they have been admitted onto the programme.

3.12 There must be a system of academic and pastoral student support in place.

Condition: The education provider must demonstrate how all relevant groups will be clear about the level and type of support that candidates are able to access through the programme.

Reason: From the documentation provided and conversations at the visit, the visitors understood that the education provider intends that this programme is not taught, but is rather based on the assessment of prior experiential learning and experience. This evidence will be presented by candidates via a Portfolio of Evidence to demonstrate that they have met all of the SOPs for a clinical scientist, which would be assessed by external assessors.

Relating to support for candidates, the visitors understood that amongst other support mechanisms:

- each candidate’s mentor would support the candidate with the application process and with providing appropriate evidence for their portfolio from their experience;
- candidates will have telephone and email access to the IBMS Education Team for support “in relation to completion of applications, evidence for completion of portfolios, application progress and outcomes”;
- “Additional support from mentors” will be available; and
- assessors would provide feedback on any standards not met in the Experiential Portfolio and “Candidates will be advised on the type of evidence that would be suitable to demonstrate the standard has been met and given a maximum of 6 months to submit further evidence”.

Considering the documentation and conversations at the visit, the visitors noted that there was not sufficient detail or clarity for candidates, mentors, assessors, or the programme staff to understand the level and type of academic and pastoral support that candidates are able to access on this programme. The visitors noted that there was a risk that advice or guidance provided by mentors, assessors or the education provider could deviate from the intended level, and begin to constitute a learning plan for candidates. In this situation, there is a risk that candidates could undertake further learning in order to fulfil the requirements of the programme, rather than basing their evidence on retrospective learning and practice only. This would not be appropriate for the model proposed by the education provider, considering that the programme has requested to be exempt from the standards in SET 5, and therefore they have not

presented any way of quality assuring learning experiences undertaken post application. Therefore, to ensure the programme model will always function as proposed, the visitors require further evidence to demonstrate how all relevant groups will be clear about the level and type of support that candidates are able to access through the programme.

3.16 There must be a process in place throughout the programme for dealing with concerns about students' profession-related conduct.

Condition: The education provider must demonstrate that there is a process for dealing with concerns about candidates' profession-related conduct, and that this is clearly documented and communicated to relevant groups.

Reason: For this standard, the visitors noted from the documentation provided that candidates must have a named mentor who is a registered clinical scientist, usually identified by the candidate, and that this mentor can contact the IBMS Executive Head of Education and a "named clinical scientist" in the relevant speciality for the discussion of concerns. However, as there is no guidance about this area for mentors, the visitors were unclear how the mentor would know that they would be expected to discuss or report concerns about candidates' profession-related conduct. Furthermore, the visitors were unclear about what the process would be at the education provider for dealing with any of these issues once the IBMS obtains this information. In addition, the visitors were unclear about where the education provider would source the named clinical scientist from for mentors to contact, or how this named clinical scientist would feed back this information into the process for dealing with any concerns about candidate's profession-related conduct. As such, the visitors require further evidence to demonstrate that there is a process in place for dealing with concerns about candidates' profession-related conduct, and that this is clearly documented and communicated to the relevant groups including candidates, mentors and the education provider.

3.17 Service users and carers must be involved in the programme.

Condition: The education provider must demonstrate that there is a policy to ensure there is service user and carer involvement on this programme, that service users and carers will be supported in their role, and that this involvement is appropriate to the programme.

Reason: For this standard, the visitors were referred to the IBMS Policy on Service User and Carer involvement in other HCPC programmes. In the service user and carer meeting at the visit, the visitors met with employers of clinical scientists and people who may put forward employees as candidates for this programme. However, the visitors were unable to determine how these individuals were service users, or how they understood their role as a service user, rather than an employer, in relation to this programme. In discussions with the programme team, the visitors heard that the education provider considers these employers to be representatives of service users. For example, one individual had an understanding of the role of a clinical scientist in an urgent clinical situation, and what they would require of them in this situation. The education provider also stated that candidates interact with service users and have to present evidence in their Experiential Portfolio which informs the IBMS' understanding of how clinical scientists interact with service users. However, the visitors could not see how the documentation provided, such as the IBMS Policy on Service User and Carer involvement, would be applied to this particular programme. They also noted that a

candidate's interaction with service users in a training environment would not be considered as service user and involvement in the programme itself, as service users contribute to a learner's development rather than to the programme. Furthermore, as the service users the visitors met were unclear about their role within the programme, the visitors could not be assured that they would be aware of what is expected of them in terms of feeding into the programme, or that they were appropriate as service users. As such, the visitors require further evidence that there is a policy to ensure there is service user and carer involvement on this programme, that service users will be supported in their role, and that their involvement is appropriate to this programme.

4.1 The learning outcomes must ensure that those who successfully complete the programme meet the standards of proficiency for their part of the Register.

Condition: The education provider must revisit the curriculum and learning outcomes to demonstrate the scope and depth of understanding and knowledge required by the programme for the clinical scientist standards of proficiency (SOPs) as listed below, as related to the profession and, where applicable, the modality.

Reason: In the programme and modality handbooks, there was insufficient detail to demonstrate how the SOPs listed below are contained in the curriculum, particularly in relation to the depth of understanding and knowledge required by the programme in order for candidates to demonstrate that they meet the SOPs for clinical scientists. Therefore, the visitors were unclear about how the education provider would be able to make a decision about whether candidates on this programme have demonstrated all of the knowledge, ability and understanding required of a clinical scientist at the point of registration.

2 be able to practise within the legal and ethical boundaries of their profession

2.3 understand the need to respect and uphold the rights, dignity, values, and autonomy of service users including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing

- For this particular SOP, the visitors could not see a reference to the role of service users in the diagnostic and therapeutic process.

2.5 know about current legislation applicable to the work of their profession

- The visitors noted that there was insufficient evidence to demonstrate reference and understanding of all current legislation applicable to the profession in the curriculum for each of the modalities.
    - **Clinical Immunology –** There was no mention of the Medicines and Health Regulatory Authority (MHRA) legislation.
    - **Haematology –** There was no mention of the MHRA or the UK's Bloody Safety and Quality Regulations. The visitor noted that this would be particularly important as blood transfusion features in the curriculum so these regulations would need to be referenced and understood.
    - **Clinical Biochemistry –** There was no mention of the MHRA.

8 be able to communicate effectively

8.3 understand how communication skills affect assessment of, and engagement with, service users and how the means of communication should be modified to address and take account of factors such as age, capacity, learning ability and physical ability

- The visitors are unclear how the learning outcome referenced by the education provider for this SOP, as well as other learning outcomes in Module 3: Communication, will ensure that candidates will understand how to modify their communication to take into account factors such as age, capacity, learning ability and physical ability, due to the limited detail provided about the education provider's expectations of candidates in this area.

8.5 be aware of the characteristics and consequences of verbal and non-verbal communication and how this can be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs

- The visitors could not see how the learning outcomes or curriculum ensures that candidates will be aware of both the characteristics and consequences of verbal and non-verbal communication and how this could be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs, due to the limited detail provided about the education provider's expectations of candidates in this area.

8.7 understand the need to assist the communication needs of service users such as through the use of an appropriate interpreter, wherever possible

- The visitors are unclear how the curriculum and learning outcomes will ensure that candidates will be aware of when it is appropriate to assist communication needs through the use of an appropriate interpreter due to the limited detail provided about the education provider's expectations of candidates in this area.

8.10 be able to summarise and present complex scientific ideas in an appropriate form

- Further evidence is required to demonstrate how the curriculum and learning outcomes ensure that candidates will be able to summarise complex scientific ideas. The visitors could see how the learning outcome referenced ensures that candidates are able to present complex scientific ideas through demonstrating an ability to educate and train others but they were unclear about how this would ensure they are able to summarise these ideas so that others can understand them.

9 be able to work appropriately with others

9.2 understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team

- The visitors could see how the curriculum ensures candidates understand the need to build and sustain professional relationships collaboratively as a member of team. However, they were unclear how the curriculum and learning outcomes ensure candidates understand the need to build and sustain professional relationships as an independent practitioner.

9.4 be able to contribute effectively to work undertaken as part of a multi-disciplinary team

- The visitors could not see how the learning outcome demonstrates an ability to contribute effectively to work undertaken as part of a multi-

disciplinary team. Rather, the visitors noted that this learning outcome requires candidates to have knowledge rather than ability.

10 be able to maintain records appropriately

10.1 be able to keep accurate, comprehensive and comprehensible records in accordance with applicable legislation, protocols and guidelines

- The visitors noted that the curriculum and learning outcomes address educating others in keeping records but they do not require candidates to be able to keep records themselves.

12 be able to assure the quality of their practice

12.4 be able to maintain an effective audit trail and work towards continual improvement

- Further evidence is required to demonstrate how the curriculum and learning outcomes ensure that candidates will be able to maintain an effective audit trail and work towards continual improvement. The visitors noted that an ability to perform an audit, as detailed in the learning outcomes, is not the same as demonstrating an ability to maintain an effective audit trail.

12.8 recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes

- The visitors noted that the learning outcome requires candidates to recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance. However, they could not see how this learning outcome or the curriculum requires candidates to recognise the need for this in relation to the improvement of programmes.

12.10 recognise the need to be aware of emerging technologies and new developments

- The visitors noted that the education provider had mapped a learning outcome but they could not see a link to this SOP.

13 understand the key concepts of the knowledge base relevant to their profession

13.7 know the basic science underpinning the modality in which they practise, understand relevant basic clinical medicine and be aware of the fundamental principles of clinical practice `

- The curriculum for Haematology and Clinical Immunology did not clearly define what the education provider understands of:
    - relevant basic clinical medicine; and
    - fundamental principles of clinical practice.
- **Haematology** – The visitor noted that there was an emphasis on diagnosis, list of techniques, and testing, but without a definition of the clinical situation(s) that these would be feeding into, or the reason for undertaking these tests.
- **Clinical Immunology** – The visitor noted that there was a lack of detail in relation to candidates understanding the effects of drugs and treatments.

13.8 understand the wider clinical situation relevant to the service users presenting to the speciality

- The visitors cannot see how the understanding of the wider clinical situation to the service users presenting to the speciality is addressed and defined by the education provider in the curriculum or the learning outcomes. The visitors noted that there is an emphasis on diagnosis, lists of techniques and tests without the understanding of the clinical situation that it is feeding into.

13.10 understand the evidence base that underpins the use of procedures employed by the service

- The visitors cannot see how the curriculum and learning outcomes ensure a clinical scientist trainee will understand the outcomes of the operating procedures of their working environment and therefore the evidence base that underpins these procedures. The visitors noted that only an understanding of the principles associated with the procedures is required.

14 be able to draw on appropriate knowledge and skills to inform practice

14.1 be able to change their practice as needed to take account of new developments or changing contexts

- The visitors noted that the education provider had mapped a learning outcome but they could not see a link to this SOP.

14.11 be able to identify the clinical decision which the test or intervention will inform

- The learning outcome mapped for this SOP describes clinical "relevance" rather than "decision". The visitors noted that relevance does not have the same meaning as decision as it is possible to identify the clinical relevance without making a clinical decision.

14.14 be able to undertake or arrange investigations as appropriate

- The visitors noted that the learning outcome refers to someone's ability to perform a test without addressing their ability to decide the appropriate test for a particular clinical situation. The visitors noted that clinical scientists need to have an understanding of appropriate tests for particular clinical situations in order to meet this SOP. However, the visitors only saw a list of tests in the curriculum without seeing evidence that candidates would be required to have an understanding of appropriate tests for particular clinical situations.

14.15 be able to analyse and critically evaluate the information collected

- The visitors noted that candidates are required to critically evaluate and analyse information in research. However, they could not see how this is addressed within the context of clinical investigation. The visitors noted that, in order to demonstrate the scope of practice of a clinical scientist, candidates would need to demonstrate an understanding of whether a result is a real result within the context of clinical investigation or whether there are other causes. In particular they would need to be able to demonstrate knowledge of how to ensure that clinical laboratory investigations have sufficient sensitivity to correctly identify patients with a certain condition and sufficient specificity to correctly identify patients without the condition. This would also include substantial knowledge of confounding factors that can affect results, for example drugs, age and pregnancy.

4.1 The learning outcomes must ensure that those who successfully complete the programme meet the standards of proficiency for their part of the Register.

Condition: The education provider must revisit the curriculum and learning outcomes in relation to how they define service users within this programme, how they are appropriate and how the learning outcomes for service user related SOPs are service user focussed.

Reason: For the SOPs listed below, the visitors noted the learning outcomes mapped by the education provider were unclear in relation to who the service users are on this programme and, therefore, they were unable to make a judgement as to whether the learning outcomes are appropriate. For some of the SOPs, the visitors could also not see how the learning outcomes were service-user focussed; further detail is provided under each SOP noted below.

2 be able to practise within the legal and ethical boundaries of their profession

2.1 understand the need to act in the best interests of service users at all times

- Although the learning outcome is service user focussed, without understanding who the education provider defines as service users on this programme, the visitors were unable to see how candidates would be required to understand the need to act in the best interests of different service users encountered by clinical scientists.

2.3 understand the need to respect and uphold the rights, dignity, values, and autonomy of service users including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing

- Although the learning outcome is service user focussed, without understanding who the education provider defines as service users on this programme, the visitors were unable to see how candidates would be able to understand a service user's role in diagnosis, therapy and maintenance of their own health.

2.4 recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility

- The visitors noted that the learning outcome was service user focussed but they were unclear about who the education provider defines as service users on this programme and in relation to this SOP.

9 be able to work appropriately with others

9.3 understand the need to engage service users and carers in planning and evaluating diagnostics, treatments and interventions to meet their needs and goals

- The visitors understood from the learning outcome mapped by the education provider that different professional groups were listed as the service users for this SOP. However, the visitors were unclear about who the education provider defines as service users across the whole

programme and why health care professionals are the only appropriate service users in this context.

12 be able to assure the quality of their practice

12.2 be able to gather information, including qualitative and quantitative data, that helps to evaluate the responses of service users to their care

12.7 be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the service user

- For SOPs 12.2 and 12.7, the visitors noted that the learning outcomes were not service user focussed and, without a definition in relation to who the education provider considers the service users to be, they cannot say that this SOP is met.

4.1 The learning outcomes must ensure that those who successfully complete the programme meet the standards of proficiency for their part of the Register.

Condition: The education provider must revisit the learning outcomes to demonstrate that they ensure that those who successfully complete the programme meet the standards of proficiency for clinical scientists.

Reason: For the SOPs listed below, the visitors noted that the module aims state that the purpose of the module is to meet these SOPs. However, the learning outcomes mapped do not reflect the aims of the module. As such, the visitors require further evidence as to how the learning outcomes will ensure that candidates meet all of the SOPs, including the SOPs listed below.

14 be able to draw on appropriate knowledge and skills to inform practice

14.22 be able to interpret data and provide diagnostic and therapeutic opinions, including any further action which the individual directly responsible for the care of the patient or service user should take

14.26 be able to perform the required experimental work and be able to produce and present the results including statistical analysis

4.2 The programme must reflect the philosophy, core values, skills and knowledge base as articulated in any relevant curriculum guidance.

Condition: The education provider must demonstrate how the programme reflects the philosophy, core values, skills and knowledge base as articulated in the curriculum guidance referenced in the documentation.

Reason: For this standard, the visitors were directed to the programme and curriculum handbooks as well as the following statement: “The curriculum is designed to show that those able to demonstrate they have met the HCPC standards of proficiency for clinical scientists.” From a review of these handbooks, the visitors identified a number of areas of the curriculum which were insufficient to ensure that candidates would meet the standards of proficiency (SOPs) on successful completion of the programme. The visitors could also not determine how the curriculum guidance referenced was utilised by the education provider in developing the programme. The visitors were therefore unable to see how the programme had used or reflected the curriculum guidance referenced in the documentation to inform the programme. Therefore, the visitors

require further evidence to demonstrate how the education provider used the curriculum guidance referenced in the documentation to ensure that the programme reflects the philosophy, core values and knowledge base for the programme.

4.5 The curriculum must make sure that students understand the implications of the HCPC's standards of conduct, performance and ethics.

Condition: The education provider must demonstrate how they ensure successful candidates understand the implications of the HCPC's standards of conduct, performance and ethics, and how they apply to clinical scientists.

Reason: For this standard, the visitors were directed to the application form, the requirements of the Experiential Portfolio and the Guidance to Candidates. The visitors could not see how the application form ensures that candidates understand the HCPC's standards of conduct, performance and ethics. The visitors acknowledged that, in the Experiential Portfolio, candidates have to demonstrate "How the HCPC code of conduct, performance and ethics apply to professional practice" and, at the visit, the programme team confirmed that this is where candidates would demonstrate understanding of these standards. However, the visitors were unclear as to what criteria assessors would use to ensure that these standards are understood and met within the Portfolio of Evidence. The visitors also read the following statement in the Guidance to Candidates: "Once accepted onto the programme the successful applicant, if not already on an HCPC register will be expected to comply with the HCPC standards of conduct, performance, and ethics." The visitors inferred from this statement that there could be an assumption that, if the candidate is already a registered biomedical scientist, then they would not need to understand how these standards relate to the scope of practice of a clinical scientist. As such, the visitors require further evidence to demonstrate that the education provider will ensure that all successful candidates understand the implications of the HCPC's standards of conduct, performance and ethics.

6.1 The assessment strategy and design must ensure that the student who successfully completes the programme has met the standards of proficiency for their part of the Register.

Condition: Considering the conditions applied to SET 4.1 for this programme, the education provider must articulate how the assessment strategy and design ensures that the candidate who successfully completes the programme is able to demonstrate that they have met all of the standards of proficiency (SOPs) for clinical scientists.

Reason: From the documentation provided, the visitors noted from the Guidance for External Assessors that candidates are expected to provide evidence they have met the HCPC standards of proficiency (SOPs) for clinical scientists. In the programme team meeting, the education provider stated that assessors would look to see if candidates have fulfilled what is required in the curriculum and programme handbooks. However, due to some of the SOPs not currently being contained in the curriculum, as detailed under 4.1, the visitors could not see how the assessment strategy and design will ensure that candidates who successfully complete the programme have met all of the SOPs for clinical scientists. As such, further evidence is required to demonstrate how each of the SOPs listed in each condition under SET 4.1 of this report are contained and assessed within this programme.

6.5 The measurement of student performance must be objective and ensure fitness to practise.

Condition: The education provider must demonstrate how the assessment of candidates will be objective and consistent.

Reason: The visitors noted from the documentation that there will be external assessors who will assess candidates' evidence of their prior experiential learning submitted in the Experiential Portfolio, and through a "viva voce" exam to make a decision about whether they meet the SOPS for a clinical scientist. The visitors also noted from the documentation that these assessors will receive initial training and refresher training related to the programme. At the visit, the programme team stated that assessors will be using their professional judgement based on documentation provided by the IBMS to assess whether candidates meet the SOPs. However, the visitors were unclear as to how the education provider will ensure parity of decision-making between different assessment panels in relation to the threshold level that candidates have to meet. As such, the visitors require further evidence to demonstrate how the education provider will ensure that the assessment of candidates is objective.

6.7 Assessment regulations must clearly specify requirements for student progression and achievement within the programme.

Condition: The education provider must demonstrate that all groups involved in this programme, including candidates, mentors and assessors, will be clear that all of the candidate's learning and experience must have been achieved before application to the programme.

Reason: From the documentation provided and conversations at the visit, the visitors understood that the education provider intends that this programme is not taught, but is rather based on the assessment of prior experiential learning and experience. This evidence will be presented by candidates via a Portfolio of Evidence to demonstrate that they have met all of the SOPs for a clinical scientist, which would be assessed by external assessors. They also noted that candidates have 12 months to complete this portfolio once they have been admitted onto the programme and, once the Portfolio has been assessed, one of the possible outcomes is as follows:

"Candidate has partially met the requirements for mapping evidence against the IBMS Clinical Scientist Certificate of Attainment Experiential Portfolio and is required to submit further evidence to address specific standards of proficiency before they proceed to Part Two; Candidates will be advised on the type of evidence that would be suitable to demonstrate the standard has been met and given a maximum of 6 months to submit further evidence. Only the standards requiring additional evidence will be reassessed" (page 15, Guidance to Candidates)

At the visit, the programme team clarified that this is not a taught programme and that the assessment of the candidate is completely retrospective with no advice or guidance provided by the education provider which would constitute a learning plan once the candidate is admitted onto the programme. However, from the documentation, the visitors could not see how candidates, mentors and assessors, will be clear that all of the candidate's learning and experience must have been achieved before application to the programme and that no further training can be undertaken in order to meet any of the standards of proficiency. The visitors noted that the statement above, for example,

could be misinterpreted by assessors, mentors, or candidates that experience can be gained following the feedback. As such, the visitors require further evidence to demonstrate that all groups involved in this programme, including candidates, mentors and assessors, will be clear about this requirement in order for this standard to be met.

6.7 Assessment regulations must clearly specify requirements for student progression and achievement within the programme.

Condition: The education provider must demonstrate that the assessment regulations clearly and consistently communicate the number of evidence resubmissions permitted, including the associated timescales, to candidates and staff.

Reason: For this standard, the visitors reviewed the Guidance to Candidates and Guidance to External Assessors which states that, once a candidate's Portfolio of Evidence is assessed, candidates are able to submit further evidence if they do not meet all of the standards of proficiency and that they would be given "a maximum of 6 months to submit further evidence." At the visit, the programme team stated candidates would only have three months to resubmit evidence and that they can only resubmit once. However, the visitors could not see from the documentation provided as to how candidates and assessors would be clear about how many resubmissions of evidence candidates would be permitted and they noted that the timescales in the documentation are different from those specified at the visit by the programme team. As such, the visitors require further evidence that the documentation for candidates and staff clearly and accurately specifies requirements for candidate progression and achievement within the programme in relation to the number of resubmissions permitted and associated timescales.

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