Example application for Chartered Scientist (CSci)

Application: Chartered Scientist

Job Title: Senior Medical Technologist

Competencies 1. A. Application of knowledge and understanding

1. Use specialist experiential knowledge and broader scientific understanding to optimise the application of existing and emerging science and technology.

I work in the UK R&D and sales support centre of one of the world's largest laboratory instrumentation manufacturers. Our product range includes spectrophotometers, ELISA plate readers, a range of basic chromatography equipment and analytical technologies including UV, visible, isotope scanners and software analytical engines for a diversity of applications, and several multi-channel analysers widely used in medical and veterinary pathology. We also manufacture evidential alcohol meters, and ion scanners for use in customs, crime and security screening.

My role is to oversee final quality control certification of pre-delivery instrumentation, and separately to coordinate with our delivery and site installation teams the final QC certification together with initial customer briefings with regard to safe and effective use of our products. I do not however engage in more extensive end-user training as we have different teams of specialist application trainer/technologists for that task. I am however involved in the training of installation teams, specialist application trainer/technologists, and supporting staff.

I spent 14 years after graduation, first in a University research laboratory, supporting the research teams and later assisting in the preparation of teaching materials, reagents, simulated test samples, instruments and consumables for use a range of both UG and PG taught courses and Diploma courses. Leaving the University, I transferred to a pharmaceutical research lab and within 1 year transferred to its production analytical facility. There I was involved in the analysis of raw material, intermediary and final (bulk) product, and of environmental samples, for active ingredient concentrations, product purity, and for a range of possible contaminants.

Having now moved to Instrumon Industries (UK) plc, I utilize my extensive training and experience of instrumental analysis to support manufacture pre-final and final testing of a wide range of instrumentation. When I started, I was one of a number of instrument analysts working as part of a team. Specialising in Quality Assurance, I was tasked to assess the changes in performance and quality assurance during instrument packaging and transportation. This involves testing of those instruments manufactured overseas on receipt in the UK, as part of a product acceptance process and to provide a baseline for further assessments. Any corrective interventions are completed and recorded.

When packaged for delivery to a customer, I first complete a pre-delivery Quality Assurance certificate, and then follow the instrument to assist in its installation and commissioning. I then repeat testing on site and issue a final Quality Assurance certificate having first made any necessary adjustment.
After successful work in this role for just over 5 years, I was asked to move up and become Senior Medical Technologist, leading the team covering the entire UK. The team comprises 11 including myself, among when are 4 specialists dealing with evidential alcometers, ion scanners, and drug analysers as these are

the products most ‘heavily’ used and often subject to a degree of abuse yet having perhaps the greatest need for accuracy and precision.

I rely on my extensive experience in analytical sciences and medical technology. I am responsible for implementation of a variety of different QA standards, occasionally conflicting in some regards depending on the intended use of a piece of equipment and its analytical purpose. Thus, for use in a medical or veterinary laboratory, the QA standards are those set by the UK, EU or US regulators, most likely the Association of Clinical Biochemists in the UK, or by the Home Office in the case of equipment used for drug and alcohol detection. The principles are broadly the same, but the standards may differ in the statistical handling of QC and QA data that are generally far higher and with more precise tolerances for equipment that will be used within judicial processes.

My role as Senior Medical Technologist includes also working closely with our R&D teams, particularly in the assessment of regulatory and other QA standards to prepare our teams to meet or exceed those standards, and to assist in the development of standardised test procedures covering all needs. In the documentation process this includes paper worksheets and electronic data downloaded from instrument interface and the software applications that allow comparison of one data set against others.

We approach much of this work in a standardised manner. However, on occasions some variation is necessary, perhaps for a new technological development or application, a new quality standard imposed on our customers, or perhaps simply because we investigate new ways to improve existing processes based on the needs of our customers, developments of our competitors, and a desire to improve QA and performance standards for our entire product portfolio.

2. A. Application of knowledge and understanding

2. Exercise sound judgement in the absence of complete information and in complex or unpredictable situations.

When checking equipment for its pre-delivery or installation assessment, the cause of any variation in performance and quality is unlikely to be a design or manufacturing deficiency. Most likely it is some residual contamination present in sample or reagent tubing, perhaps picked up from packaging materials, or from unexpected mechanical damage occurring during shipping.

Our first approach is to follow an instrument- or component-specific fault finder flowchart. This usually allows us to resolve all but a small number of issues. Those which cannot be resolved will be approached on the basis of knowledge of the technologist or product specialist. On some occasions, cases will be referred to me for advice and suggestions that will be directed at resolution but, on rare occasions, result in product replacement.

We are able to learn from every variance and the field reports and all relevant data are added to a larger database. From this, I will review and as necessary revise our troubleshooting flowsheets, enrolling support from manufacturing and engineering staff, from R&D teams and from my own team as appropriate.

As the main US R&D teams develop new or improved instruments, we are informed in advance. This allows us to investigate the prevailing and impending QA standards to which they have designed, and for myself and my team to consider the practical impact on our pre- and post-delivery assessments and QA checks. This may sometimes necessitate learning a new technique of application when a novel technology is introduced. In this case, we will gather information from our R&D colleagues, and I will study the new instrument or technology in great detail. Usually working with a relevant product specialist and/or another member of the team, we will endeavour to get up to speed long before we receive a first shipment of

instruments and spares. We will identify reagent requirements that are likely to be different from those used in the US.

We attempt to predict likely problem areas and draft a troubleshooting guide. We have time to study all manuals and technical spec sheets, and will take time to examine in detail the first instruments received. In this way, we are able to support our customers with the best possible service standards, without delay, and to UK rather than US performance standards.

Having learned much about the new product line, I place myself in a position where I can train and support my other team members, ensuring continuity of support and service standards for all of our customers.

3. A. Application of knowledge and understanding

3. Demonstrate critical evaluation of relevant scientific information and concepts to propose solutions to problems

When I or one of my team members cannot bring an instrument back into a satisfactory standard of accuracy, precision and reproducibility, and when all fault finding checklists have proved unhelpful, we may decide to provide a replacement instrument and return the defective equipment to our service laboratory for more detailed examination. This is not always a realistic option since, in the event of a multi-channel analyser or large and complex GC-MS instrument there may be several practical constraints.

It is a decision I must take, to support our customer and return their instrumentation to working conditions, hopefully quickly and without excessive cost. If a replacement is required, we endeavour to do this within 24 hours. If this cannot be done, I will speak with the client, with our field technician and engineer, and consult the various technical resources I have available. A solution may be to replace a single channel instrument and isolate that inbuilt channel in the defective instrument. I will also consult with the senior engineer and request a review of service interventions, component checks and replacement etc. I also consult the US knowledgebase to gather any other helpful intervention.

I always work to get customers up and running with minimal delay, and return their work to the required accuracy and QA certification state. This sometimes involves thinking outside the box, to change the assay reagents perhaps to one using a different fluorochrome such that excitation and secondary filters can be changed as this can sometimes rectify the problem. Other examples have been found by several team members and I make sure that we share these tips and tricks, so that we retain compliance with relevant regulatory and performance standards with each other and throughout the company.

The client may have concerns about a ‘fix’ that they believe might risk regulatory compliance or introduce some unwanted irregularity in their ongoing research studies. The ultimate decision rests with the client. However, it is my responsibility to maintain fully up-to-date not only with the various regulatory and other standards applicable to those analyses performed with our instruments, but remain close to those regulatory and standards organisations, to fully understand any permitted flexibilities and variations and to advise our clients accordingly at the time of their crisis.

4. B. Personal Responsibility

1. Work autonomously and take responsibility for the work of self and others.

I am required to set my own timetable and task schedule, and the schedules for my team. Response times are guaranteed by the company and that takes priority over everything else. Occasionally, demands may outstrip the availability of technologist staff, and especially of product specialists at times of holiday or

sickness absence and when successive calls are geographically widely separated incurring considerable travel time.

We manage this as best we can, all pulling together. Where priorities must be ranked, I prioritise hospital calls in line with company policy, followed by calls to support regulators, police, Customs etc. We also try to give the best possible support to new customers but this is not always possible.

I am conscious of the working hours of myself and my team, and will always try to accommodate their rest periods, to maintain their health and welfare but also to ensure that errors do not creep into our work due to tiredness and lack of concentration etc. I am responsible for ensuring my team members adhere to company driving policy and do not exceed maximum driving hours without a full intervening rest period, and that this is quality rest away from working and not simply away from the vehicle.

For the first year in this current post, I was reporting at regular intervals to my appointed line manager. Subsequently, this has fallen to an annual appraisal though I can call on her for advice and support, and to request new or additional resources whenever needed.

5. B. Personal Responsibility

2. Promote and implement robust policies and protocols relating to health, safety and security.

The Company is aware that any of its instruments may be used with biological materials of human or animal origin, with hazardous chemicals and with narcotic residues. There are additional mechanical and electrical risks.

It is Company policy to require full or component decontamination before any maintenance intervention. Thus, if our initial testing and adjustment fails to return QA performance to within limits, then the system must be decontaminated. We may request that our customers do this decontamination, but generally prefer to do it ourselves to satisfy us that decontamination is complete and appropriate for all likely risks.

When handling instruments of components for decontamination, adjustment or repair, and recalibration and QA testing, we each wear appropriate protective equipment comprising a clean lab coat and nitrile gloves, and additionally a disposable cap, goggles and facemask is required by the customer’s lab standards or some feature of the decontamination process.

Compliance is not negotiable and the entire team is aware that this is essential. Safety precautions are noted as a simple checklist on field worksheets. Safety supplies or PPE and decontamination products are carried be each one of us, but we will often relay also on the customer’s own supplies, and for safe disposal of same.

Very occasionally, a customer will vary from the recommended care instructions for one of our instruments, using decontamination procedures that deviate from those which we recommend and that appear on our user manual. When this happens, we rely on the experience of the technologist to decide if that variation is adequate, for the instrument protection and for their own safety and the safety of others. Where there is any disagreement, this is referred to me. Though I have the authority to stop our staff from working on an instrument when the customer has varied from our recommendations, this has never happened and in each of the few cases that have arisen we have resolved differences amicably.

6. B. Personal Responsibility

3. Promote and ensure compliance with all relevant regulatory requirements and quality standards.

This requirement is at the core of all our work, as described above.

To do my work I must comply with all appropriate company and statutory regulatory requirements to ensure the health, safety and welfare of myself, my team and my customers. As we deal with a wide variety of potentially hazardous reagents and other products I must ensure we all comply with the requirements of COSHH. Making this still more difficult, we are exposed on occasions to controlled drug products, as test samples and calibration standards and must comply with the appropriate security and other regulations regarding their storage, use and disposal.

When I or my team visits a customer, we must be careful to comply with their own safety requirements and may have to undergo a site induction and sign a note regarding safety compliance.

The basis of our work is to ensure that our instruments can deliver to customers a reliable and QA certified analytical platform. To ensure that this is so, we must each remain conversant with UK and other regulatory and other standards applicable to healthcare and clinical chemistry, to pharmaceutical manufacture, and to any other application that our customers may require. Though we are exclusively UK based, this may include regulations and standards applicable mainly outside the UK but within the territories appropriate to our customers' business.

To achieve this, our US parent maintains a global database of applicable standards that is available to me at all times. I must remain up-to-date and aware of any recent changes, though we have a flag system to identify new or revised documentation. I am however occasionally caught out by a customer who plans to use our equipment in an area that we hadn't foreseen. In this case, I will gather as much information as possible from the customer, access original copies of relevant regulatory or other standards to which we will be required to comply, and to disseminate this information to my team and to our US colleagues such that they can update their database content for the benefit of everyone in the Company.

7. B. Personal Responsibility

4. Oversee the implementation of solutions with due regard to the wider environment and broader context.

I must ensure that my own work and the work of my team members is compliant with the Company ethos and operational standards, with our H&S obligations and with all other prevailing standards. Among these are the environmental regulations that dictate our approach to work, to the production of our instrumentation and management of manufacturing wastes, and to the management of packaging wastes. We do not manufacture but do use and supply many reagents, calibrators and other chemicals and have a responsibility for their safe use, storage and transport, and the disposal of those reagents and the containers in which they are supplied and used.

In the undertaking of our work, we often replace electrical and electronic components, and this creates additional demands regarding environmentally compliant disposal. In the first instance, we may return these components to base for more detailed examination, and perhaps ship them back to US or directly to a subsidiary manufacturer. At all times, we hold responsibility for safe packaging and transport, and for compliant final disposal. We do not permit removed components to be tossed into any waste bin, other than one that is dedicated that to the compliant disposal or waste electronic and electrical equipment (WEEE). This becomes even more serious when we need to dispose of microprocessors that may contain proprietary information. In this case, chips are first flashed to erase all sensitive information that may

include in some cases personal information relating to patients or to those under investigation for possible criminal activities.

8. C. Interpersonal Skills

1. Demonstrate the ability to communicate effectively with specialist and non-specialist audiences.

It is essential that I communicate effectively with members of my team, and with other sales, delivery and installation teams, with the procurement and inventory section, with our US parent, and with our clients.

Communication is generally via email, with phone calls when convenient between team members. Within the team, we rarely meet on a regular basis but I make a point of keeping in touch every few days, if only to check that there are no unresolved concerns.

We occasionally receive clients to Instrumon Industries (UK) plc, generally invited by the sales teams but visiting our workshops and laboratory to be reassured about the level of support they can rely upon. We do not show too much of the work in progress, of equipment under repair, but I do demonstrate our calibration and pre-delivery Quality Assurance checking processes, and the installation support they will receive. This is particularly importance since we will cover matters not covered by out trainers. Thus, we do not teach about the normal use of an instrument but of its installation requirements that may include exhaust ventilation, piped gas supplies, and 3-Phase power supply. My presentations to clients and potential customers is thus complimentary to the presentations given by sales and the post-sales training team.

Though we have only modest turnover of staff, I am responsible also for the introductory part of new staff inductions, and subsequently overseeing their in-service training as they rotate through different team sections. I must also make sure I deliver various mandatory training sets, and arrange for on-line training and self-assessment in Company HR, data protection, confidentiality and related core packages that are required for every employee. When new starters struggle with these, I must provide support, or arrange support from one of my team to support the individual.

9. C. Interpersonal Skills

2. Demonstrate effective leadership through the ability to guide, influence, inspire and empathise with others.

It is my responsibility to ensure that we deliver the best possible service to our customers, being responsive to their particular needs and demands.

I must ensure that I am fully up-to-date with current trends in quality management and in the developments in instrumentation and reagent use applicable to a diversity of analyses applicable to our business sector and instrumentation portfolio.

I make sure to share that knowledge with my team, and with colleagues in other Departments. In some situations, an issue may be understood far better by one of the product specialists than by myself and I do what I can to learn from them.

I ensure that other knowledge acquisition is share extensively, to support my team and our clients. As we rarely hold formal meetings, I summarise new useful information by email, and ensure that I provide a fully detailed briefing note and technical worksheet that can be accessed online from our secure server.

At times, I must place myself between team members and clients, at times when workload is great or when an instrument is giving particular problems. It is my role to keep everyone happy. Internally, this is particularly necessary when excessive workloads, perhaps with large travel distances, place extra pressures on us. This might require redistribution of workload among team members or stepping in myself to help out. Alternatively, I might take the decision to provide a temporary replacement instrument to ease the situation. Since this puts extra costs on the Company, and additional workload for our delivery and installation team it is rarely the preferred option. However, in the few occasions I have taken this decision there has not been any adverse repercussions and the focus in on the support of both customers and staff.

10. C. Interpersonal Skills

3. Demonstrate the ability to mediate, develop and maintain positive working relationships.

My team work well both together and individually, and I work hard to make that continue. We have few problems, except from occasional high workload issues that I try to resolve as described above.

We rarely have any real discord with our clients, but this has happened when successive breakdowns and/or Quality Assurance failures have occurred. Since these will be hugely disruptive to the customer and their work, we work hard to resolve these issues.

Generally, a second of subsequent performance failure will be unrelated to a previous issue but this does happen when we have a new issue not previously recognised, or when a client is using a reagent or consumable item that we have not checked and approved and which is the cause of unacceptable variance in performance.

In this circumstance, we double check our findings and check against our knowledgebase, and advise accordingly. Only once have I had to deal with a disgruntled client who had purchased on a call-off arrangement a costly reagent kit that was not suitable for use. This accusation was that we should have flagged this prospectively, though how we could be expected to check every possible non-compliant third part product and list these in our literature is difficult to understand.

To keep everyone happy and resolve the situation, I got approval to supply the client with a modest supply of an approved product at our expense, to get them up and running again without delay. I also phoned the supplier to encourage them to cancel the call-off order.

As this situation could be repeated, I have run an extensive series of tests in-house, to identify the underlying cause of incompatibility. This work is on-going, but it does appear that we can provide a software modification to accommodate this variant reagent kit product. When this work is complete, and I have had my results double-checked by a colleague, I will send product samples and a technical report to our US headquarters for confirmation. Subsequently, a commercial decision will be made as to whether or not we will implement this ‘fix’.

In my report, I have given some preliminary appraisal of the market share that the non-compliant reagent packs hold in the UK; it seems large enough, and is provided by a major supplier, so we must take this seriously. If we implement a software fix this must be implemented only when these kits are in use and not with others. A standard solution to this problem is to agree with the producer to uniquely barcode their product to give not only the test type but also to flag the need to capture data with the revised software option. Thus, any product will become compliant but without any possibility of a mix-up giving poor results quality.

11. D. Professional Practice

1. Scope, plan and manage multifaceted projects.

My responsibility for precision performance, reliability and Quality Assurance testing spans over fourteen different instrument modalities and for each of these several major versions. I must remain conversant with all these, and as time passes and new or improved equipment is brought to market the list continues to grow. It is not improbably that every revision has its own requirements, and often significant technical and performance differences that make Quality Assurance certification particularly complex.

Across the UK, we have several thousand instruments in use, often in applications that require certification against rigorous Home Office or Department of Health/Medicines Commission standards but also against overseas standards that are applicable to our customers' spheres of operation.

There is little opportunity for me to initiate new projects since this begins with our R&D teams in US. However, we can act as the eyes and ears of the Company and I have on several occasions fed back information to advise regarding customer requirements and/or unexpected and novel applications of our equipment items. Occasionally I am asked to provide further details and have found on one occasion reference to a novel application that I first reported in our literature.

12. D. Professional Practice

2. Demonstrate the achievement of desired outcomes with the effective management of resources and risks.

My work with non-compliant third party reagent packs is a recent and strong example of this, and is described above.

Other examples include the use and further development of our checklist worksheets. This is a development of mine, that includes provision for capture of key customer information, instrument details, serial number etc., a description of any known problems, and the results of preliminary QA testing, any adjustments made, and QA outcomes. These checklists now include coded links to our local knowledgebase, and where necessary to the main US knowledgebase. This provides immediate online access to solutions and workarounds that can support our customers.

I am always available for my team, and can be contacted at any time, to provide technical support and guidance, and to mobilise other resources that may be required such as urgent instrument replacement.

13. D. Professional Practice

3. Take responsibility for continuous performance improvement both at a personal level and in a wider organisational context.

I keep a constant eye on technical and related developments that impact on our instrument range, and the work of our clients. This includes reading many reviews and original articles, and attendance at conferences and workshops, most particular workshops organised by Instrumon Industries.

These Instrumom workshops are often sales-related, seeing new customers or client upgrades. However, they are an ideal forum in which to network, to pick up on ideas, trends and current thinking that might impact on our commercial activities. This aspect of my work contributes considerably, perhaps more than 50%, to my own professional development. Most of these activities contribute to my CPD, and will often lead to yet wider opportunities for professional developments for me and for members of my team.

My line manager has raised the possibility of sponsorship for me to advance further in the Company, either in R&D or in a wider managerial role. I refer the R&D role as this would include the opportunity of yet more hands-on science. However, it has also been suggested that I could get funding for an MBA if I want this, as a stepping stone to an entirely management position. As yet, I am undecided but favour at present to scientific route rather than becoming a professional manager.

14. E. Professionalism

1. Demonstrate understanding and compliance with relevant codes of conduct.

With a background in university research my own product specialty is the ELISA reader range and associated software packs. However, as it is a major part of our product portfolio I also lead on the support of evidential alcometers and ion drug detection equipment.

This brings me into close contact with relevant regulators and with the Home Office, as well as endusers. Since these are items of equipment used by individuals with almost no scientific background and perhaps minimal training, the risks are high. Individuals may end up in Court or worse depending on the results of analyses run on our machines. This, as well as compliance with relevant codes and standards, is a primary concern for us, and is the driver behind our constant drive for excellence.

I must adhere to the Company Codes of Professional Standards and of Health & Safety, as well as to all HR Codes of Conduct. I am first line manager for a small team and must ensure their compliance also. I must also ensure that my own work, and the work of my group, is compliant with overarching Health & Safety legislation including, among others, COSHH. We all comply with our customer's relevant Codes and undertakings when visiting and working on their premises, and comply with data protection obligations to secure any personal data that may be help within instrument software systems.

I have been a member of the Royal Society of Biology for over 10 years and am happy to adhere to their rules and Code of Conduct. In accord with the additional expectation of Instrumon Industries (UK) plc, I adhere also to The UK Department for Business, Innovation & Skills (previously the Department of Trade and Industry (DTI)) Universal Ethical Code for Scientists.

15. E. Professionalism

2. Demonstrate a commitment to professional development through continuing advancement of own knowledge, understanding and competence.

I enjoy the opportunities that my current post provides, to attend conferences and visit a wide diversity of laboratories, engaging with scientists and instrument users throughout the UK. I also meet and work with many regulators, policy makers and others working on aspects to standards development that may involve assays run on our instrumentation. Together, most of this contributes also to my CPD record.

This is essential in my role, since I must be aware of and understand what our clients are doing with our instruments, why and how, and what regulatory standards they are obliged to meet. This necessitates working closely with regulators and standards organisations, with whom we foster a good working relationship. We can make representation to ISO, EN and BS standards groups, to make representation where appropriate and to bring back to Instrumon Industries information regarding performance standards that are expected of our clients and of the Instrumon analysers that they use.

Career Overview/Prof. Background

Senior Medical Technologist
Instrumon Industries (UK) plc,
2005 – to date

1997 – 2005
Analytical Service and Product Quality Officer
Big Pharma plc

I moved to the Analytical Service section of Big Pharma plc, with a responsibility for quality and purity assays using a range of analytical techniques of raw materials, intermediate and final pharmaceutical products, and for screening for product for contaminants.

Though it was not a main responsibility, I was taught also the use of a range of instrumentation to assess, for example, the resilience of compressed tablets, and the dissolution rate of film coated tablets and capsules, teaching me to use a different range of equipment and techniques, and approaches to quality assurance assessments for product QC and regulatory compliance.

1996 - 1997
Research Technician
Big Pharma plc

I was initially employed by Big Pharma plc to support the research activities of a group using ELISA and other techniques to develop gene splicing into plant tissues with a view to the development of antibody production in plant crops, using techniques now successfully employed for therapeutic and diagnostic Ebola virus antibodies.

1991 – 1996
Laboratory Support Technician (Teaching)
University College of Birmingham
Division of Plant Biology

In this role, I developed a particular interest in ELISA assays and, of necessity, in the care and preparation, the calibration, maintenance and cleaning, and repair of analytical instruments.

Declaration
Signed: 2016-06-01