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Science and Technology Feature

Review of core principles and best practice in the teaching of aseptic manufacturing in UK Schools of Pharmacy

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As a Level 7 MPharm project, a study was carried out on how the Schools of Pharmacy within the United Kingdom teach aseptic technique to undergraduate students. A questionnaire with open questions was sent to all the schools offering a validated Master of Pharmacy degree in the academic year 2010–2011. The data were then used to design a second questionnaire with closed questions. The responses were analysed and areas of good practice identified. How these areas may be incorporated into the Liverpool John Moores University programmes is discussed.

Key words: Aseptic Manufacture, Cleanroom, Education, Clothing, School of Pharmacy, Environmental Monitoring.

Introduction

The aim of this paper is two-fold. Firstly, it will give industry an understanding of the expertise that might be expected of Master of Pharmacy (MPharm) graduates and, secondly, inform the teaching of aseptic manufacture in universities in the United Kingdom. This study was carried out by Mohammed Sheikh[1] as a final year MPharm project.

Aseptic manufacture is an example of a skill that requires the ability to use very specialised equipment where failure to carry it out correctly can be potentially life-threatening to the patient. For many reasons discussed below, it is not possible to replicate the conditions used in industry. Therefore, one must try to achieve the best simulation of these conditions.

Certain pharmaceutical products must be sterile[2]. Examples are those for delivery under the skin, such as infusions, injections and total parenteral nutrition (TPN) solutions, and those for use in the eye. Where the product cannot be sterilised in its final container, it must be manufactured aseptically under controlled conditions[3]. This work is carried out in a cleanroom – a carefully controlled environment designed to minimise microbial and particulate contamination[3]. While most of these products are made on an industrial scale, the hospital pharmacist is required to make some of these products extemporaneously. Aseptic technique is, therefore, an important skill for the pharmacy graduate.

There are 29 schools offering a Master of Pharmacy course in the academic year 2013–2014 (http://pharmacyregulation.org/education/pharmacist/accredited-mpharm-degrees, accessed 27 February 2014). Some of these have been teaching pharmacy for over 150 years and some only began in 2013. They all have different aseptic facilities and staff expertise and, consequently, have their own approach to teaching. All teach 4 years of the MPharm programme at University, although some now integrate the pre-registration year into a 5-year programme. The final university year is referred to as M level or Level 7.

A search of the internet using standard search engines and literature databases uncovered very little information on the teaching of aseptic manufacturing in higher education. Furthermore, the General Pharmaceutical Council gives very little guidance on what should be taught. The General Pharmaceutical Council also says very little about aseptic training in *Future Pharmacists: Standards for the Initial Education and Training of Pharmacists* (see Outcomes [10.2.3] and Appendix 1, A1,1)[4]. Given the lack of guidance, there is a great deal of variation in the way aseptic technique is taught in universities in the UK.

There are many issues to consider with respect to teaching aseptic manufacturing. Several factors make it impossible to replicate the industrial or hospital cleanroom environment,

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including the need for expensive, highly specialised equipment and the fact that the more people in the cleanroom the greater the risk of contamination. Professional training requires that the trainee complete several hundred media fills, i.e. performing aseptic transfers without introducing any contamination.

The aim of this project was to explore how aseptic technique is taught in UK universities and to promote examples of good practice and discourage bad practice if it is found. The information will have value in developing aseptic teaching at Liverpool John Moores University (LJMU), in guidance for other Schools of Pharmacy, especially those that are newly validated, and in giving employers some guidance in what might be expected of graduates.

Method

The questions we particularly wanted to address were as follows.

1. What equipment is available?
2. Who teaches it?
3. How many students are taught at one time?
4. What clothing do students wear?
5. Where does it fit into MPharm and other programmes?
6. What teaching resources are used to support the activities?
7. What exercises do the students carry out?
8. How is the work assessed?

In order to design a suitable questionnaire, a preliminary questionnaire of eight questions was sent out to the Head of Pharmaceutics at the Schools of Pharmacy in the UK asking the above as open questions. Of 26 Schools to whom questionnaires were sent, 11 replied (42.3%). These responses were then used to design the main questionnaire with 20 closed and three open questions. There were 16 responses (61.5%) to the second questionnaire.

Results

The results presented here show the key findings from the second questionnaire.

What equipment is available?

This is the area in which one might expect the greatest variability. Equipment, such as cleanrooms, isolators and uni-directional (sometimes also called laminar) airflow cabinets are not only expensive to buy but also to maintain. The uni-directional airflow cabinets (UDAFs) recently bought at LJMU cost in the order of £3000 each. Prospective students attending for interview were told that the new cleanroom suite at Cardiff University cost about £1,000,000. Commercially, such equipment must be regularly tested and maintained, something normally beyond the teaching budget of a School of Pharmacy, but this may be financed if the facility can be used for research or commercially, such as the facility at Cardiff University. However, to do this, a number of licences must be held including Manufacturer Investigational Medicinal Products (MIAIMP) License for clinical trials, a Manufacturer's/Importer's License (MIA) and a Wholesale Dealer (GSL) Licence (WDL) amongst other requirements. (www.cardiff.ac.uk/phrmy/research/Research%20Office/Research%20Facilities/gmp-suite.html; accessed 27 February 2014).

For sterile products manufacture, the cleanliness of the manufacturing environment is graded A–D[3] depending on the number of particles

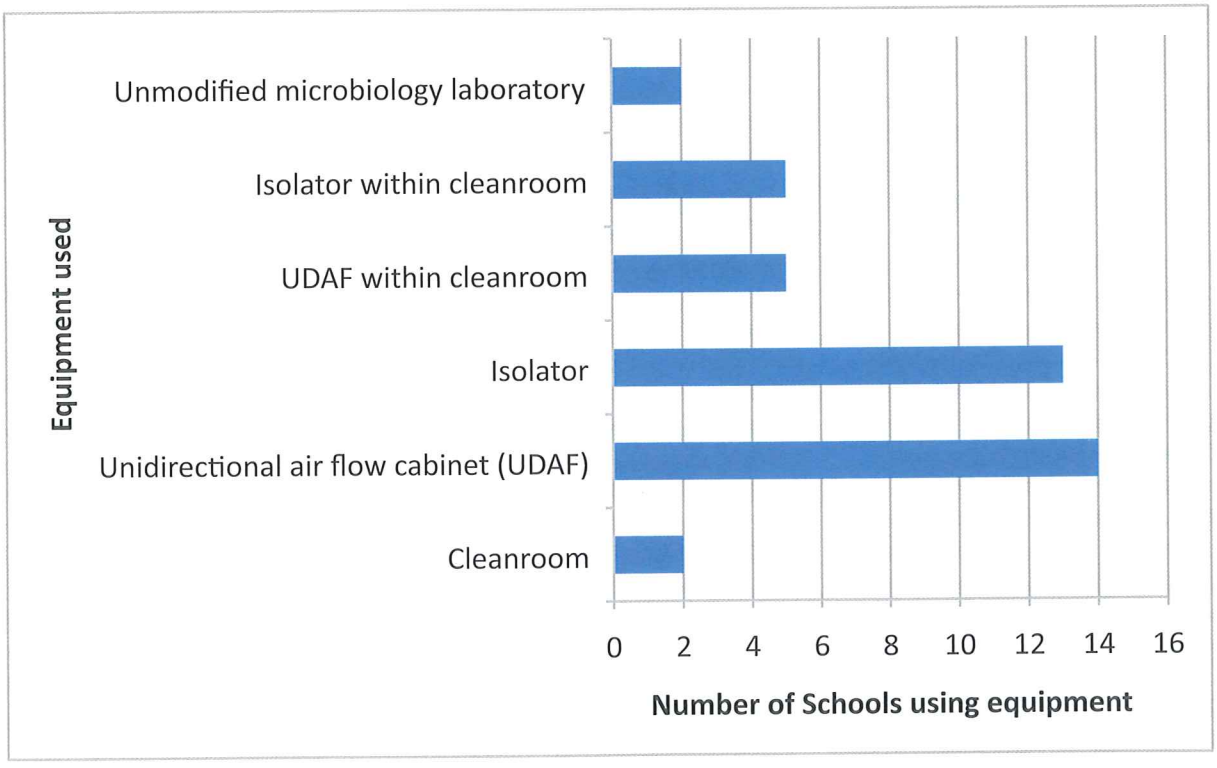

Figure 1. The number of Schools of Pharmacy using cleanrooms, UDAFs and isolators.

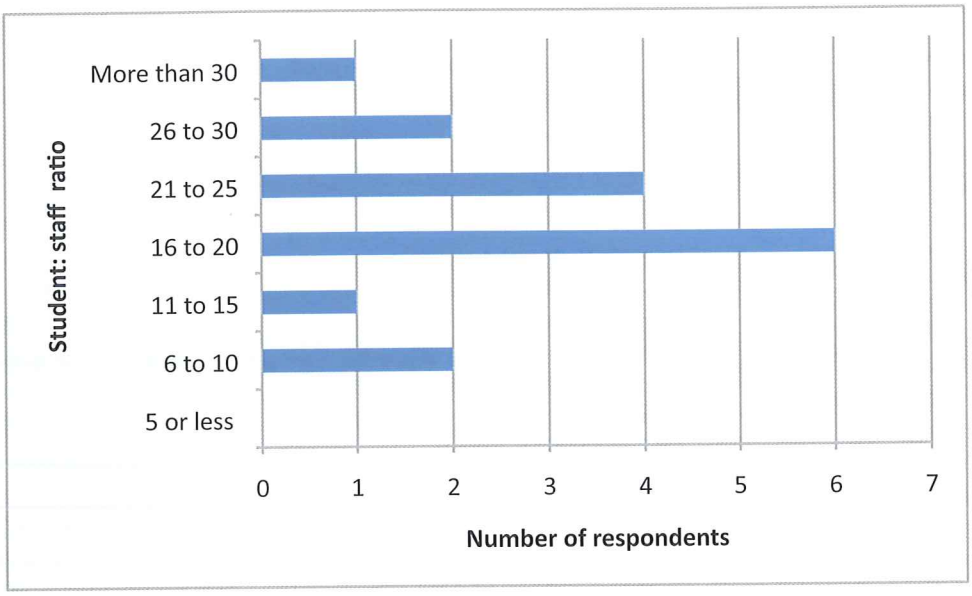

Figure 2. Distribution of class sizes in the aseptic lab.

and attributes of microbial cleanliness[3]. For aseptic processing work, grade A air is achieved using a traditional unidirectional airflow cabinet (UDAF) in a grade B surrounding room or an isolator in a room of grade D or better. **Figure 1** shows the collated responses. The most common type of equipment is the UDAF. These have the advantage that they are easier to use than isolators, and are, consequently, more popular with students based on ease of manipulation, although an isolator is more able to maintain integrity. UDAFs are also portable and further cabinets can be added when required, whereas isolators are much larger and more expensive. Two schools use an ordinary microbiology laboratory.

Who teaches aseptic technique?

Staff teaching aseptic technique are spread over Pharmaceutics/Dosage Form, Microbiology and Pharmacy Practice (data not shown). Four of the 16 respondents had been given no continuing professional development (CPD) in aseptic training. Of those who had training, five had previously worked in the NHS and two in industry. Seven respondents had been to workshops or meetings.

How many students are taught at one time?

It is widely accepted that people are one of the main sources of cleanroom contamination[5]. It is, therefore, not surprising that manufacturing should be carried out with the minimum number of operators[3]. It is unrealistic to teach a cohort of 180 students in groups of two so a compromise measure must be adopted. The upper limit on class size is usually the number of UDAF cabinets or isolators available.

Figure 2 shows the range of class sizes reported. The most common class size is 16 to 20, with only three schools (19%) attempting to teach more than 25 students at once and only one teaching more than 30. None of the responding schools teaches less than 5 in a class.

Another important consideration is the student:staff ratio. The lower the ratio, the more time is available for observation and feedback. However, availability of suitable staff puts a constraint on the lower limits. Two schools reported a ratio of between 1:6 and 1:10 and seven between 1:11 and 1:15 (data not shown). Three schools had a ratio of between 1:16 and 1:20 and four had a ratio as high as 1:20–1:25. None were above 25. The latter ratio is normally the upper limit allowed by Health and Safety at most institutions.

What clothing do the students wear?

Figure 3 shows the types of clothing worn. Ideally, the operator would wear a full cleanroom suit covering the entire body, including face and hair, to minimise the shedding of particles from the body. In reality, the cost and time taken to put on the clothing precludes this. It is more informative here to look at what is not worn. Ten out of 16 (62.5%) schools do not use safety glasses and six out of 16 (37.5%) do not use gloves. The hands are used for all manipulations and are, therefore, always close to the materials manipulated. One would thus expect gloves to be worn for any aseptic work. Only one school uses Tyvek® suits, the sort with which any viewer of television forensic dramas will be familiar. These provide better protection of the environment but are single use garments.

These data show a shortcoming in the design of the questionnaire which only asked about single items and thus leaves the study devoid of any information on combinations of equipment.

Where does the aseptic teaching fit into MPharm and other programmes?

The questions were designed to find out how the teaching of aseptic work fits into the programmes run by the schools. Five schools teach the subject in the second year, nine in the third year and two at Masters level. Nine schools teach it exclusively in

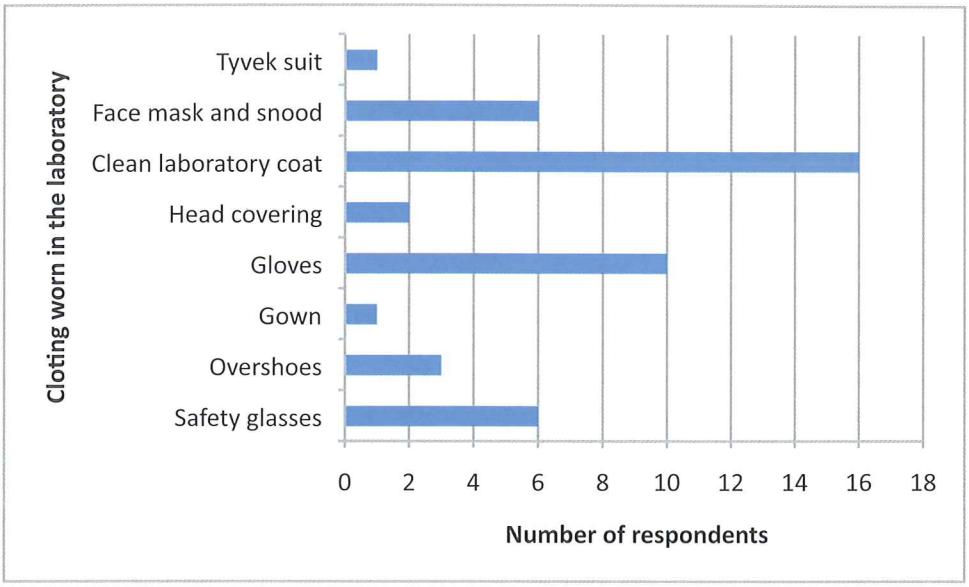

Figure 3. Clothing worn in the aseptic laboratory.

one module and the remainder spread it out across several modules. Only three schools (19%) teach it on courses other than MPharm. This was not specified on the questionnaire but many schools run a Pharmaceutical Sciences or similar 3-year honours course.

What teaching resources are used to support the activities?

All 16 schools gave a demonstration within the laboratory and all but one provided students with a standard operating procedure (SOP). Only nine listed lecturers and technicians but one wonders if this was an oversight and should have been specified on the questionnaire. Computer-aided learning (CAL) is also widely used. The associated lectures at all schools cover similar topics: sterilisation, cleanroom design, microbiology, good manufacturing practice and regulations.

Abbott[6] delivered a CAL package to Pharmacy undergraduates prior to attending the aseptic lab. Students found this a useful resource. When questioned about activities required to be completed by students prior to attending the laboratory, five schools stated that the students must complete COSSH (Control of Substances Hazardous to Health) forms and batch record sheets and two stated that students must complete dosage calculations.

What exercises do the students carry out?

Another area showing variation is the type of task carried out. Ideally, this should involve an aseptic transfer of the type that would be carried out in a hospital, backed up with environmental monitoring, product labelling and record keeping. In industry, an operator might do several hundred media fills as part of his or her training and accreditation. **Figure 4** shows the activities carried out. Activities include the following.

- Aseptic preparation of infusion bags.
- Aseptic preparation of syringes.
- Aseptic preparation of eye drops or lotions.
- Filling and sealing medicinal products, such as ampoules.
- Dispensing and labelling a sterile formulation.

Fourteen schools also tested their product for sterility. Only 12 of the schools mentioned environmental monitoring and only seven mentioned labelling, although this might be a result of a flaw in the design of the questionnaire. **Figure 5** shows a breakdown of environmental monitoring in response to the question, "How do you monitor the processing area?" Environmental monitoring involves measuring airflow rate, microbial contamination of surfaces and microbial and particulate contamination of the air. Such monitoring should be an integral part of record keeping. The simplest method is to qualitatively measure air quality using settle plates, where organisms in the air settle onto agar plates which are then incubated to yield colonies if there is contamination. It is not surprising, therefore, that this is the most commonly used method (13 out of the 14 schools that have controlled environments).

Fourteen schools carry out sterility tests on the products made. It should be pointed out that passing a pharmacopoeial sterility test does not guarantee sterility of a product, but is a regulatory requirement, and students need to be aware of where this testing fits into Quality Assurance.

How is the work assessed?

One of the most important aspects of any teaching is the assessment. Assessment is how we measure the extent to which learning outcomes have been met and there needs to be a good match between learning outcomes and assessment[7]. The types of assessment used are shown in **Figure 6**. Fourteen of the responding schools use observation, which seems the most appropriate for measuring a skill. The questionnaire

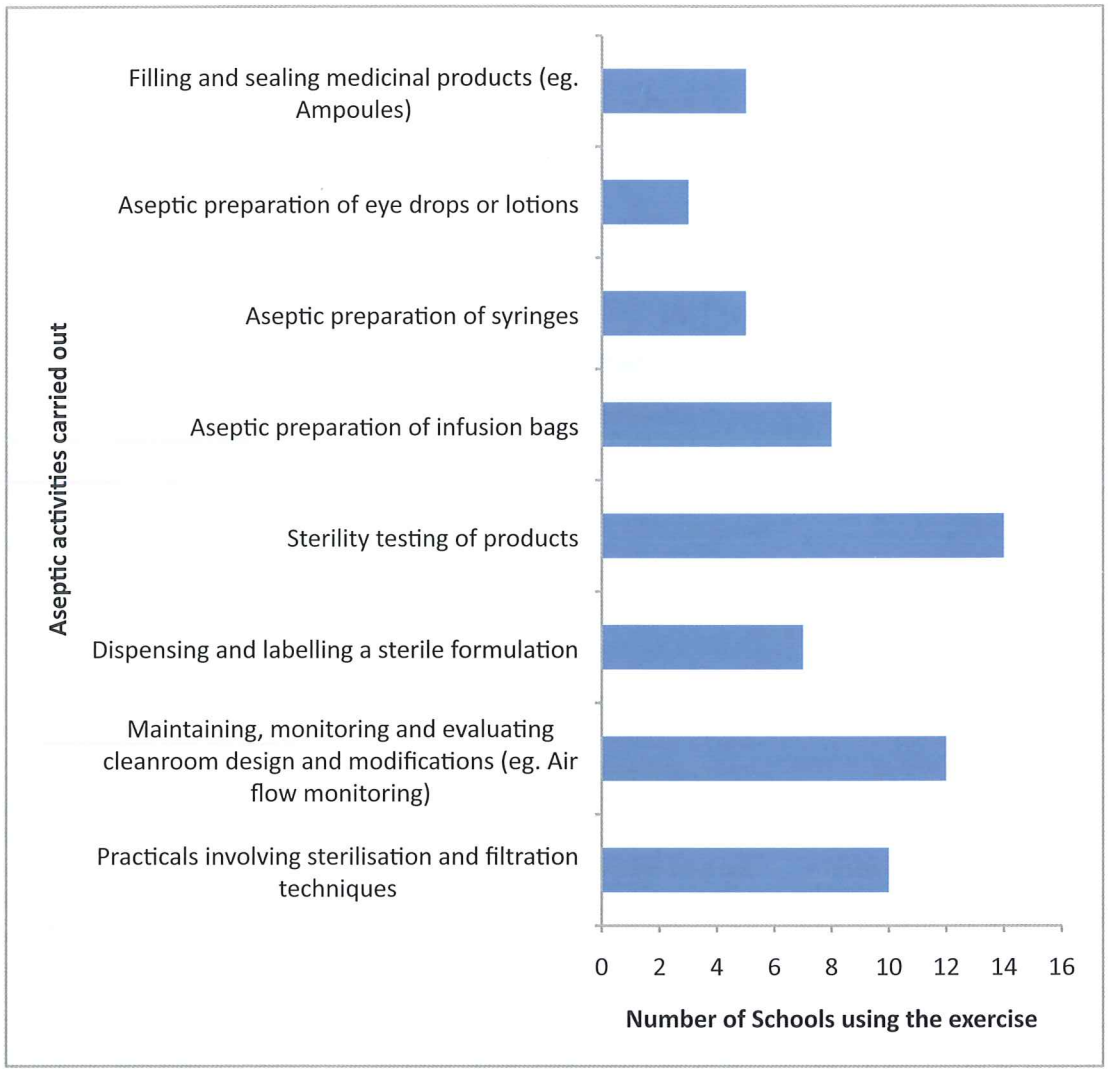

Figure 4. Exercises carried out in the laboratory.

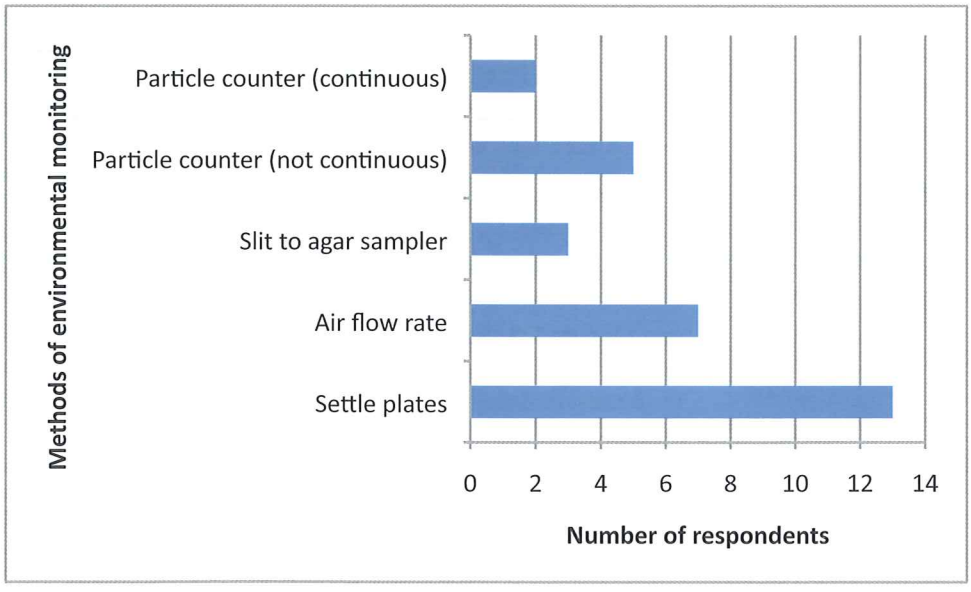

Figure 5. Environmental monitoring carried out.

did not ask about labelling or record keeping, but, in the preliminary questionnaire, only one school reported that they use observation, record keeping and labelling.

Discussion

The aim of this project was to identify areas of good practice. These are discussed under the topic headings of the results section. There were no aspects of bad practice that stood out.

Equipment

This is the area over which we have least control. Many of us are constrained by facilities that were chosen by somebody else, often before we began employment at an institution. To replace the current equipment would be too expensive and cause much disruption. Even if one has the luxury of starting from scratch on a newly accredited course, one has to decide, within budget, what to install. A state of the art cleanroom would show exactly how things are done, but, in practice, one might be very wary of letting students use it as they lack the skills and experience to prevent contamination, especially if more than one or two use it at a time. The other extreme is for students to perform the exercises on a normal laboratory bench. That way, large numbers can work at the same time. A compromise would be to have a number of isolators or UDAFs in an uncontrolled environment. That would allow about 20 students to work at a time and get some idea of the difficulties of working with these pieces of equipment and also of the environmental monitoring involved. It also has flexibility because more isolators or UDAFs can be added or old ones replaced as finances dictate. At least one School of Pharmacy, as I learned on a School Open Day, uses facilities in a local hospital. This has the advantage of students' using correctly validated facilities and performing realistic activities. It does, however, require a good working relationship with the hospital and could conceivably cause problems with timetabling and transportation.

At LJMU, we have six double isolators and nine UDAFs and these are situated in an open laboratory. New UDAFs have been added over the years. The equipment is not validated due to the cost.

Whatever facilities are available at or to a school will dominate the other aspects of the teaching.

Academic staff

The academic staff involved in teaching belong to Pharmacy Practice, Pharmaceutics or Microbiology. The history of the academic divisions within a School of Pharmacy would involve a project itself. However, one would expect staff with this expertise to be teaching aseptic work. Ideally, one would like to see the staff studying this topic as part of CPD. Organisations, such as PHARMIG (www.pharmig.org.uk/who-we-are.html), PHSS (The Pharmaceutical and Healthcare Society; www.phss.co.uk) and RPS (Royal Pharmaceutical Society; www.rpharms.com/home/home.asp), and many commercial companies provide conferences and training, but it often costs several hundred pounds per delegate. With recent cuts in higher education, funding this can be prohibitive. Another alternative is to visit local hospitals and pharmaceutical companies to see what they do. We at LJMU have been fortunate to do some training at Novartis in Liverpool. This presented a unique opportunity to observe the workings of a vaccine manufacturing site and to learn from their staff. We are also trying to establish cooperation with the Aseptic Services at the Liverpool University Hospital.

How many students are taught at one time?

When working within a Grade A environment, it is desirable to have only one or two people working in the area at any one time. To process 180 students in this way would mean using at least 90 sessions. For teaching purposes, it is common to

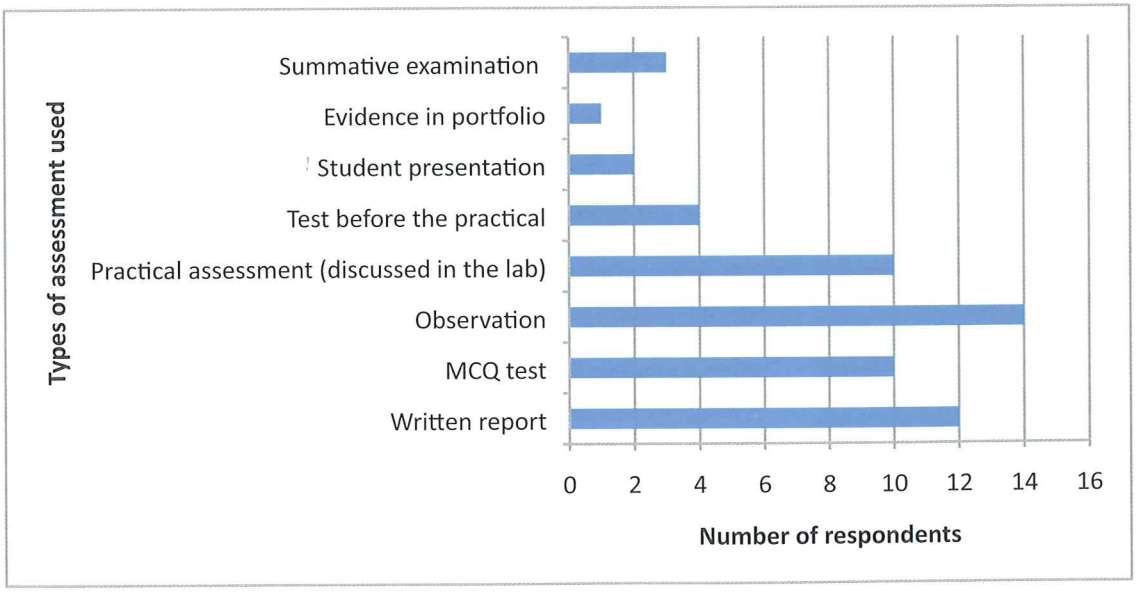

Figure 6. Methods of assessment.

allocate one student per UDAF or isolator. This would mean teaching up to 20 students per group in nine sittings. One would expect Health and Safety to set an upper limit on the number of people in a room and the student:staff ratio.

Student numbers are also influenced by the activities taking place. When students are being assessed by observation, it is difficult for one member of staff to deal with more than 10 students. At LJMU, we decided that the optimum was about 20 students supervised by two members of academic staff. This allows one to move around the laboratory and the other to mark labels and paperwork.

Clothing

Correct gowning is an integral part of professional manufacturing. Such gowning procedures are part of company training and involves its own SOP. Clothing in an aseptic environment should completely cover the operator to reduce the risk of any particles or microorganisms being shed thus contaminating the product. This process is time-consuming. It is also difficult to provide suitable clothing for large numbers. If the clothing is reusable then it must be adequately cleaned and sterilised between uses and must be of sufficient durability to withstand this. Disposable Tyvek® suits are expensive to use for large numbers although they may be no more expensive than reusable suits when decontamination costs are taken into account. It is, therefore, not surprising that most schools find a laboratory coat and gloves will suffice. This is not ideal as significant contamination may be transferred, but it is a compromise that is often necessary. Schools with more sophisticated licensed facilities will obviously need to use full gowning procedures. Correct gowning procedures can still be instilled into the student using photos, diagrams, animations or videos[8]. It was surprising that some schools did not insist that students wear safety glasses and gloves. Many institutions require students to wear safety spectacles for any laboratory classes, although this is to protect the eye rather than prevent contamination. We insist on safety spectacles, gloves and a white laboratory coat. This coat will be used in other classes. Ideally the students should wear a Howie coat that buttons to the neck and has elasticated cuffs, but providing such coats presents difficulties in cost and storing.

Where does aseptic teaching fit into MPharm and other programmes?

Fourteen of the schools (87.5%) teach aseptic technique in the second or third year, the other two teaching it at Masters level. It seems appropriate to teach this in second and third years as students need some microbiology background and the thought processes needed for aseptic work may not be fully developed in the first year.

Nine schools teach it in just one module and seven spread it across several modules. The obvious problem with modular courses is that, very often, topics are shoe-horned into what is often not the ideal module. LJMU requires all modules to be 24 credits, which often involves moving topics from one module to another. Aseptic technique is taught by the staff in Pharmaceutics, but is currently in a Pharmacy Practice module. This school is currently planning for a forthcoming reaccreditation. A more integrated approach will replace the discipline-based one now in use and aseptic manufacture will move to a more appropriate module.

Only three of the responding schools report teaching the subject on other degree courses. At LJMU, we offer a 3-year degree in Applied Chemical and Pharmaceutical Sciences (ACAPS), and aseptic technique is taught in a third year Pharmaceutics module.

What teaching resources are used to support the activities?

All 16 schools begin the aseptic class with a demonstration of the techniques to be used. Only one of them provides the students with an SOP. For the current academic year, we have introduced an SOP, not only for the exercise to be carried out but for the related procedures that the students do not carry out but need to be aware of, such as gowning and entry into a cleanroom. Other resources listed were CAL packages, videos and audiovisual aids. At LJMU, we show students videos produced by Valiteq (www.valiteq.com/fnimall/LABSAFETY/V1001D/product.phtml, accessed 31 March 2014) and MVI/Micron Training (www.mvitraining.com, accessed 3 March 2014). Five of the schools require students to do some work prior to coming to the class. At LJMU, we have decided that, in future, we will require students to perform dose calculations and read the SOPs before coming to the laboratory. Compliance will be monitored by the tracking facility in Blackboard (www.blackboard.com/International/EMEA/Overview.aspx?lang=en-us, accessed 3 March 2014).

Nine respondents mentioned staff as a resource in the section classified "other". It is more likely that this was an oversight on the part of these remaining respondents. Academic and technical staff are integral in providing support and maintaining a good working environment.

What exercises do the students carry out?

This is one of the areas over which we do have some control. The types of activity carried out are listed in **Figure 4**. Hospital pharmacists may be required to prepare syringes, infusion bags and eye drops and these are, therefore, good training exercises.

At LJMU, we have completed three exercises with our MPharm students. Two of these involved filling and sealing ampoules and one involved preparing eye drops. However, we have decided to replace the ampoule filling and sealing exercise, as hand sealing of ampoules is rarely done. Instead, we will do a simple exercise in which students learn how to disinfect a UDAF or isolator and then perform simple aseptic transfers into broth so contamination will be clearly visible. The other new exercise will be to add a "cytotoxic drug" (in fact, a coloured dye) to an infusion bag.

Only seven respondents mentioned labelling, although, on reflection, the questionnaire should have asked specifically about labelling and

record keeping. Twelve schools do some monitoring of the environment. The rigour of this monitoring will be dictated by the sophistication of the equipment. It is not advisable to measure airflow rates when the UDAF has not been serviced and the filters are clogged. The monitoring methods are then probably better taught using suitable videos.

Fourteen schools do a sterility test on the product. While it is good to demonstrate the sterility of the product, a single sterility test is of limited value[2]. This is why training exercises involve filling into broth so that contamination can be visualised. A sterility test must be carried out under aseptic conditions. Any substances that might inhibit growth, such as antibiotics and preservatives, must be inactivated and positive controls should be used to demonstrate that contamination could be detected. At LJMU, we used to get students to test a range of products showing the different inactivation methods. However, this was time-consuming for the students and the staff preparing the media, and we now test only the eye drops that our students manufacture.

Until recently, second year MPharm students worked in groups of four or five to plan and carry out the manufacture of a sterile product. Some products could be terminally sterilised and some needed to be made aseptically. This exercise brought home to the students the need for planning, the washing and sterilisation of components, the manufacturing process and sterility testing. We found this difficult to organise with a cohort of 180 students. However, it was the need to transfer a second year mini-project to the third year that led to the loss of this exercise within the course. We still use this mini-project in the final year ACAPS module for which we have about 50 students.

How is the work assessed?

This is where academics have total control. Fourteen out of 16 (87.5%) schools use direct observation. This allows us to see that students are carrying out procedures correctly and to give them suitable advice and feedback. Ten schools use a practical assessment that is discussed with students in the laboratory and 12 mark a written report. No further clarification was sought at the time, but this would be worth exploring further. One school assesses a portfolio which should have the advantage of exploring thought processes. Ten schools use a multiple choice question test, two use a student presentation and three test students with an exam. Four schools use a test before the practical. Unfortunately, the questionnaire failed to address combinations of methods. None of them mention labelling or record sheets. We have always used observation, deducting marks for poor technique, and assessment of labels and written records. We believe that nothing on the questionnaire represents a better practice. We contend that correct labels and record keeping are an indispensable part of manufacture. The theory behind the work, such as cleanroom design, clothing and monitoring can be assessed in written examinations.

How have we used the information at LJMU?

This current academic year (2013–2014), we have made a number of changes to our teaching of aseptic work in order to implement what we regard as good practice. Previously, the exercises carried out involved aseptic preparation of ampoules and of eye drops. It was felt that the ampoule filling exercise was no longer appropriate as it involves hand sealing of ampoules and students tended to be distracted from the filling process. For all exercises, students were given SOPs for all the key activities, such as disinfecting UDAFs, and a batch record sheet.

For the introductory class, we asked the students to carry out some media transfers. By using growth media, contamination is easy to detect. Students were given formative assessment on the sterility of the product and completion of the batch record sheet. Students were then asked to add a coloured solution to an infusion bag as a simulation of the addition of a cytotoxic drug to an infusion. Before coming to the laboratory, students were asked to calculate the required dose based on the allocated patient weight. Correct dilution was verified spectrophotometrically. The other exercise was to prepare eye drops based on WHO document WHO/PBL/01.83[9]. The product chosen was sodium cromoglycate preserved with either phenylmercuric nitrate or cetrimide. The preservatives were chosen to get students to think about their inactivation in a subsequent sterility test. Summative assessment for these tasks was the correct completion of the documentation and printing of appropriate labels. Students were observed throughout and marks deducted for any bad practice.

In a different module, the eye drops were subjected to a sterility test. The assessment for this exercise was a 2-page report.

Conclusion

We have investigated how 16 of the UK Schools of Pharmacy (50% of the current number) teach aseptic technique. We have identified good practice that we have decided to incorporate into teaching at LJMU.

Activities are constrained by the equipment available. However, we recommend that students should carry out some aseptic manipulations, preferably those that reflect what might be done in a hospital, in a real or simulated aseptic environment. Examples include aseptic media transfers, filling of ampoules, making additions to TPN bags and manufacturing eye drops. Where complete gowning is not essential, i.e. where a validated cleanroom is not used, students should still be aware of the correct procedures and their rationale. A juggling act is required for student numbers; keeping the number of students as low as possible in a particular cleanroom without having to run the class too many times. These numbers should be low enough to allow observational assessment of student activities and completion of appropriate paper records and labelling. Academic staff should be able to undertake aseptic training as part of their CPD.

Many courses will soon be undergoing reaccreditation and it is expected that changes will be greater than in the past.

Employers will no doubt deliver their own in-house training[10], but, with good teaching at university, the graduates will be better able to benefit from such training.

On reflection, some of the questions asked failed to gather the precise information sought, and it would be of great value to explore in more detail the tasks carried out and how they are assessed. A follow-up study in a year or two would be desirable to take into account new Schools of Pharmacy and modifications at more established institutions led by reaccreditation, and to ascertain LJMU's student feedback on the impact of the changes made this year.

References

1. Sheikh M. The teaching of aseptic manufacturing in Schools of Pharmacy. MPharm Honours Project, Liverpool John Moores University; 2011.
2. Ford J, Jones R. Sterile pharmaceutical products. In Hugo and Russell's Pharmaceutical Microbiology, 8th Edition. Denyer S, Hodges N, Gorman S, Eds. Oxford: Blackwell; 2011, Chapter 22, pp. 381–401.
3. Jones R, Chaudary S, Ehtezazi E, Ford J. Principles of GMP. In *Hugo and Russell's Pharmaceutical Microbiology, 8th Edition*. Denyer S, Hodges N, Gorman S, Eds. Oxford: Blackwell; 2011, Chapter 23.
4. General Pharmaceutical Council. *Future Pharmacists: Standards for the Initial Education and Training of Pharmacists*; 2011. www.pharmacyregulation.org/sites/default/files/Standards%20for%20the%20initial%20education%20and%20training%20of%20pharmacists.pdf, accessed 27 February 2014.
5. Reinmüller B, Ljungqvist B. Modern cleanroom clothing systems: people as a contamination source. *PDA J Pharmaceut Sci Technol* 2003;**57**(2):114–125.
6. Abbott C. A novel approach for teaching aseptic processing to pharmacy undergraduates. *Int J Pharmacy Practice* 2001;**September**:R23.
7. Jenkins A. 3.7 Assessment as learning; a departmental assessment strategy. In *Curriculum Design in Geography*. Cheltenham: Geography Discipline Network; 1998.
8. Jones RW. The use of moving images to enhance teaching. LJMU Learning Teaching Press 2007;**6**:17–24. www.ljmu.ac.uk/lid/lid_docs/LTPress_July_2007.pdf
9. WHO. The local small-scale preparation of eye drops: eye drop update; 2002. www.whqlibdoc.who.int/hq/2001/WHO_PBL_01.83.pdf, accessed 6 March 2014.
10. Dalmazio D. Current thoughts on module-based GMP training. *EJPPS* 2012;**17**:142–147.