

TECHNICIAN INVOLVEMENT IN MODERNISING A CLEAN ROOM

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Rebuilding the West Middlesex University Hospital provided the ideal opportunity to modernise the clean room. A pharmacy technician was among the key members of the team responsible for ensuring that the new facilities met the needs of staff and supported the licensing of the unit



Marion Taylor (right) and Clarissa Armstrong standing outside the newly-built West Middlesex University Hospital

Delivering patient-centred, high-quality health care was among the reasons to install a modern clean room, with isolators rather than laminar flow cabinets, at the West Middlesex University Hospital when it was being newly built as a result of a PFI (private finance initiative) project.

Among the key members of the team responsible for planning, commissioning and validating the new facilities was the senior technician at the hospital's technical services unit. This article explains the process adopted, highlighting the roles carried out by lead pharmacy technical services staff, according to the following action plan:

- Managing preliminary issues
- Setting up a project team
- Designing and constructing the clean room
- Commissioning, validating and handing over the clean room
- Training staff and implementing new ways of working
- Passing MHRA (Medicines and Healthcare products Regulatory Agency) inspections

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PRELIMINARY ISSUES

Plans for the clean room were drawn up as part of the tendering process to award the PFI contract for the new hospital. Meetings with the NHS quality assurance specialist pharmacist for London and inspectors from the Medicines and Healthcare products Regulatory Agency revealed that there were issues with these plans. In particular, important information required to license the facilities (such as details about the ducting systems to be used, isolator types, room pressures and room grades) was not included.

The way forward was, therefore, to engage trust executives to support the modification of the plans, advise the PFI contractors of the issues and suggest that a specialist clean-room firm be brought onboard to help design and commission the facilities.

PROJECT TEAM

Having brought onboard a specialist firm, a project team to manage the design and installation of the clean room was set up. This comprised the following members:

- Principal pharmacist, cancer services and technical services unit (project leader)
- Quality assurance specialist pharmacist for London (lead adviser)

- Senior technician, technical services (technical officer)
- Senior staff member from Daws Technologies, specialist clean room contractor (design contractor)
- Senior manager of Bouygues (main PFI contractors for hospital)

CLEAN ROOM DESIGN

The initial plans for the clean room required a certain amount of additional work before they could support the licensing of the facility. These designs were also complicated and it was believed that they could be simplified to ensure that the resulting clean room would be user-friendly, with good product workflow and comply with the European Union guide to good manufacturing practice.

Members of the project team therefore put together a specification that incorporated the main design features of the new clean room. An appreciation of current practice, the range of products manufactured and capacity played an important part in the final design. Examples of these features are set out in Panel 1 (p 254).

Building work then went ahead, according to the detailed specification. Every stage in the construction process was monitored closely, with the principal pharmacist, senior technician and quality assurance officer making regular site visits.

CLEAN ROOM COMMISSIONING

The next stage was the commissioning of the isolators and clean room. This needed to be done to strict timescales, so that the new facilities would already be running when the old ones were closed down. It was also important that the handover of the facilities fitted in with the handover timetable agreed on a hospital-wide basis.

The commissioning process included, for example, monitoring the critical performance criteria (ie, room pressure, air changes, temperature and humidity) and carrying out the environmental (eg, using settle plates) and physical monitoring required for validation. Monitoring of the critical performance criteria was performed automatically by the building maintenance system (an electronic system controlled from the plant room). In order to comply with licensing requirements, uninterrupted monitoring periods are required, and so access into the new clean room was restricted to the principal pharmacist, senior management from the PFI company and to those performing the environmental and physical assessments (ie, the senior technician).

It was also necessary to compile a validation master plan (VMP) — a quality assurance document providing evidence that the clean room would perform consistently to defined licensing standards. It comprises design, installation, operation and performance documents, put together by the relevant people (for example, the isolator manufacturers provide the necessary information and protocols about the isolator installation) and signed off appropriately at each stage.

In preparation for handover, the new facilities were cleaned by the specialist clean room

contractor and then by lead technical support staff. One of the final stages of commissioning was the MHRA inspections (see later).

All the time that the commissioning of the new facilities was underway, existing production services (at a different building at the same hospital site) were maintained. This required the staff involved to organise their time meticulously.

STAFF TRAINING

There were two main aspects in training — instruction on how to use isolators (as opposed to laminar flow cabinets, with which the technical staff were familiar) and a more comprehensive training plan of performance to standard operating procedures (SOPs) relating to good manufacturing practice.

Isolator training was initially provided by the manufacturers, with input from the quality assurance officer. This formed the basis of more comprehensive training, which was carried out by the senior technician and managed by the principal pharmacist, once the standard operating procedures for the isolators and new ways of working had been compiled.

In order to devise the comprehensive training plan, the quality assurance pharmacist, senior technician and principal pharmacist visited a similar NHS clean room in Woolwich, London that had been recently commissioned and met up with their lead technical staff.

MHRA INSPECTIONS

Clearly, it was of upmost importance that the MHRA approved the transferral of the “specials” license from the old facilities to the new ones. The MHRA inspection to enable this to happen comprised the check-



The assembly room, part of the newly-built clean room, designed so that pressure differentials run from rooms of high to low classification

ing of both the physical nature of the facilities and the supporting documentation, which included the VMP, SOPs and other commissioning and validation documents (such as the methods and results of the environmental and physical monitoring and of the operator and isolator validations.)

It was the senior technician's role to put together much of the supporting documents and to assist the principal pharmacist in ensuring that all members of the project team were in attendance at the relevant inspections, depending on the skills required to support the MHRA licensing requirements.

In all, three inspections took place before the clean room was licensed. The need for further environmental and physical monitoring was among the reasons that the facility was not licensed after the first and second inspections. In addition, the retrospective pressure test decays reflected some discrepancies between isolators (these were, however, within limits and plans to increase the frequency of “leak testing” further satisfied the MHRA that their requirements were met). The project team also had to justify using turbulent isolators instead of the “old technology” of laminar flow cabinets and for using negative pressure isolators to prepare CIVAS (central intravenous additive service) products.

CONCLUSION

The opportunity to lead in a redevelopment project was an exciting and challenging prospect for the whole project team, which provided them with a great sense of achievement. Their experience shows that it is important to work collaboratively, identify senior management leads, develop a credible network, communicate the effects of proposed actions to relevant staff and engage in training early in the process. Most important of all, however, is to ensure that technical services pharmacy staff are involved throughout the process, particularly during the initial planning and designing stages.

Panel 1: Design requirements for the new clean room

- Air handling unit and alarm system to be dedicated specifically to the clean room to support the ducted system for the isolators
- To be one positive pressure isolator for making TPN and three negative pressure isolators for making CIVAS and cytotoxic chemotherapy products. Isolator cabinets to support shutdown leak testing and airflow rate and HEPA filter pressure differential monitoring and to have a pressure loss alarm
- Room pressure differentials to run from rooms of higher classification — ie, rooms housing isolators for cytotoxic reconstitution (highest classification and pressure) to rooms where operators “gown up” to rooms where operators assemble the items they need to make the product (“assembly”) to rooms at ambient pressure.
- Pressure differentials across a HEPA filter in both cytotoxic and assembly areas are to be monitored
- All pressure readings to be displayed on magnahelic gauges contained within the control box located in the assembly room of the clean room
- Room grades to be sufficient to support the use of turbulent isolator technology
- All materials including power switches, interlock transfer hatches, names plates, vinyling, shelving, workbenches and furniture are to be of clean room type
- Power to the facility to be connected to an emergency supply as well as to main generators

“TPN” means total parenteral nutrition, “CIVAS” means central intravenous additive service and “HEPA” means high-efficiency particulate air filter