

► Impact of GMP introduction in NM daily practice

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Good Manufacturing Practice (GMP) is a concept in pharmaceutical regulation which aims to ensure consistent production of a safe and effective product. The three main components are facilities, documentation and training. For many current radiopharmacies in nuclear medicine departments, achieving GMP compliance will likely involve small changes in documentation and training but possibly large and expensive changes in facilities. Furthermore, at times the requirements of pharmaceutical GMP can be in conflict with radiation protection principles.

GMP compliance in documentation requires written and approved standard operating procedures (SOP) which are reviewed on a defined basis, usually every 2 or 3 years. There must be complete recording of information about every product (e.g. supplier, batch number, quantity, volume, reference date and time, expiry date and time). This applies to all components used (e.g. generators and their eluates, kits, saline). The objective is to have complete details on all processes carried out and materials used, so that if a problem is reported later there is a record which can be followed back. All entries must be legible, made in real time rather than retrospectively, and signed and checked. Having a second person available to witness and check all processes may also require a change in practice and staffing levels.

GMP compliance in training involves not only the employee's education but also their training in the specific SOPs which they undertake. There must be a record of all training, such as a signature on the back of each SOP. For operators performing aseptic processes, it will also require regular demonstration of competence in aseptic manipulations, such as broth transfers performed every 3-6 months.

It is the facilities which can require the biggest changes. The objective is segregation, so that there is an exclusive area where radiopharmaceutical preparation is performed. In that area there must be a filtered air supply at positive pressure relative to the outside world and with an adequate exchange rate. There are requirements for the construction materials used in such rooms, mainly to minimize shedding of particles and to allow regular cleaning without deterioration. There must be records of airflow rates and pressure differentials between areas. There must also be regular monitoring of airborne particulates and microbiology. The requirement for segregated areas may also necessitate an increase in staffing since multi-tasking is not possible.

While GMP compliance may seem to produce few tangible advantages from the patient's perspective, it is an essential component of a general international trend toward tighter governance of all aspects of healthcare. There is a learning curve and it can be expensive to implement, but once in place it does provide a more robust system to maximise patient safety.

References

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