THE LINDE GROUP

QI Point Analysis.
Assuring quality in your healthcare facility.

On closer inspection

Accurate analysis and certification of gas quality at point-of-use is essential to ensure compliance with National and International Standards. As a pharmaceutical product, medical gases delivered to the patient must at all times be in compliance with Pharmacopeia Standards. The on-site pharmacist is personally responsible, and must be able to demonstrate effective procedures are in place to ensure compliance.

Two levels of monitoring are required:

1. Gases transported in liquid form (to a tank or for filling in cylinders) must be delivered with a Pharmaceutical Certification (medical oxygen, medical nitrous oxide, medical air, etc.).
2. Gases manufactured on-site (medical air) where demonstration of compliance with Good Manufacturing Practice (GMP) is required, more frequent analyses are required to demonstrate compliance with Pharmaceutical Standards.

For the first group, monitoring at point-of-use is required to demonstrate no product contamination has occurred in the pipeline/delivery equipment. Therefore, analysis is essential every time modifications are made and should be an integral part of the commissioning procedure. In addition, it is good practice to periodically check gas outlets (e.g. on a random sampling basis), especially critical gas outlets, such as in operating theatres and emergency areas.

For the second group, more frequent checks are vital as products manufactured on-site do not have the conformity certification of externally provided medical gases. Analysis is required at least once per quarter, although more frequent tests are required if deviations from Standards have been found.

QI Point Analysis provides a high quality analysis service, covering gases delivered from external sources as well as those manufactured on-site. We utilise the same equipment installed at Linde Healthcare medical gas cylinder filling facilities, which are used to provide the Pharmaceutical Quality checks for bulk and cylinder-delivered products.

Important check points

Gas samples are collected in the hospital or clinic/on-site by trained personnel using specially designed evacuated vessels and sample cylinders. Three gas samples are normally taken at each point to enable cross checking.

The gas sample cylinders are sent to a certified gas laboratory where, under strict quality controls, the gas is analysed to ISO 17025 Accreditation. Result certificates are presented with details of impurities according to Eur Ph. and the analysis method. Individual calculations of the analytical uncertainty are also included.

A complete QI Point Analysis service package is available. Linde Healthcare will agree a programme of sampling of critical outlets with the pharmacist to ensure a representative data set is always available to meet compliance with Standards. With this package, all delivery points are covered in sequence and higher risk areas receive special attention, such as on-site manufacture and after modifications to pipe work. This allows the pharmacist and hospital management to be assured that this important issue is managed by capable, expert hands. The analysis certificates can be stored and analysis data re-used in analysis at a later stage if needed, with full transparency on historical records.

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