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## Qi Point Analysis

### Assuring quality in your healthcare facility

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#### On closer inspection

Accurate analysis and certification of gas quality at the point where it is used by the patient is an essential requirement to ensure compliance with National (AS2568) and International Standards.

As medicinal gases delivered to the patient must, at all times, be in compliance with Pharmacopoeia Standards. The hospital is responsible for this, and must be able to demonstrate effective procedures are in place to ensure compliance.

Two levels of monitoring are required:

1. For medicinal gases delivered to site (medical oxygen, nitrous oxide, medical air etc.).
2. For gases manufactured onsite (medical air) where, in addition to demonstration of compliance with the principles of Good Manufacturing Practice (GMP), more frequent analyses are necessary to show compliance with Pharmaceutical Standards.

For the first level, monitoring is needed to show no change of the product has occurred in the pipeline/delivery equipment. Analysis is therefore 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.

For the second level, more frequent checks are vital as the product is manufactured onsite and is not provided with conformity certification. Analysis is required annually and recommended more frequently if deviations from Standards are found.

Qi Point Analysis provides a high quality analysis service covering medicinal gases delivered to site as well as those manufactured onsite. We utilise BOC NATA/IANZ certified and GMP audited laboratories to ensure complete compliance to relevant medicinal pharmacopoeia and standards.

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### Important check points

Gas samples are collected onsite by trained personnel using specially designed evacuated vessels. Two samples are normally taken at each point so that cross checks can be made in case of any quality issues. The samples are returned to a BOC NATA/IANZ certified laboratory where, under strict conditions, quality analyses are carried out.

A certificate of analysis is produced, detailing the method of analysis, the standard specification and impurity results. A complete Qi Point Analysis service package will deliver the hospital a programme of sampling, in discussion with BOC, to ensure that a representative set of data is always available that complies with Standards and Hospital accreditation requirements.

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