BRITISH COMPRESSED GASES ASSOCIATION
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TECHNICAL INFORMATION SHEET 42

MEDICAL GASES – DATA INTEGRITY POLICY

Background

Medicinal gases have to meet stringent requirements to ensure they are supplied at the correct quality and to ensure that the procedures used for filling and testing medical gas cylinders are compliant with the basic principles of Good Manufacturing Practice (GMP). One of the primary ways in which the quality of medicinal gases is controlled is the management of the data generated during this process. Data integrity is fundamental in a Pharmaceutical Quality Management System.

NOTE: This policy refers to the data integrity requirements necessary as part of the batch management of medicinal products in accordance with GMP. This document is not about protecting an individuals' personal data for which compliance with the *Data Protection Act* (1) is necessary.

Data Integrity

Data integrity is defined as "*the extent to which all data is complete, consistent and accurate, throughout the data lifecycle*" by the Medicines and Healthcare products Regulatory Agency (MHRA) within their industry guidelines. Data integrity applies to all elements of the Pharmaceutical Quality Management System and the principles apply equally to data generated by electronic and paper-based systems. Poor data integrity practices and vulnerabilities undermine the quality of records and evidence, and may ultimately undermine the quality of medicinal products.

BCGA provide guidance on managing data integrity in Guidance Note 37 (2), *Medical gases. Data integrity.*

Data Governance

Data governance is the sum total of arrangements which provide assurance of data integrity. Data governance systems should be integral to the Pharmaceutical Quality Management System as described in the Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-Operation Scheme (PIC/S), GMP and Good Distribution Practice (GDP). It should address data ownership throughout the lifecycle, and consider the design, operation and monitoring of processes / systems in order to comply with the principles of data integrity, including control over intentional and unintentional changes to, and deletion of information.

Such arrangements will ensure that data (irrespective of the process, format or technology in which it is generated) is recorded, processed, retained, retrieved and used to provide a complete, consistent and accurate record throughout the data lifecycle.

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An effective data governance system will demonstrate Management's understanding and commitment to data governance practices including the necessity for a combination of appropriate organisational culture and behaviours and an understanding of data criticality, data risk and data lifecycle.

The data lifecycle refers to how data is generated, processed, reported, checked, used for decision-making, stored and finally discarded at the end of the retention period. The data shall be available for use when required. Data relating to a product or process may cross various boundaries within the lifecycle. This may include data transfer between manual and electronic systems, or between different organisational boundaries; both internal (e.g. between production, quality control (QC) and quality assurance (QA)) and external (e.g. between service providers or contract givers and acceptors).

Senior management is responsible for the implementation of systems and procedures to minimise the potential risk to data integrity, and for identifying the residual risk, for example, using the principles of Pharmaceutical Quality Risk Management within ICH-Q9 (3).

The effort and resource assigned to data governance should be commensurate with the risk to product quality and patient safety, and should also be balanced with other quality resource demands. Not all data or processing steps have the same importance to product quality and patient safety. Risk management should be utilised to determine the importance of each item of data and its appropriate processing step.

Policy

To maintain a data integrity policy, each company should:

- design and implement good data governance practices;
- control all records, which must remain attributable, legible, contemporaneous, original and accurate (ALCOA) throughout the data lifecycle;
- endeavour to develop and implement suitable software that includes electronic audit trail functionality;
- use electronic signatures, where appropriate, in the place of handwritten signatures with appropriate controls to ensure their authenticity and traceability to the specific person who electronically signed the record(s);
- assess data management systems for potential vulnerabilities;
- document and regularly review the arrangements for data governance within their Pharmaceutical Quality Management System;
- assess periodically the effectiveness of data integrity control measures over the data lifecycle as part of self-inspection (internal audit) or other periodic review processes;
- ensure that personnel are aware of the importance of their role in ensuring data integrity within their activities to assure product quality and patient safety;

- configure and enforce user access controls, both physical and electronic, to prohibit unauthorised access to, changes to and deletion of data;

- consider the vulnerability of data to involuntary or deliberate alteration, falsification, deletion, loss or re-creation, and the likelihood of detection of such actions, using data risk assessment;

- consider control of access by external parties, including the inclusion of cyber security preventative measures;

- develop a business continuity plan to ensure complete data recovery is available in the event of a disaster;

- document a process for the disposal of records.

References:

(1) Data Protection Act 1998
(2) BCGA Guidance Note 37, *Medical gases. Data integrity*.
(3) International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use. Quality risk management. (ICH-Q9).

For more information:

British Compressed Gases Association (BCGA) www.bcga.co.uk

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