Bad Soden, Germany, 08 August 2014

Messer: Strict quality assurance of medical gases

Medical gases enter the human body directly or are used on it. They must therefore meet particularly high quality standards. To ensure that this happens, Messer complies with the strict Good Manufacturing Practice guidelines issued by the European Commission.

The required composition of medical gases is defined in the European Pharmacopoeia, that is to say, in the relevant monographs. Strict adherence to these monographs is, of course, one of the requirements for Good Manufacturing Practice (GMP). While quality management systems such as the well-known ISO 9001 system create good foundations, they are no replacement for adherense to the GMP guidelines. "GMP adopts a comprehensive approach", explains Matthias Thiele, Vice President Medical an Pharma Gases at Messer. "For example, it also includes organisational structures and personal responsibility". Thus, for example, the heads of production and quality control must be two different persons. A Qualified Person (QF) ist responsible for personally approving each batch of medicinal products. The QP must have a certificate of competence an be registered with, and recognised by, the relevant authority.

The regulation also takes account of virtually every other aspect of manufacturing; quality management, rooms and equipment, documentation, production methods, quality control systems and measures, as well as self-inspection and dealing with complaints or production recalls. The section on personnel provides a description of general principles while also dealing, in particular, with the responsibilities of staff in key positions as well as the subjects of training and personal hygiene. "All staff who are invlved in the manufacture of sale of medicinal products must be familiar with the product properties as well as GMP in their area, with the main focus on drug safety at all times", explains Matthias Thiele.

Messer's national subsidiaries carry out self-inspection every year; official inspections by the authorities take place at least every three years or as and when required. The Messer headquarters in Bad Soden also carries out an audit of the national subsidiaries every three years. This involves simulating recalls, tracing batches and carrying out meticulous examinations of the status of the documentation.

"Besides GMP, which is mainly geared to the manufacturing process, the related processes are also increasing being managed in terms of defined, good practise," the expert explains. This includes the sales department per road tanker or cylinder, for instance, which has to comply with Good Distribution Pracice (GDP), and the area of drug safety, for which Good Pharmacovigilance Practice (GVP) has been specially defined. GxP is also used as a general term for good practice. Matthias Thiele does not view this comprehensive set of rules as a burden: "We are talking about people and their health. Compliance with the rules is a matter of course for us. Furthermore, we constantly strive to use the strict control regime and regular inspections and audits to further optimise our processes in every respect."

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