

ISO STANDARD 13022 - A NOVEL TOOL FOR THE MANAGEMENT OF RISK OF CELL-BASED PRODUCTS.

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The International Organization for Standardization (ISO) is publishing a new standard document (ISO 13022) which addresses the requirements for risk management for medical products based on viable human cells.

The standard ISO 13022 specifies a procedure to identify the hazards and hazardous situations associated with such products, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, and expected medical benefit as compared to available alternatives. It will cover viable human materials of autologous origin as well as allogeneic human material.

The document is intended to provide requirements and guidance on risk management related to the hazards typical of medical products manufactured utilizing viable human materials such as:

- a) contamination by bacteria, moulds or yeasts and parasites,
- b) contamination by viruses,
- c) contamination by agents causing Transmissible Spongiform Encephalopathies (TSE),
- d) contaminating material responsible for undesired pyrogenic, immunological or toxicological reactions,
- e) decomposition of the product and degradation products caused by inadequate handling including procurement, packaging, storage, transport and application, and
- f) complications resulting from the mix up of human raw materials.

These considerations apply to all stages of the manufacturing process from donor selection to application of the product.

By definition of the relevant European Directives and Regulations products including human tissues and cells are currently considered as medicinal products in Europe, and standards are not commonly used for medicinal products in the European Community. However, there is an obvious benefit in a close coordination of the work on regulatory guidelines in Europe and internationally harmonized standards for all manufacturers of these products who are focusing on the international market.