State of the Art

Medical device manufacturers are often concerned about the concept of “State of the Art”. While medical devices need to embody symbols of state-of-the-art is not always clear what that means. One source is ISO 14971:2007 on risk management for medical devices.

The introduction to ISO 14971:2007 explains that medical device manufacturers are stakeholders the safety of the device including the acceptability of risks. This involves taking into account the generally accepted state-of-the-art to determine whether a medical device is suitable to place on the market intended use.

As part of this responsibility, Top Management defines and documents a policy to determine risk acceptability criteria. The basis for the criteria clued generally accepted state-of-the-art and known stakeholder concerns.

For any given medical device, the manufacturer utilize the policy determine the risk acceptability criteria and documented in the risk management plan. These criteria form the basis for evaluating the risk resulting from each hazardous situation and harm as well as the residual risk after implementing any risk control measures.

As part of the risk management process, the manufacturer receives and evaluates both production and post-production information. This information, often derived from actual use of the device, can affect risk estimates. The evaluation of this information should take into account the state-of-the-art. This process closes the loop from the original risk estimates, which may use modeling and other techniques, two risk estimates based on experience with the device or similar devices.

ISO 14971:2007 does not specify acceptable risk; the manufacturer must decide. Among the methods are:

- using applicable standards that result in risk acceptability for certain kinds of medical devices or particular risks
- comparing risk levels to medical devices that are already in use
- conducting clinical evaluations or clinical investigations to help set acceptability criteria
- considering the state-of-the-art, the technology, current practice

According to ISO 14971:2007 clause D.4, “State of the art” means currently and generally accepted good practice. There are various methods to determine "state of the art" for a particular medical device. They include:

- standards for the same or similar devices
- best practices for the same or similar device types
- the results of accepted scientific research

State of the art does not necessarily mean the most technologically advanced solution.