



**GHTF.SG3.N15-R8**

**Implementation of Risk Management  
Principles and Activities Within a  
Quality Management System**

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- **Medical device manufacturers are generally required to have a quality management system as well as processes for addressing device related risks.**
- **These processes have become stand alone management systems.**



- **While manufacturers may choose to maintain these two management systems separately, it may be advantageous to integrate them as it could reduce costs, eliminate redundancies, and lead to a more effective management system.**



- **This document is intended to assist medical device manufacturers with the integration of a risk management system or the risk management principles and activities into their existing quality management system by providing practical explanations and examples**



- **The document is based on general principles of a quality management system and general principles of a risk management system and not on any particular standard or regulatory requirement.**



- **An effective quality management system is essential for ensuring the safety and performance of medical devices.**
- **It includes safety considerations in specific areas.**
- **Given the importance of safety, it is useful to identify some **key activities** that specifically address safety issues and ensure appropriate input and feedback from these activities into the quality management system.**



- **The degree to which safety considerations are addressed should be commensurate with the degree of the risk, the nature of the device and the benefit to the patient.**
- **Some devices present relatively low risk or have well-understood risks with established methods of risk control.**



**In general, risk management is characterized by four phases of activities:**

- 1. Determination of acceptable levels of risk**
- 2. Risk analysis**
- 3. Determination of risk reduction measures**
- 4. Risk control and monitoring activities**





## **Determination of acceptable levels of risk:**

- **Risk acceptability criteria should be defined.**
- **These criteria may come from:**
  - **an analysis of the manufacturer's experience with similar medical devices**
  - **currently accepted risk levels by regulators, users, or patients, given the benefits from diagnosis or treatment with the device.**
- **The criteria should be reflective of state-of-the-art in controlling risks.**



## **Risk analysis:**

- **This phase starts with identifying hazards that may occur due to characteristics or properties of the device during normal use or foreseeable misuse.**
- **After hazards are identified, risks are estimated for each of the identified hazards, using available information.**



## **Determination of risk reduction measures:**

- **In this phase, the estimated risks are compared to the risk acceptability criteria.**
- **This comparison will determine an appropriate level of risk reduction. This is called risk evaluation.**
- **The combination of risk analysis and risk evaluation is called risk assessment.**



## **Risk control and monitoring activities:**

- **Actions intended to eliminate or reduce each risk to meet the previously determined risk acceptability criteria.**
- **One or more risk control measures may be incorporated.**
- **Risk controls may begin as early as design input and continue over the medical device life time.**



## **Risk control and monitoring activities:**

- **Some regulatory schemes prescribe a fixed hierarchy of risk controls that should be examined in the following order:**
  - **Inherent safety by design**
  - **Protective measures in the device or its manufacture**
  - **Information for safety, such as warnings, maintenance schedules, etc.**



## **Risk control and monitoring activities:**

- **Throughout the life-cycle of the device the manufacturer monitors whether the risks continue to remain acceptable and whether any new hazards or risks are discovered.**
- **An effective and well defined Quality Management System is key!**



## **Risk control and monitoring activities:**

- **Information typically obtained from the quality management system, for example, production, complaints, customer feedback, should be used as part of this monitoring.**

**Let's examine this a little closer ...**







## **Risk control and monitoring activities:**

- **If, at any time, a risk is determined to be unacceptable, part or all of the existing risk analysis should be re-examined and appropriate action taken to meet the established risk acceptability criteria.**
- **If a new hazard is identified, all four phases of risk management should be performed.**

# Risk Management In Design Controls

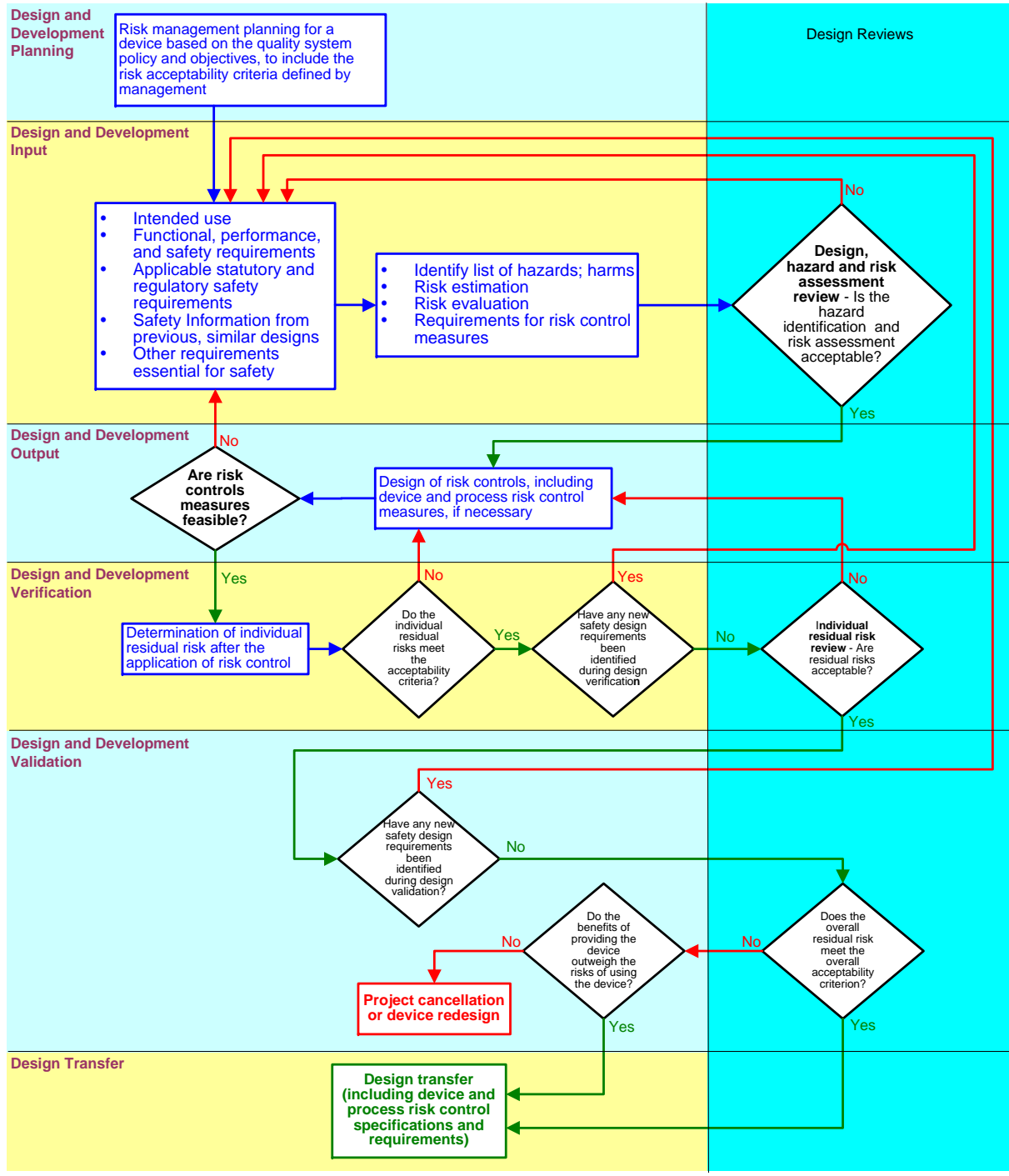


- **Identify hazards, develop a hazards list**
- **Determine the source of the hazard (any combination of product design, manufacturing, user)**
- **Analyze the hazard using appropriate tools (FTA, FMEA, HACCP, Human Factors Analysis, etc.)**

# Risk Management In Design Controls



- **Minimize risks** (redesign, process validation or process variability reduction, labeling, user education, etc.)
- **Determine the overall or total risk from all sources**
- **Determine risk acceptability as a part of the completed design validation**



# Risk Management In The Quality System



- Risk Management decisions and documentation from design and development becomes a living and ever changing design input as experience and post market feedback occurs!



# Risk Management In The Quality System

- Risk Management needs to be procedurally tied into:
  - Design Controls
  - Purchasing procedures and criteria
  - Acceptance Activity procedures and criteria
  - Manufacturing activities
  - Process validations
  - Rework procedures and decisions
  - Corrective and preventive actions



# **Risk Management Principles and Activities Within a Quality Management System**

## **Case Study**



# Temporomandibular Joint (TMJ) Implants



# Temporomandibular Joint (TMJ)



**The TMJ is comparable to a ball-in-socket joint.**

**The ball (condyle) is a part of the lower jaw (mandible).**

**The socket (fossa) is part of the skull.**

**These two parts come together to form the moveable joint, which can be felt when placing fingers over the skin in front of the ears while opening and closing the mouth.**



# TMJ Implants

**In March 1983, a company began marketing a Interpositional Implant (IPI) to treat TMJ problems. The firm claimed substantial equivalence to an existing product, silicone sheeting, which was also used as a TMJ implant.**

**Both products included Teflon as key components.**



# TMJ Implants

**Warnings against the use of Teflon in these type of applications date back to 1963 and 1974**

**Study published in 1984 concludes Proplast coating (consisting of Teflon) has insufficient strength.**

**Subsequent studies published in 1986 raise further concerns regarding the use of teflon in these applications.**



# TMJ Implants

**Patients and physicians began reporting problems, including:**

- **severe pain around the ear and in the jaw area**
- **radiographic evidence of severe bone loss to the condyle and glenoid fossa**
- **limited lower jaw movement**
- **bone degeneration/soft tissue deterioration**
- **joint noise in the jaw**
- **nausea, dizziness or ringing in the ear**
- **fragmentation and/or displacement of the implant**
- **infection**
- **vision and hearing problems**



# TMJ Implants

**Complaints in conjunction with data published earlier led to these implants being taken off the market.**



# TMJ Implants

**Could this have been avoided or prevented under current approach to Risk Management?**



**As discussed in previous slides....**

- **The degree to which safety considerations are addressed should be commensurate with the degree of the risk, the nature of the device and the benefit to the patient.**

**Use of teflon in joint replacement was known to be problematic as early as 1963 – further research appears to have been indicated before starting production or placing on the market.**



## **Determination of acceptable levels of risk:**

**Known issues and published concerns regarding the use of teflon based materials in implants were not properly recognized during the development period.**





## **Risk analysis**

**Known and published general hazards were not properly recognized**

- **Intense “foreign body” reactions**
- **Insufficient strength to withstand normal weight-bearing loads**
- **Deterioration of bone and tissue**
- **Intended as a long-term implant?**



## **Risk estimation**

**Overall activity appears to have been incomplete!**

**Certain aspects not included in the Risk Analysis may have easily been ....**

**For example:**

- **Adverse tissue reactions caused by wear debris (concern published in 1963)**
- **silicone rubber and Teflon-Proplast are not biologically acceptable implant materials in the functional TMJ (study published 1989)**
- **Results of laboratory tests on IPIs (published in 1992) showed a service life of about three years. Intermediate and long-term survival of implant was uncertain.**



## **Determination of risk reduction measures:**

**Since not all risks were properly identified, risk reduction measures were not identified for key aspects!**

- **Package insert states “Prognosis for the implant’s success beyond 3 years was unknown”**



## **Risk control and monitoring activities**

**Risk control measures taken by the firm as a result of post market information were limited to:**

**1988 – product distribution suspended**

**1990 – Company issues advisory letter to physicians**



## **This is a case where risk management:**

- might have helped determine that teflon was not an appropriate material for TMJ implants.**
- might have helped the company recognize the problem with the product sooner, before thousands of patients received the implants.**



**Thank you on behalf of Study Group  
3 and the GHTF for your time and  
attention.**

**Questions?**



# APPENDIX



# Definitions

## ➤ Harm

- physical injury or damage to the health of people, or damage to property or the environment [ISO/IEC Guide 51:1999, definition 3.1]

## ➤ Hazard

- potential source of harm [ISO/IEC Guide 51:1999, definition 3.5]

## ➤ Residual Risk

- risk remaining after protective measures have been taken [ISO/IEC Guide 51:1999, definition 3.9]

## ➤ Risk

- combination of the probability of occurrence of harm and the severity of that harm [ISO/IEC Guide 51:1999, definition 3.2]





# Definitions

## ➤ Risk Analysis

- systematic use of available information to identify hazards and to estimate the risk [ISO/IEC Guide 51:1999, definition 3.10]

## ➤ Risk Assessment

- overall process comprising a risk analysis and a risk evaluation [ISO/IEC Guide 51:1999, definition 3.12]

## ➤ Risk Control

- process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels [ISO 14971:2000, definition 2.16]



# Definitions

## ➤ Risk Evaluation

- judgment, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society [NOTE Based on ISO/IEC Guide 51: 1999, definitions 3.11 and 3.7]

## ➤ Risk Management

- systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk [ISO 14971:2000, definition 2.18]