RISK MANAGEMENT FOR MEDICAL DEVICES

AS DEFINED BY ISO 14971

The purpose of this infographic and the ISO 14971 standard is to help med device manufacturers establish a risk management process that they can use to:

- **Identify Hazards**
- **Estimate And Evaluate Risks**
- **Develop, Implement And Monitor The Effectiveness Of Risk Control Measure**

RISK MANAGEMENT PROCESS OVERVIEW

1 Establish a risk management framework

- ☐ Define your risk management process
- ☐ Establish management roles and responsibilities
- ☐ Document your risk management plan
- ☐ Establish a living risk management file

2 Specify intended use

Understand and define the scope of your device and document its intended use

3 Identify hazards

Identify the potential sources of harm associated with your product. These are known as hazards

4 Define hazardous situations and foreseeable sequences of events

Estimate risk of each hazardous situation

5 Estimate risk

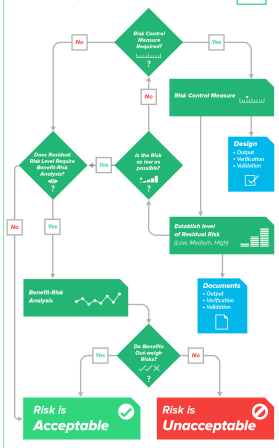
Risk is the combination of severity of potential harm and probability of that harm occuring

6 Evaluate the risks identified

- Are these risk levels acceptable?
- Is risk reduction required?

7 Risk Control

Use Risk Controls to reduce risks to acceptable levels:



8 Evaluation Of Overall Risk Acceptability

Evaluate risk of the product in its entirety.

- Is the risk level acceptable?
- Do the benefits outweigh the potential risks?

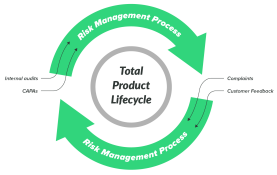
9 Risk Management Review

Carry out a risk management review and prepare a risk management report before sending your device to commercial production.

10 Production And Post-production Information

Internal audits, CAPAs, complaints, customer feedback and non-conforming material all 'feed' into the risk management process.

Risk management is a total product lifecycle process.



(317) 960-4220 | LetsChat@greenlight.guru

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