Risk in the Quality System

FDA Small Business
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Learning Objectives

- Understand risk, risk-based decisions and risk analysis to comply with the Quality System Regulation, 21 CFR 820.
- Identify risk analysis tools and resources to help you make risk-based decisions.
- Learn about risk management and the ISO/ANSI/AAMI 14971 Standard.

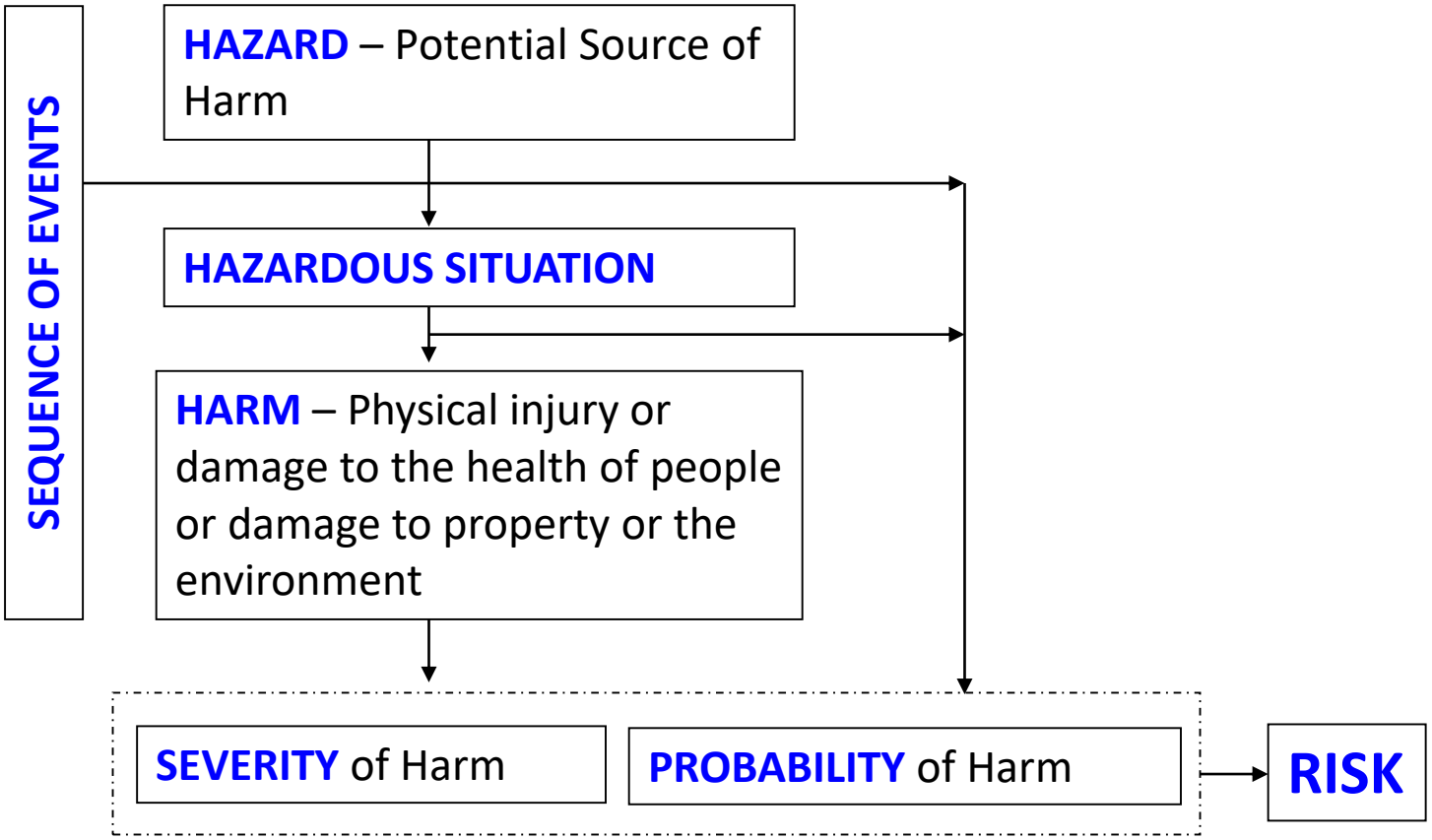
Definition of Risk

- **No formal FDA definition of the term "risk."**

- **Starting Point:**
  - The risk of the medical device to patients, end users and environment, which includes the risk of the device if it were to fail, i.e., not operate as intended.

- **From International Organization for Standardization (ISO) 14971:2007 2.16:**
  - Combination of the probability of occurrence of harm and the severity of that harm.

HAZARD -- HARM -- RISK



ISO 14971:2007 Fig. E.1

Regulatory Requirements

What you are required to comply with:

- Federal Food, Drug and Cosmetic Act (FDCA)
- Safe Medical Devices Act (SMDA) of 1990
- Title 21 Code of Federal Regulations (CFR)
- 21 CFR Part 820 – Quality System Regulation

Risk-Based Decisions in the QS Regulation Preamble

CFR Section	Name	Comment #
820.1	Scope	4, 13
820.30	Design Controls	81, 83
820.50	Purchasing Controls	115
820.65	Traceability	121
820.70	Production/Process Control	31
820.90	Non-Conforming Product	161
820.100	CAPA	159
820.200	Servicing	200

Scope – Risk-Based Decisions

"…gives the manufacturer the flexibility to determine the controls that are necessary commensurate with risk. The burden is on the manufacturer, however, to describe the types and degree of controls and how those controls were decided upon."

Preamble Comment #4

"The extent of the documentation necessary to meet the regulation requirements may vary with the… risk associated with the failure of the device, among other factors."

Preamble Comment #13

Who makes these Risk-Based decisions?

Management has final responsibility in making these risk based decisions. They:

- Provide the resources
- Establish the policy and objectives for and commitment to quality
- Determine the organization
- Decide on their Quality System

Quiz

What section of the Quality System Regulation requires Risk Analysis?

1. 21 CFR 820.70 - Production and Process Controls
2. 21 CFR 820.30 - Design Controls
3. 21 CFR 820.100 - Corrective and Preventive Action
4. 21 CFR 820.50 - Purchasing

Risk Analysis in the Quality System Regulation

21 CFR 820.30 (g) Design Validation:

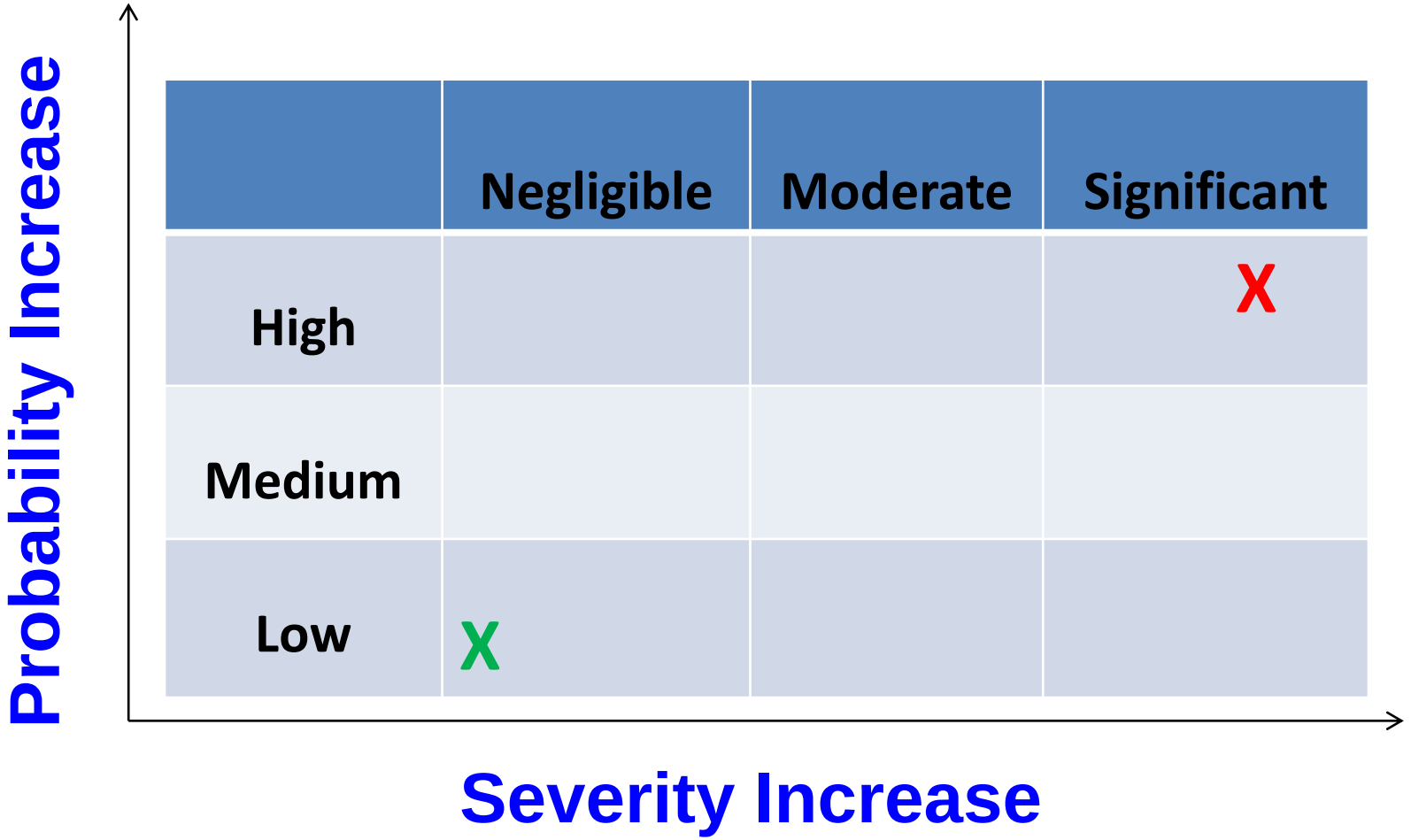
"Design validation shall include software validation and **risk analysis**, where appropriate"

What is the Intent of Risk Analysis?

- Identify possible hazards, including user error
- Calculate risk, under normal and fault conditions
- Determine risk acceptability
- Reduce unacceptable risks to acceptable levels
- Ensure changes introduce no new hazards

per Preamble Comment #83

Risk Assessment Matrix



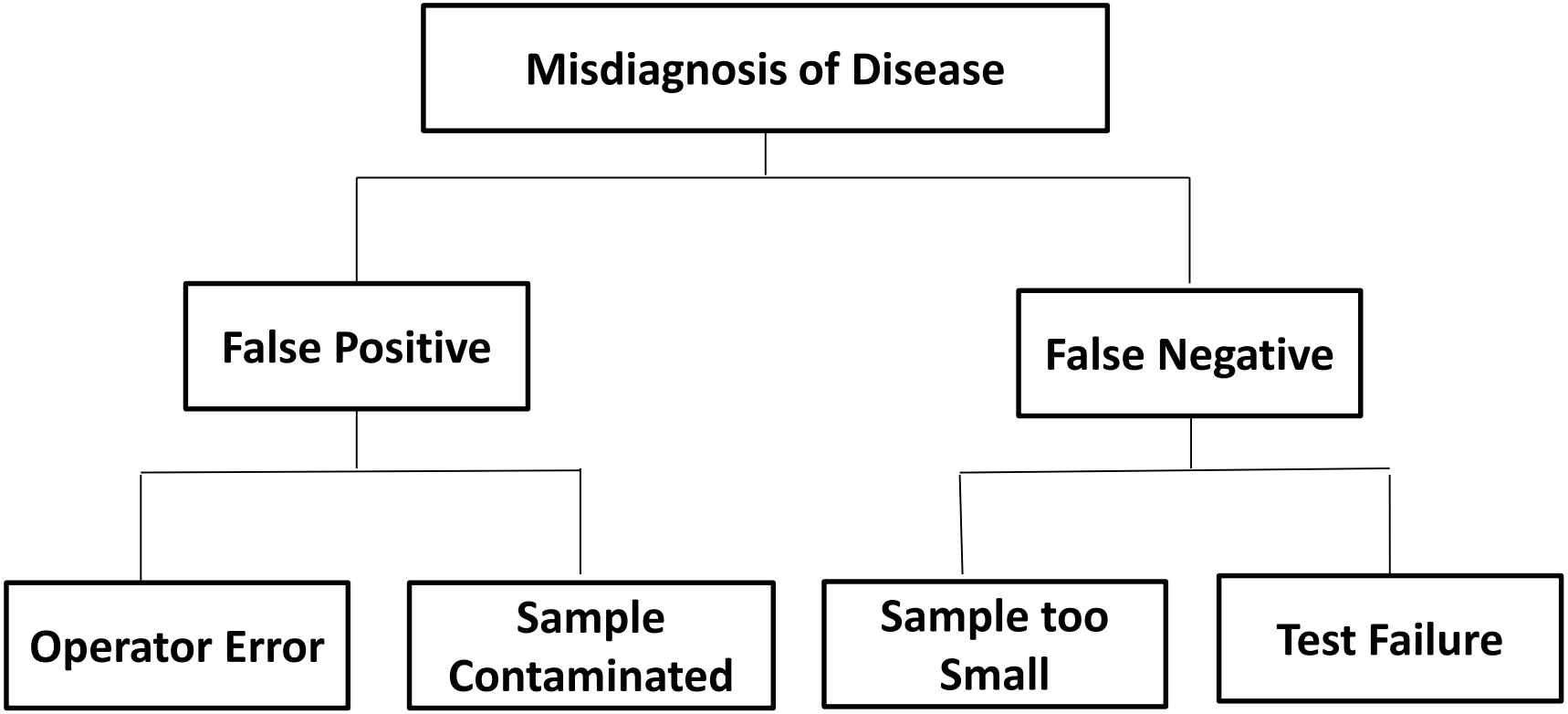
	Negligible	Moderate	Significant
High			X
Medium			
Low	X		

Risk Analysis Tools

- Preliminary hazard analysis (PHA)
- Fault Tree Analysis (FTA)
- Failure Mode Effects Analysis (FMEA)
- Hazard and Operability Study (HAZOP)
- Hazard Analysis and Critical Control Point (HACCP)

Example of Risk Analysis Tool

Fault Tree Analysis (FTA): IVD



Example of Risk Analysis Tool

Failure Mode Effects Analysis (FMEA)

Requirement	Potential Failure Mode	Potential Effects	Severity (S) (1-5)	Occurrence (O) (1-5)	Detection (D) (1-5)	RPN
Implant Strength	Break	Failure Replace	5	1	2	10
Implant Sterility	Contami-nation	Infection	4	2	4	32
Sterile Package	Broken Seal	Infection	4	3	2	24
Implant Label (IFU)	Misread	Improper Placing	3	2	3	18

Risk Mitigations

Mitigation is a broad term which means elimination, reduction or control of the risk by:

- Design and redesign
- Protections and alarms
- Labeling
- Training

Risk-Benefit Determination

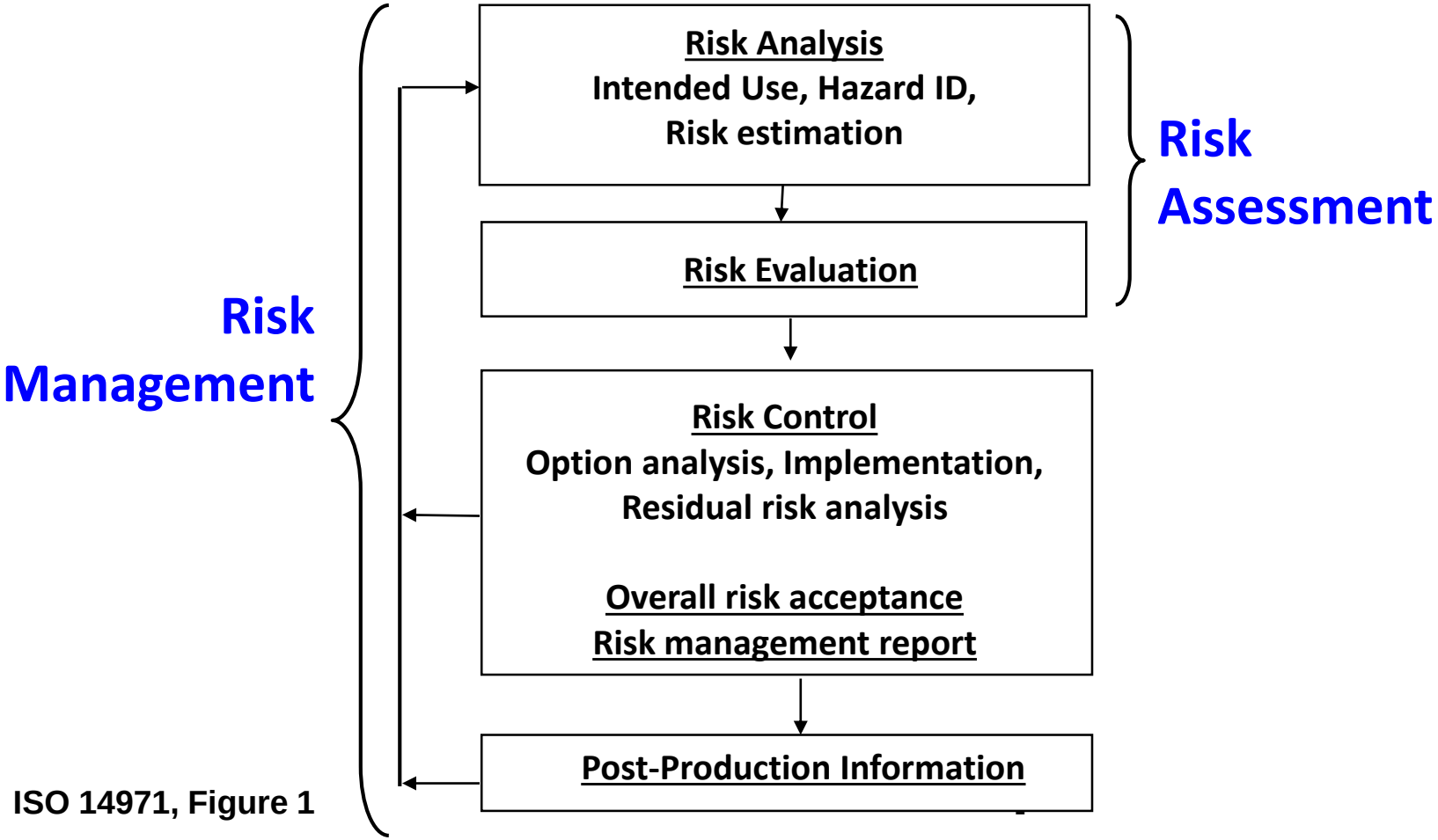
Justifies remaining residual risk, once you've applied all reasonable measures to reduce risk.

- Applies decision to whole device
- May justify abandoning design
- Considers anticipated clinical benefits
- Must approve and communicate final determination

What is Risk Management?

- Is the current approach
- Is both systematic and comprehensive
- Begins with product design and follows it through the Total Product Life Cycle (TPLC)
- From a practical standpoint, integrate into your Quality System

Risk Management and Risk Assessment



Risk Management Standard

ISO/ANSI/AAMI 14971:2007(R)2010

Title: Medical devices – Application of risk management to medical device

FDA-Recognized Consensus Standard

ISO 14971: Overview

- **Main Content Body**
  - Normative text with nine sections
- **Ten Annexes**
  - Informative with ten annexes

ISO 14971: Scope

The international standard specifies a process for medical device manufactures to:

- Identify hazards
- Estimate and Evaluate Risk
- Control the Risk
- Monitor the Effectiveness of the Controls
- Evaluate the Residual Risk Acceptability

and are applicable to all stages of Total Product Life Cycle (TPLC)

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S03

Your Call to Action

- Medical Devices pose a risk both to their end users and patients. Understand what is meant by risk and understand your device's risk.
- Know your regulatory requirements for risk analysis and for making risk-based decisions, and meet or exceed them.
- Learn about the ISO 14971 standard, a useful tool for understanding and establishing risk management.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