CONCEPT

# Healthcare FMEA and Clinical Risk Management: HFMEA, Hazard Scoring and Risk Registers

9 – 13 August 2027
Amsterdam - Zuidas business district hotel



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## Introduction:

Healthcare FMEA gives hospitals a way to find where a care process can fail before a patient is harmed, yet most clinical risk work still starts only after an incident. Risk registers are often lists of vague concerns with no scoring rule, owner or escalation route, and new services open without anyone mapping their failure points. This Core Concept course gives patient safety, quality and clinical risk staff a working HFMEA method and a scored clinical risk register. Participants produce an HFMEA Worksheet for a case care process and a Department Clinical Risk Register.

## Course Objectives:

- Select high-risk care processes for proactive analysis using volume, harm potential and change criteria, and charter an HFMEA team
- Draw a graphic process flow of a care process and list its failure modes and their potential causes step by step
- Score each failure mode on the hazard scoring matrix and apply the HFMEA decision tree to decide which to act on
- Choose eliminate, control or accept actions with owners and outcome measures, and test the redesigned process before full roll-out
- Build a department clinical risk register with a rating scale, controls, risk owners and escalation thresholds up to the board
- Apply proactive risk analysis to care transitions and new clinical services, and feed results into accreditation evidence and incident learning

## Target Audience:

- Patient safety staff who lead proactive risk assessments and advise clinical teams on hazard control
- Quality managers who hold departmental quality plans and report risk and safety results to committees
- Clinical risk staff who maintain risk registers and prepare risk reports for executive and board committees
- Nurse managers and clinical unit heads who own the processes and risks of their ward or service
- Pharmacy, laboratory and allied health leads who redesign medication, specimen and diagnostic processes
- Service development and project staff who plan new clinical services, units or care pathways

## Course Outline:

### Day 1: Proactive Clinical Risk: From Reacting to Harm to Anticipating Failure

- Reactive Versus Proactive Risk Methods: Incident Reports, Trigger Review and Prospective Analysis
- Clinical Risk Vocabulary: Hazard, Failure Mode, Effect, Likelihood and Consequence
- High-Risk Process Selection Matrix: Volume, Harm Potential, Complexity and Recent Change
- Human Factors in Care Processes: Latent Conditions, Workarounds and Tight Coupling
- Current-State Review of a Department Risk Profile Using Existing Data Sources

### Day 2: HFMEA Method: Team Charter, Process Flow and Failure Modes

- HFMEA Five-Step Structure Compared with Industrial FMEA and the IHI FMEA Tool
- HFMEA Team Charter: Advisor, Process Owner, Front-Line Staff and Timeline
- Graphic Process Flow Diagram: Main Steps, Sub-Processes and Hand-Offs
- Failure Mode Brainstorming Techniques: Walk-Through, Observation and Staff Interviews
- Failure Cause Listing: Equipment, Communication, Environment, Staff and Patient Factors

### Day 3: Hazard Scoring Matrix, Decision Tree and Action Design

- Severity Scale From Minor to Catastrophic and Probability Scale From Remote to Frequent
- Hazard Score Calculation and Cut-Off Setting on the Hazard Scoring Matrix
- HFMEA Decision Tree: Single Point Weakness, Existing Control Measure and Detectability
- Action Type Selection: Eliminate, Control or Accept With Strength Rating
- Outcome Measure Design and Action Owner Assignment on the HFMEA Worksheet

### Day 4: Clinical Risk Register, Board Escalation and Special Risk Areas

- Clinical Risk Register Structure: Risk Statement, Cause, Consequence, Controls and Owner
- Five-by-Five Likelihood and Consequence Rating With Inherent, Current and Target Scores
- Risk Appetite Statements and Escalation Thresholds From Ward to Board Risk Committee
- Proactive Risk in Care Transitions: Handover, Transfer, Discharge and Readmission Points
- New Service and Process Change Risk Assessment Before Go-Live, Linked to Accreditation Evidence and Incident Themes

### Day 5: Case Work: HFMEA Worksheet and Department Clinical Risk Register

- Case File: Blood Transfusion Pathway From Prescription to Bedside Administration
- Team HFMEA of the Case Pathway: Flow Diagram, Failure Modes and Hazard Scores
- Redesigned Process Test Plan: Simulation, Pilot Unit and Measure Tracking
- Department Clinical Risk Register Drafting With Ratings, Controls and Escalation Routes
- Risk Committee Presentation of the HFMEA Worksheet and Register With Peer Challenge

## Skills You Will Gain:

- Proactive Risk Assessment
- Care Process Flow Mapping
- Failure Mode Identification
- Hazard Scoring
- Decision Tree Analysis
- Risk Control Design
- Risk Register Management
- Board Risk Reporting

## Why Attend This Course:

- Leave with an HFMEA Worksheet for a case care process and a Department Clinical Risk Register you can adapt to your own service
- Stop harm before it happens by finding single point weaknesses in a care process while it is still on paper
- Turn a list of vague concerns into scored risks with owners, controls and clear triggers for escalation
- Compare proactive risk practice with patient safety, quality and risk peers from public, private, teaching and specialist healthcare providers

## Conclusion:

Proactive clinical risk management works when high-risk processes are chosen deliberately, analysed by the people who run them and tracked on a register that leaders read. The course moves from reactive versus proactive methods and process selection, through the HFMEA team, flow diagram and failure modes, to the hazard scoring matrix, decision tree and action design, then to the clinical risk register, board escalation, care transitions and new services. The final day produces an HFMEA Worksheet and a Department Clinical Risk Register.