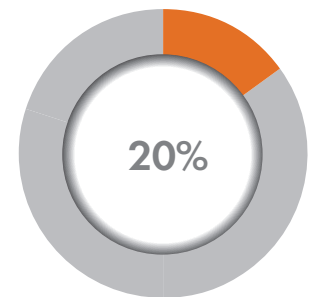


Risk Management Specialized Credential Content Outline

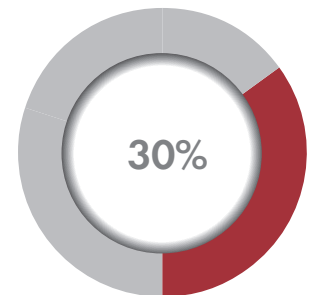
RISK MANAGEMENT FUNDAMENTALS

- Understand basic terms including risk, risk management, hazard, event, consequence, likelihood (occurrence, probability, rate), and control
- Define risk management scope and context
- Understand and distinguish between various stages of risk management, including risk management planning, risk identification, risk analysis, risk evaluation, risk assessment, risk treatment (response, mitigation, control), risk reporting, and risk monitoring
- Apply risk-based thinking and decision making to various situations
- Define types of **enterprise** risk management including strategic, software/cybersecurity, business, regulatory, medical/health, and audit
- Define types of **operational** risk management including supplier, supply chain, safety, project, manufacturing/operations, service, and quality system
- Define types of **product** risk management including design, process, use, and safety
- Understand the requirements of ISO 31000 and the risk-based requirements of the ISO 9001 series of standards



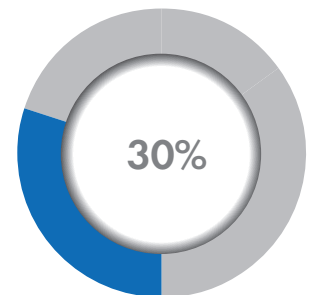
RISK MANAGEMENT PLANNING

- Prepare a risk management plan that includes objectives, risk criteria, stakeholder identification, team member roles and responsibilities, scope, methodology, communication, and tool identification
- Utilize a risk matrix and risk priority number (RPN) to define risk acceptability criteria and levels of risk
- Understand methods of documenting risk such as risk registers
- Understand the risk management plan and, where applicable, its interaction with the organizational quality plan



RISK IDENTIFICATION, ANALYSIS, AND EVALUATION

- Apply failure mode and effects analysis (FMEA) and understand the various types of FMEA including design, system, process, and use scenarios
- Define and interpret the results of a fault tree analysis, hazard analysis, and strengths-weaknesses-opportunities-threats (SWOT) analysis
- Understand hazard analysis and critical control points (HACCP), preliminary hazard analysis (PHA), hazard operability analysis (HAZOP), process decision program chart (PDPC), and bow-tie analysis
- Understand and describe decision/event tree analysis and scenario analysis



RISK TREATMENT AND MONITORING

- Understand risk response planning and utilize risk treatment strategies including avoid, mitigate, transfer, and accept
- Understand risk management reporting, communicating, and review as well as the role of management review
- Use change impact analysis to assess risks created by design, process, and system changes
- Understand how to monitor risk using post-market surveillance and metrics such as risk levels and trends
- Use corrective and preventative action (CAPA) to address risks

