# PHASE 2 ~ CONCEPTUAL DESIGN
# Deliverable 9 ~ Early Risk Assessment

**INSTRUCTIONS.** Complete an early risk assessment for your engineering design project. Your assessment is due electronically and you should add it to your design history file as well. Your document should have the filename convention Team-*yournumber*_del9_early_risk_assessment.

## Purpose

An early risk assessment is a risk-based graded approach used in engineering projects. This assessment helps the project team to evaluate the level of risk in various risk elements, highlight high-risk categories, and determine the appropriate level of controls and review that the project will need. Typically, the early risk assessment applies to subprojects; however, for the purpose of this course, you may apply it to the overall project.

## Critical Information

***You will need to use the BME450_Early_Risk_Assessment.xlsx workbook.***

In the Risk Element Scores worksheet, you should use the dropdown lists on the right to select risk integer values between 1 and 5, as follows:

1. Low risk
2. Low to medium risk
3. Medium risk
4. Medium to high risk
5. High risk

Definitions of the risk levels with example risk element criteria for levels 1, 3, and 5 are given in the worksheet. Levels 2 and 4 are implied to fall between those provided.

The Risk Element Scores worksheet contains the following risk elements to assess:

***Engineering Risk Elements***

- *Technology*. The degree of technical complexity the engineering team will face in executing the project.
- *Environmental Impact*. The potential level of environmental impact.
- *Vendor Issues*. The degree of complexity to be expected with vendors. Complicating factors may include long-lead-time items and issues with vendor qualification and reliability.
- *Resource Availability*. The availability of internal and external resources to plan and execute the project.
- *Quality Requirements*. The effort required to achieve the quality level the stakeholders assign to the final product.

- *Safety*. The safety issues the engineering team will encounter while completing the project.
- *Manufacturing Complexity*. The degree of complexity to be expected when combining the elements of technology, operations and schedule in product manufacturing.

***Project Risk Elements***

- *Schedule*. How much time the engineering team will have to complete the project.
- *Interfaces*. The risk associated with the complexity of integrating multiple subprojects.
- *Experience/Capability*. The level of experience and capability engineering team members will have.
- *Regulatory Requirements*. The degree to which oversight by governmental or other regulatory agencies will impact the project.
- *Project Funding*. The availability and approval status of project planning and execution funds.
- *Project Reporting Requirements*. The level of reporting that the project requires.
- *Public Impact*. How much the project will affect the public or public opinion.
- *Project Cost*. How much the project is projected to cost.

Each risk element represents an aspect of the project that could prevent its successful completion, without appropriate control measures.

Various engineering risk elements determine the risk for the following engineering process steps:

1. *Requirements and Specifications*. The first step in the design process, which defines the objectives and requirements of the project.
* *Engineering Risk Assessment*. The heart of this deliverable is the process of determining the level of rigor required for documentation and review of an engineering project based on technical, cost, and schedule risks.
3. *Requirements and Specifications Review*. The process of reviewing the adequacy of the resulting specifications.
4. *System Design*. The steps of the design phase.
5. *Engineering Design Review*. The required reviews the design must undergo.
6. *Procurement and Implementation*. The process engineers follow to make their projects a reality.
7. *Testing and Validation*. The process of verifying that the design meets the requirements.
8. *Release to Operations*. The operating and maintenance documents the team must produce before the project is complete and becomes operational.
9. *Final Documentation*. The final documentation the team must create and archive in order to complete a project.

## Format of the Early Risk Assessment

Two worksheets (Risk Element Scores and Risk Summary) from the BME455_Early_Risk_Assessment.xlsx workbook are the deliverable.

## Interpreting the Risk Summary

If the project has a risk score of 5 in any *engineering risk element* (A - G) or the subtotal of these scores are higher than the associated high-risk threshold, it will require additional control measures and reviews to assure project success.

If the project has a risk score of 5 in any *engineering or project risk element* (A - O), or the *project management risk* (H - O) subtotal is 25, then the project leader may choose to elevate formal control requirements to address this elevated risk.

Example high-risk control measures are as follows:

- *High-risk Requirements and Specifications Review* projects require a formal technical review with subject-matter experts from outside the engineering department or university. Subsequent design reviews may result in changes to the requirements, which will necessitate an additional requirements and specifications review.
- *High-risk System Design* projects require detailed calculations and/or detailed software documentation that are subject to review and the change-control process.
- *High-risk Engineering Design Review* projects require a formal technical review with subject experts from outside the engineering department or university. Reviews will occur at various stages of the engineering process, such as prototyping, conceptual design, preliminary design and final design.
- *High-risk Procurement* projects require the project leader to retain specifications in a file accessible to project and collaboration members, assign an appropriate document number and record revision dates, keywords and authors, and keep a record of any change-control documents.
- *High-risk Implementation* projects require that the project leader develops, reviews, approves, implements, and controls implementation procedures. Implementation procedures include quality-assurance, fabrication, assembly, and installation procedures.
- *High-risk Testing and Validation* projects require the project leader to take all the following steps in the testing process: devise a strategy for testing the device or system; document the testing plans, processes and procedures; conduct the tests; analyze the test results and compare them to system requirements, and document the test results.