Today:

- What is risk identification
- Example problem
- Tools and Methods
‘Risk’ - Any issue that could arise during a project or section of a project

- Commercial
- Technical
- User Experience
- Intellectual Property
- Manufacture
- Regulatory
- Health & Safety
- Etc...
Each ‘Risk’ has a severity rating based on how easily the risk could be overcome if it occurs.

- The severity ratings are calculated by scoring risk against:
  - **Impact** - effect of risk on project outcome
  - **Likelihood** - probability of risk being realised
  - **Scale** - effort required to mitigate risk (this could also be used for associated cost)
  - **Uncertainty** - degree of familiarity with identified risk
The Risk profile

Likelihood vs Impact
## Scales Used For Scoring Risk (adapted to each project)

<table>
<thead>
<tr>
<th>Impact</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Minor benefit lost</td>
<td>Major benefit lost / cost target missed / phase repeated</td>
<td>Commercial viability of product marginal</td>
<td>Project fails</td>
<td></td>
</tr>
<tr>
<td>Extremely unlikely</td>
<td>Unlikely</td>
<td>50 / 50 likelihood</td>
<td>Likely</td>
<td>Extremely likely</td>
<td></td>
</tr>
<tr>
<td>Scale</td>
<td>&lt; 1 week</td>
<td>1 week</td>
<td>1-3 weeks</td>
<td>1 Month</td>
<td>&gt; 1 Month</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>We have done it before</td>
<td>We have done similar before or others have solved this before</td>
<td>Others have solved similar before</td>
<td>Not solved before but it is clear how to approach it</td>
<td>Research project needed before problem can be tackled</td>
</tr>
</tbody>
</table>

- **Impact**
  - Negligible
  - Minor benefit lost
  - Major benefit lost / cost target missed / phase repeated
  - Commercial viability of product marginal
  - Project fails

- **Likelihood**
  - Extremely unlikely
  - Unlikely
  - 50 / 50 likelihood
  - Likely
  - Extremely likely

- **Scale**
  - < 1 week
  - 1 week
  - 1-3 weeks
  - 1 Month
  - > 1 Month

- **Uncertainty**
  - We have done it before
  - We have done similar before or others have solved this before
  - Others have solved similar before
  - Not solved before but it is clear how to approach it
  - Research project needed before problem can be tackled
When to evaluate risk

- At the brainstorm phase
  - Selection criteria
- At the concept selection
  - Critical Path
- At technical review
  - Areas for further analysis
- Prior to manufacturing
  - Assembly
  - Process restrictions
You have been given the task to Designed the next generation Auto Injector
Methods to identify risk

- Module
- Part by part
- Function
- User Based
What are the next steps

- Make sure scores makes sense
- Identify risks that need mitigation
- Determine mitigation plan
  - How can you best reduce the likelihood that a problem will occur
Ways to reduce risk

- Research
  - Existing solutions
  - Similar mechanism
  - Talking with Manufacturers

- Modeling
  - Calculations
  - FEA

- Prototyping
  - Quick and dirty and Cheap
Prototyping

- Looks like
- Works like
- Made like
- Feels like (user studies)

- Dangers
  - Not representative of final system
  - Works good enough team not willing to iterate
  - Prototype to costly in time and money
  - Not considering how it will be made later (manufacturing tolerances / cost)