

Significant Gaps | Foundational Programme

Multiple Gaps | Emerging Programme

No Gaps | Advanced Programme

Planning / Strategy

- No development strategy
- Limited programme visibility
- Undefined development pathway
- Rushing to get the product to market

- Fragmented development strategy
- Numerous blind spots in programme
- Moderately defined development pathway
- Planned but expedited development

- Extensive development strategy outlined
- Full end-to-end visibility across development
- Fully defined development pathway
- Phased developmental programme

Resource

- Extremely limited budget for development
- No awareness of funding support - not applied

- Somewhat limited budget for development
- Limited awareness of funding support - applied but not received

- Fully budgeted development costs
- Good awareness of funding support - funding secured

Usability

- No user analysis carried out
- Lack of usability insight
- Conflicting user requirements

- Some user analysis conducted
- Some insight gained into usability
- User requirements somewhat aligned

- Full user analysis conducted
- All user requirements fully identified
- User requirements fully aligned

Programme

- Siloed engineering teams
- No defined requirement specifications
- Technology works sometimes
- No ability to prototype
- No testing implemented in the programme

- Alignment across some teams
- Some requirement specifications defined
- Some elements of the technology proven
- Limited access to prototyping services
- Summative testing factored in

- Fully integrated engineering disciplines
- Fully defined requirement specifications
- Technology works consistently & reliably
- Full access to prototyping services
- Full iterative and summative testing factored in

Risk / Regulations

- No regulatory knowledge & expertise
- No idea about device classification
- No technical file structure in place
- No risk analysis undertaken

- Limited regulatory knowledge
- Some device classification issues
- Poorly maintained technical file documentation
- Limited risk analysis

- Specialist regulatory expertise applied
- Device classification identified
- A complete and regularly updated technical file
- Full risk analysis carried out