Guideline number	**50.016A**	Version	**1.0**
Title	**Creating A Process Development Plan**		

1. How Do I Determine If I need To Use Process Development?

There is no set answer for this question, the use of process development all relates back to the level of perceived risk and how likely a process is to be stable when released or require changes.

The Key considerations to make when arriving at this decision are:

- Scope and Scale
  How far reaching is the process? How many staff will be involved in following the new process and will it be a large or small change of practice for them?

- Stability
  How stable is the updated process likely to be? Is there sufficient understanding and real world experience to ensure future updates will not be needed?

- Risk Limitation
  If the process was to go live and issues were present, what is the potential impact and risk to operations?

2. Completing Form 50.016A

Form 50.016A is intended to capture the details of the planned update to process, the headings are used to capture the relevant information that will enable a fully thought out process to be implemented for a controlled period of time.

- **Summary**
  This is simply a space to describe what it is that will be changing, it is intended to convey a reasonable understanding of the process for those that will be involved to grasp the changes. It is also to be of sufficient information that it can be understood by others not directly familiar with the process can understand. This does not need to cover the fine level of detail of the process as that will come later.

- **Stakeholders**
  This is simply a space to detail who will be involved, this can be named individuals which will include their job role or staff groups more widely. As a trial may be limited to a particular trial this level of detail can be added to show which staff groups specifically. The intended purpose of this section is to allow for a consideration of those that need to be involved, informed and may be impacted.

- **Current Process**
  This allows for a summary of what currently takes place, if the process is defined within an SOP then the SOP and version number can be referenced. If it is a specific section of the SOP then provide the detail of which area. In the event it is a new process then state None or NA.

- **New Process**
  This is where the real detail of what will be different is described. This must be of a similar level of detail as an SOP to describe the Who, What, Where and When of the process. The intended level of detail is that the stakeholders identified previously that will be following this process can understand what it is they have to do. This may require additional documents, if new forms are to be followed then they can be referenced within this section and clearly labelled. Naming convention can be discussed and agreed with QA if this is the case. This is the section in which you fully explain and detail what you will be doing in the new process.

- **Validation**
  This is a description of how you will check the new process works, it may be through measurement of results, i.e. tasks completed on time, open actions or from stakeholder survey to ask if the process is working for them. It may be a combination of several factors.

  This section is intended to describe how you will make the decision at the end if the new process works.

- **Deviation**
  This section is intended to describe if the new process will require you to go against what an existing SOP states. This is only required for complete deviations, i.e. if an SOP says to complete an action with 10 days and the updated process says to complete within 15. In the instance the new process asks for it to be completed within 7, this would not be a deviation as you will still be compliant with the original process.

  This is only intended to capture where following the new process would otherwise result in a Non-Compliance to the old process. This is acceptable as long as it is detailed and agreed in advance.

Guideline signatories

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Document history

Version	Date	Description
1.0	09/09/2025	First Release