2.1.5. The meeting to include: the area Production Manager, Production Planner, Technical Services, QA and Engineering representatives.

2.1.5.1. During this meeting the Trial is to be discussed and decisions made as to the need to manufacture one or more product batches and how large these batches need to be. If the Trial involves manufacturing production batches, a decision needs to be made if they will be a saleable product. In this case a separate Trial Protocol must be enclosed with the Final Packing documents and a QN needs to be raised.

2.1.6. **Trial Coordinator**:

2.1.6.1. At the Pre Trial meeting a Trial coordinator is to be selected, who will be responsible for the following:

2.1.6.2. Filling in a Trial Preparation Summary (see Attachment 1.). This document is sufficient to document simple Trials that don't require production of a specific batch.

2.1.6.3. Ensuring a Trial protocol/report is written (see Section 4 for guidance) and approved by either Quality Assurance, Production Management or Technical Services Department as applicable.

2.1.6.4. Coordinating the Trial documentation, ensuring that at the end, a Trial conclusion is written and the Trial documentation is filed in the appropriate Technical Files or together with any subsequent Change Control.

2.2. The Trial is executed in appropriate area and data/comments collected and conclusion formed.

2.3. Complete Protocol sheet and submit to committee to authorise acceptance of change, if successful. Use Change Control to introduce the change.
Note: If the Trial does not eventuate as scheduled, the documents must be returned to the Originator.

3. Trial Preparation Checklist (Considerations)

Attachment 1. Trial preparation summary and conclusion is to be used as an aid to summarise the Trial. This document will only need to be signed off if it is to be used in lieu of a more extensive protocol, (i.e. type batch document),

Some of the following suggestion may or may not be applicable to the specific Trial, thus the Trial protocol or documentation needs to be flexible and suited for the Trial in question.

3.1. **New component:**

- Are all Trial components available?
- Specifications and inspection plan available for Laboratory tests?
  Note: Product should be tested before Trialled. This implies a method should be available.

(tick one option)

Trial protocol:

Trial Preparation Summary and Conclusion suffices ☐
Needs additional Master Data protocol ☐ Needs validation protocol ☐
(tick one option if applicable)

Conclusion of Trial:

Trial Batch Number:	Line clearance attached:	Production Coordinator:	Date:

Trial Batch Number:	Line clearance attached:	Production Coordinator:	Date:

Follow up action required:

Supplier feedback. Yes ☐ No ☐
More Trial material required. Yes ☐ No ☐
Change Control raised; CC_____

Trial Originator Date	Prepared by Date	Checked by Date	Approved b Date