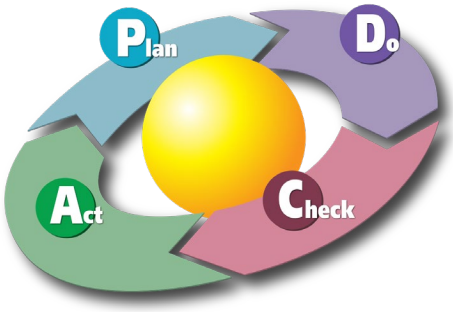
Proof-of-Concept Line Trial Guidelines

Definition: A proof-of-concept line trial is a controlled trial conducted to understand whether a processing line and/or process design concept, or continuous improvement produces the desired and expected results, specifically relating to safety, quality, manufacturability, and efficiency.

Methodology:



A proof-of-concept line trial should follow a Plan Do Check Act/Adjust (PDCA) methodology. Each phase of the PDCA is important, however, planning for a line trial is critically important in order to effectively complete the 4 phases and to maximize the benefits and results. It should be anticipated to take a great deal of time and thought to properly prepare for a trial. A common point of failure is often the lack of planning.

Plan:

Purpose: planning should start with determining a specific purpose of each trial by clearly articulating and documenting a specific goal or outcome of the trial. Examples may include, confirming process to process balance, confirmation of build step sequence, or attainment of targeted takt time, to name a few. The purpose should be shared with all stakeholders so that there is a clear understanding of what is trying to be achieved and will focus attention towards the purpose.

Preparation: with the purpose of the trial well defined, preparations can be taken to ensure the greatest probability of a successful trial. Success can be defined as the expected outcome is achieved and therefore proven, barriers are determined that need further action to be overcome with the belief the expected outcome can be achieved, or the concept is evaluated to be invalid. A failed trial is one where inadequate planning or uncontrolled execution leads to inconclusive or suspect results.

When preparing for a trial, focus must remain on ensuring all aspects necessary for the trial are aligned to the purpose while taking protective actions to safe guard from abnormalities that could negatively impact the trial that are outside the intended purpose of the trial. For example, if the purpose is to confirm the step sequence, part shortages, although a potentially real abnormality, fall outside of the stated purpose. Steps should then be taken during the preparation planning to ensure all parts are present necessary to complete the trial. Experiencing part shortages during a trial to confirm the step sequence only disrupts the trial and those involved unnecessarily and is irrelevant to the purpose of the trial of ensuring the correct step sequence has been determined or not.

Within the preparation phase consideration and planning needs to occur to select the best products or work orders, where relevant, to be used during the trial, again that

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align to the purpose of the trial. In addition, consideration as to who is to be involved in the build that is most appropriate for the given trial also needs to be determined. For example, if the purpose of the trial is to confirm that the takt time is obtainable, selection of the most skilled operators would be most appropriate. Planning for breaks and end of shift needs to be taken into account and aligned with trial start/finish times. You want to avoid just starting a trial and then needing to stop for a break or the end of shift, as an example.

Metrics: careful consideration in determining the most appropriate metrics to establish and track during the trial needs to be made. Selection should be based on primary metrics that will either prove or disprove the purpose of the trial. It is also a good practice to establish secondary metrics indicating the effectiveness of the trial regardless of the outcome of the primary metrics, such as how many units build during the trial, how many issues with planning experienced, how many barriers or issues identified. In essence the primary metrics can be used to assist with determining the proof of concept whereas the secondary metrics indicated the preparation and effectiveness of the trial itself.

Set-up: in advance of the trial commencement, actions need to be completed to set-up the line for the trial itself. Actions such as ensuring tooling, components, raw materials, packaging, job aids, standards, safety equipment/PPE, and any other items that will be required to complete the trial are in place and ready. Set-up also includes "charging" or "wetting" the line by pre-building any work in process for buffer locations.

As it is a trial, set-up items do not have to be the final version of what will be used in the final design but should be close approximations or simulations as to what is expect in the final design. Trials should be fast, easy and economical. Therefore time, effort, and money should not be spent on items or areas that are not proven or critical to the purpose of the trial. For example, if the purpose is to prove the step sequence, a temporary tool board/box is all that is needed versus a more permanent, clearly visual and standard tool board. This avoids unnecessary preparation time and minimizes costs should the trial result in changes that may affect these items.

Roles/responsibilities: it is very important during a trial to have adequate resources that have clearly defined responsibilities to manage, control, and assist operators during the trial. Too few people may result in important observations to be missed or lack of trial support impacting the outcome. Undefined roles and/or too many people may lead to an out-of-control situation where people with the best of intentions, start taking actions or making changes on the fly that which may negatively impact the trial.

A list of all roles necessary to prepare and support the execution of the trial is required. Each role should then include very specific definitions of what the responsibilities are of that role. The responsibilities should include detail on what observations the role is to be watching for and how those observations are to be documented. Determination of the best person suited for each role is then assigned.

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Ensuring each person understands their role and the associated responsibilities is important and it should not be assumed people will know without review or instruction.

Standards/expectations: even though it is a trial, the normal operational standards must be established, visualized, and communicated. The trial must simulate as close to the normal environment as possible, taking into account safety and quality and the purpose of the trial. Consideration must also be given to any new or revised standards that may be unique to the trial.

Escalation: escalation standards and expectations need to be established so that it is clear what operators are supposed to do if they experience an abnormality, have a question, or need assistance. Equally, escalation standards and expectations for the trial support team is also required to be defined so there is a clear path of escalation for any issues experienced that are impacting the execution of the trial.

Control: it is a best practice to a designate trial lead or captain. The main responsibility of the trial captain is to oversee the entire trial and PDCA process. An important role the trial captain plays is to ensure that control of the trial is maintained throughout. Control includes that the trial remains focused on the purpose, operators are following standards and expectations, trial support team members are performing their roles and responsibilities, or that casual observers don't interfere and disrupt the trial. In the event that the trial captain feels that there is an abnormality that needs to be addressed, or that a situation has arisen that may impact the trial, they have the responsibility to delay, pause or stop the trial. It is more important to maintain control throughout the trial phases rather than continue and lose control or impact the outcome of the trial.

If the trial is utilizing customer products, it is imperative that a quality gate be prepared for implementation during the trial that will check and confirm that there is no negative impact to the customer's product. Even if the trial is not expected to create any new or high risk to quality, since a trial is an abnormal build situation, it is imperative to always plan for and have a quality gate as part of any line trial involving customer products.

Do:

Start-up Communication: immediately in advance of the trial build a communication including the operators, trial support team and any other key stakeholders should occur. The communication should clearly outline the purpose of the trial, trial metrics, roles/responsibilities, escalation standards and expectations, and the importance of maintaining control, trial duration, as well as an overview of immediate next steps. Any other key messages, expectations, or team building events should also be communicated at this time.

Execution: the trial is initiated and conducted. During this phase the responsibilities of the trial support team are carried out including providing operator support,

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recording and documenting of observations, barriers, and challenges faced by the operators during the trial. Data required for the defined metrics are recorded and tracked.

Throughout the full duration of the trial, the trial support team must be present and visible to the operators conducting the trial. This is to provide line support and ensure all aspects of their roles/responsibilities are completed.

The quality gate is implemented and confirms quality safe guarding the customer from any negative impact that could result from the trial.

Check:

Metrics: the metrics as determined must be tracked, posted, be visible, and updated at the trial line throughout the duration of the trial.

Issue tracking: A means (flip chart/white board) to visibly record issues as they arise during the trial is to be established at the trial line. Visibility is important so that the operators are aware that the issues they are experiencing are being documented.

Debrief: immediately following the completion of the trial, the trial captain will facilitate a debrief with all stakeholders involved in the trial including operators, trial support team and project team members. The debrief should start with a review of the metrics focusing on plan vs actual and when the plan was not achieved, discussing what the potential causes may have been.

All stakeholders are given the opportunity to provide their lessons learned, what worked, what didn't work, and any observations they had from the trial. All items identified need to be documented and recorded.

Act/Adjust:

Prioritization: as part of the debrief, prioritization of the items identified needs to take place involving all stakeholders. It is important that all stakeholders have some input to the prioritization and take part in the determination of them. This provides better buy-in and ownership.

Prioritization ranking must be clearly defined, and is recommended to be determined n the planning phase. The ranking system should differentiate between criticality of the items and help determine the timing required to complete. Typically, an A, B, C type ranking is used for this purpose with the following definitions:

- A – significant safety, quality or process design item preventing the successful achievement of the trial purpose. Requires countermeasures prior to next trial.

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- B – creates medium impact to the trial or discomfort/inconvenience to the operators but does not negatively impact the trial outcome or purpose. Countermeasures can be completed as soon as possible, but not necessary in order to initiate the next trial.

- C – minor items that improve the process or trial, or nice to have items. Countermeasures are optional or can be implemented in the final line design.

Countermeasures: when reviewing each item and determining the necessary actions, there are three levels of countermeasure to be considered:

1. Mitigation – either during a trial when an unexpected abnormality is identified that is impacting the purpose and outcome of the trial, mitigation can be taken to isolate the abnormality in real time from the trial. For example, if a part issue is identified during the trial and the issue resulting from the issue is outside of the purpose of the trial but will negatively impact the trial, mitigation to rework the part while not directly impacting the trial may be taken. Similarly, mitigation steps can also be taken between the next trial to temporarily isolate a problem from the next trial.

2. Containment – containment are temporary actions implemented in an up-stream process or supplier to prevent the reoccurrence of an identified issue. Containment actions are implemented until such time as permanent actions can be taken or implemented that prevent reoccurrence of the issue.

3. Corrective Actions (fix): corrective actions, once implemented fix the issue and prevent re-occurrence. Corrective actions may be more difficult to implement, require longer lead times and financial business cases.

Engagement: During the determination of the countermeasures, it is critical to obtain the engagement and input from the operators. They typically have great ideas and are the most knowledgeable about the process. In addition, their early and continual involvement will lead to improved adoption and ownership.

Tracking & monitoring: all of the above lessons learned and actions need to be documented, action owners assigned, target dates determined, and then tracked to completion. Metrics and tracking needs to be established that show over time, how many issues have been identified, their ranking, the closure rate, past due items, and be a point of escalation if items are not being closed out in a timely manner or assistance is required to remove any barriers to closure.