

INSPIRING PERFORMANCE

From a Quality Assurance strategy to an operational reality in a heavily regulated industry

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UTi Pharma

Taming the compliance beast



The purpose of Quality Assurance

Why do we exist?

Who are we providing assurance to and of what?

What does Quality mean to us?

“Provide UTI Pharma business and external clients with assurance that they have the tools and the knowledge required to efficiently and effectively meet or exceed the quality and regulatory requirements of our products & services.”



Our Vision for the QA Department

What will be the ultimate fulfillment of our purpose?

“We provide a QA service that is regarded as the international benchmark in assuring the consistent delivery of the correct results the 1st time to companies all over the world on an outsource model”



Our Strategy

How will we move from where we are now to where we want to be?



Effectiveness

Provide assurance that key business processes are consistently producing quality results

Compliance

Provide assurance that all governance requirements are being adhered to

Efficiency

Provide assurance that all business processes are continuously improved to achieve maximum efficiency



Being consistently effective CSFs

“Provide assurance that key business processes are consistently producing quality results”



CSF 1:

A shared understanding of how to perform the key business processes so that they produce quality results



CSF 2:

Processes are measured and appropriate corrective action is taken to address failure to achieve KPI targets



CSF 3:

Effective management of the risks that could prevent us from achieving the quality results consistently



CSF 4:

Controlled implementation of process improvements (Changes) to prevent deviation from the quality results

Strategic objectives to produce the CSFs



CSF(1.2)
a shared understanding
of how to perform the
key business processes
that need to consistently
produce the correct
results to achieve UTI
Pharma's Strategic
Objectives



Strategic Objective 1.2
100% training records for annual
SOP training



Strategic Objective 1.2
100% of staff trained on using the
mUti manual



Strategic Objective 1.2
No findings on internal process
compliance audit



Strategic Objective 1.2
100% pass rate on self assessments



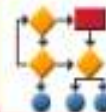
Responsibility:
Leon Patras?



KPI:
Number of audit findings?



Target:
0 Findings



Related process or project:
Internal process compliance audit

An intelligent strategy Mind Map in Nimbus

Go To Edit Diagram Favorites Administration Help

Memos (0) | CRs (0) | Actions (0) | Sub | Man | Auth

Home | Maps | Docs | Actions (1) | To-Dos (37) | Diagram - UTI Pharma QA Strategy Map, Draft 1

UTI Pharma QA Strategy

Our Purpose
"Provide UTI Pharma business with assurance that they have the tools and the knowledge required to efficiently and effectively meet or exceed the quality and regulatory requirements of our products & services."

Our Vision
"We provide a QA service that is regarded as the international benchmark in assuring the consistent delivery of the correct results the 1st time to companies all over the world on an outsource model"

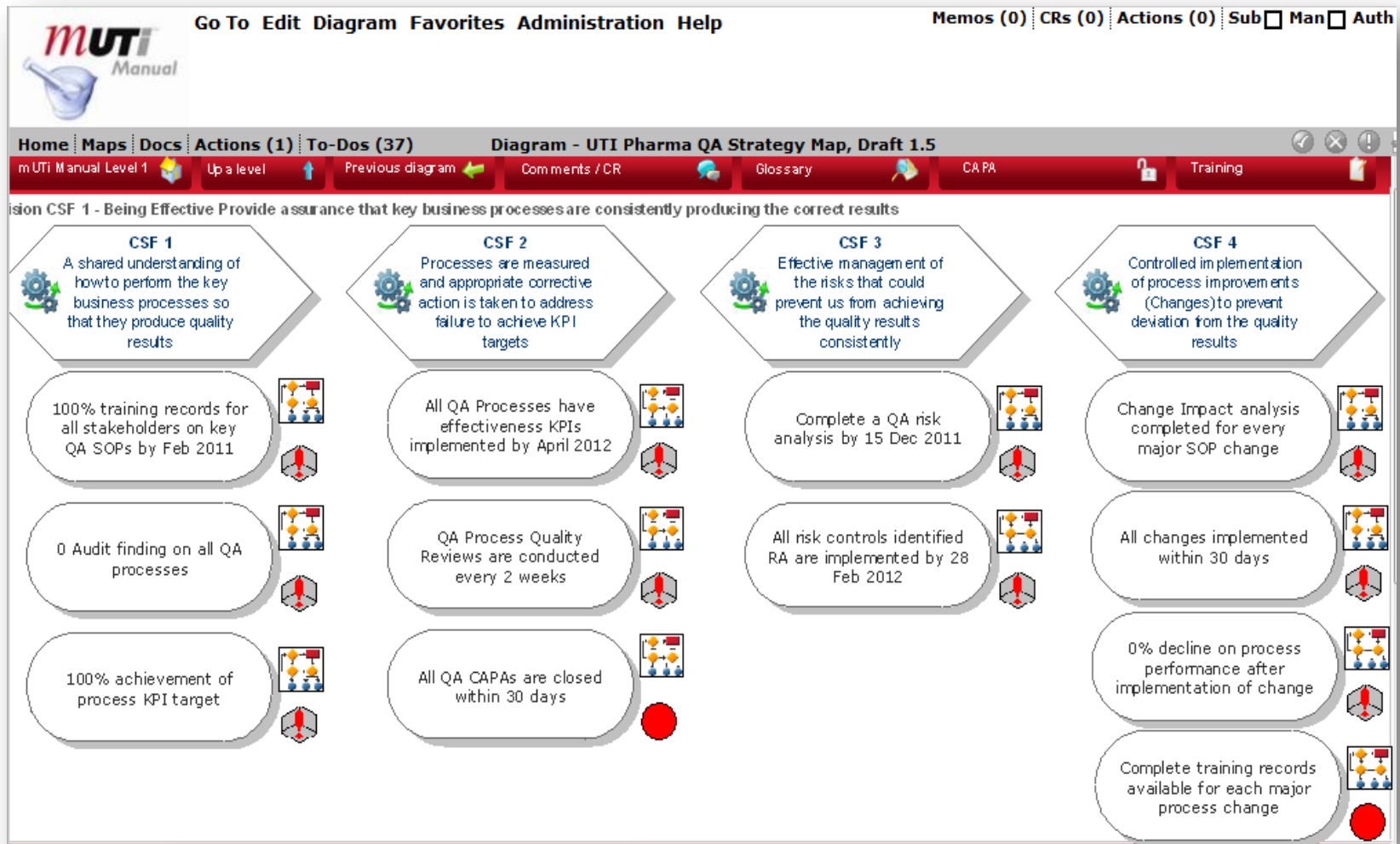
Key Quality Assurance Areas

Being Effective
Provide assurance that key business processes are consistently producing the correct results

Compliance
Provide assurance that all governance requirements are being adhered to


Efficiency
Provide assurance that all business processes are continuously improved to achieve maximum efficiency

An intelligent strategy Mind Map in Nimbus



An intelligent strategy Mind Map in Nimbus linked to operational processes

 Purpose

 Vision

 CSFs

 Objectives



 CSFs

 Objectives



 CSFs

 Objectives





 IDP IDP



 IDP IDP



 IDP IDP

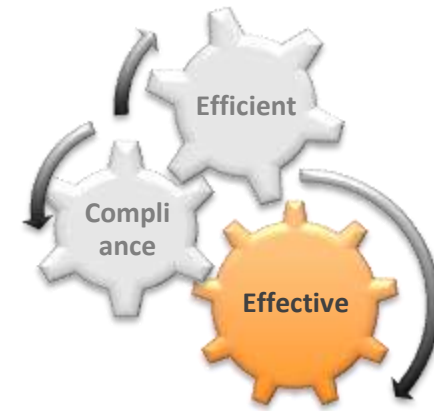


Goal 1 - Being consistently effective



CSF1:

a shared understanding of how to perform the key business processes that need to consistently produce the correct results to achieve UTI Pharma's Strategic Objectives

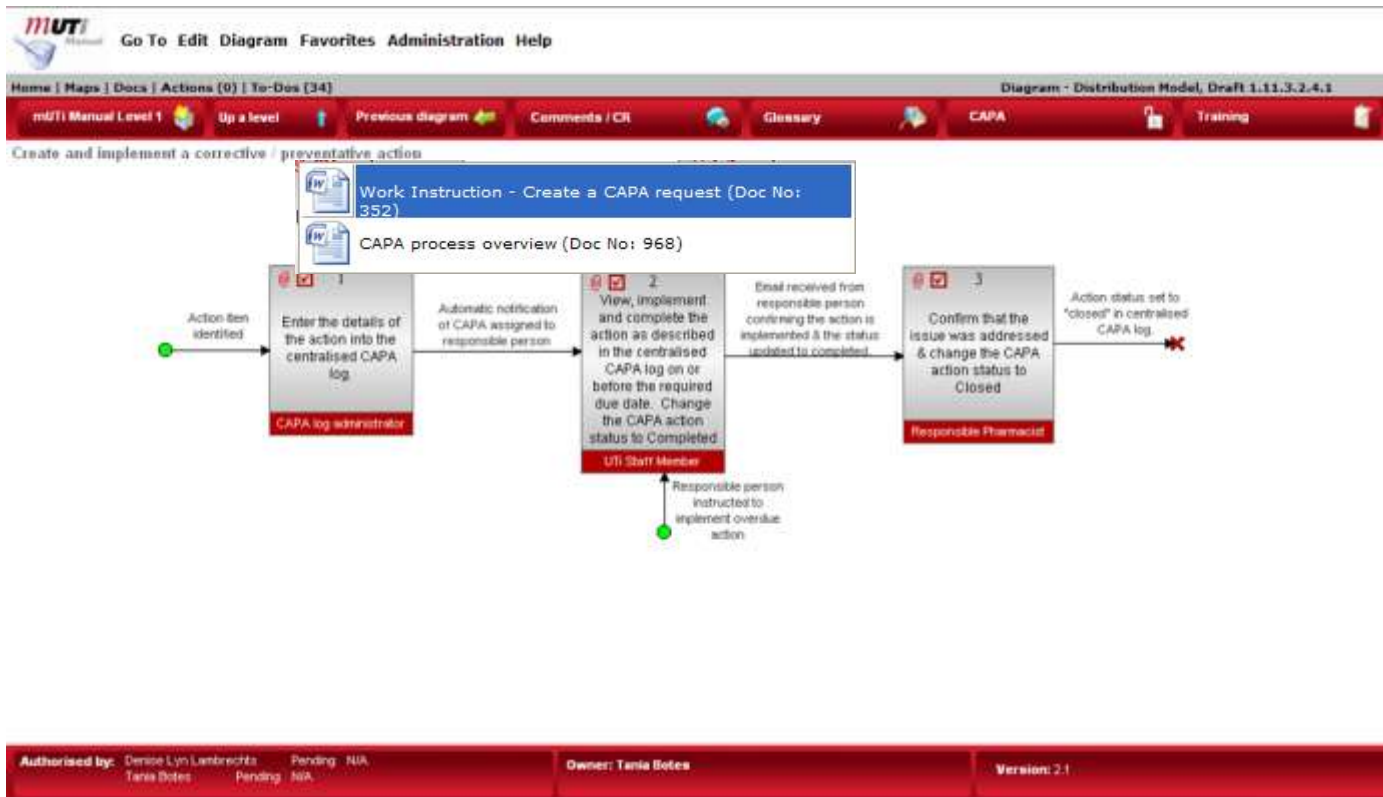
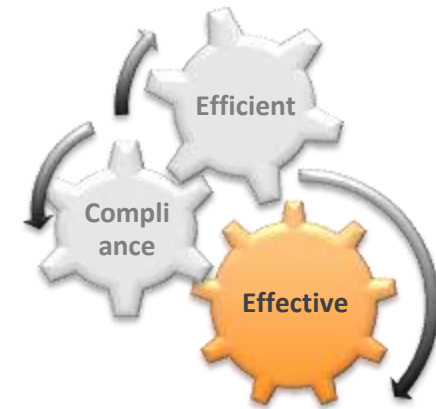


Goal 1 - Being consistently effective



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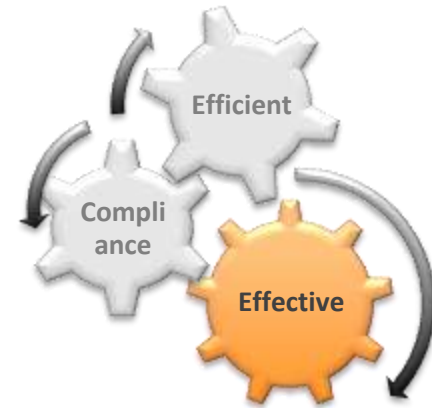


Goal 1 - Being consistently effective



CSF1:

a shared understanding of how to perform the key business processes that need to consistently produce the correct results to achieve UTI Pharma's Strategic Objectives



Step 3: Record the details of the action required

A window will open where you must enter the details of the action required.

IMPORTANT NOTES:
Use this field to describe the actions to be taken to resolve the specification. This field will contain the information that will be included in the email notification to the person responsible for completing the action. It must therefore be clear and to the point. The person responsible to implement the action must know EXACTLY what to do when reading this.

It is suggested that you copy this information once you have finished describing the action as you will have to provide the details of the action again in the next screen (To copy: Highlight the text and then press Ctrl-C).

Only log one action at a time. E.g. if an action involves a facility to be re-validated and the SOP to be updated. Log 1 action for the facility that must be re-validated and 1 action for the SOP that must be updated. In other words: both actions must be logged twice, as they have more than one action that is required.

Step 4: Populate the additional fields

A window will open with fields regarding the additional detail required for the action. Please complete these fields, by using the drop-down lists (use the notes below as a guide).

Use the following notes to help you:

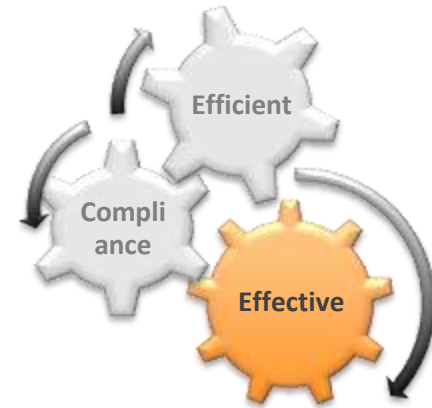
CAPA log field	Option	Notes
Action Source	3 rd Party Audit	If an action has been identified as part of a 3 rd Party Audit. E.g. Audit observations that were identified as part of a supplier audit.
	Incidental findings	If an action has been identified "by accident". E.g. While you were walking in the warehouse, you notice of ambient product being stored in the refrigerator. These actions you noticed "by accident", you did not go out to look for them on purpose.
	Calibration / Verification	If an action has been identified during the verification / calibration of a piece of equipment. E.g. during the calibration of a scale, the calibration technician noticed that the scale is unable to "tare". Or during your

Goal 1 - Being consistently effective



CSF1:

a shared understanding of how to perform the key business processes that need to consistently produce the correct results to achieve UTI Pharma's Strategic Objectives



Accessing the mUTi Manual in the warehouse



Goal 1 - Being consistently effective



CSF 2:

Processes are measured and appropriate corrective action is taken to address failure to achieve KPI targets

“If you can’t measure it you can’t manage it.”

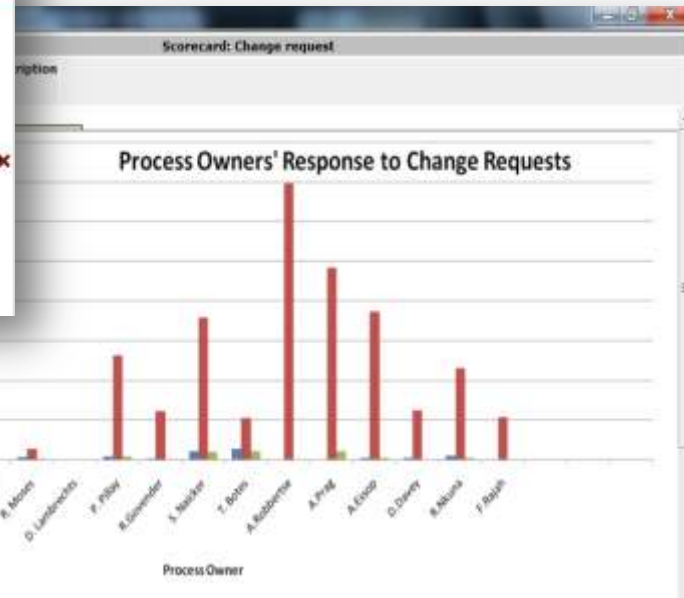
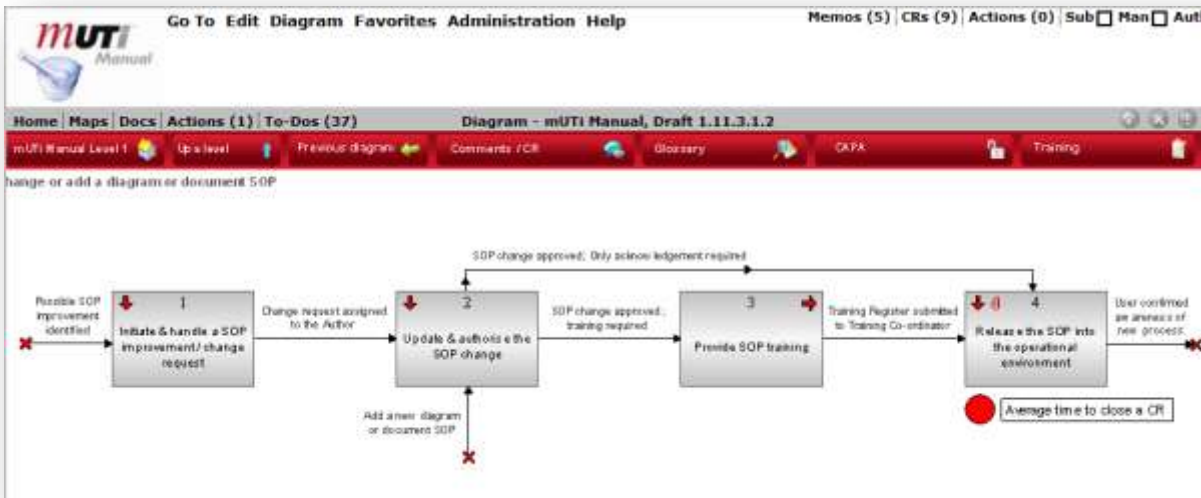
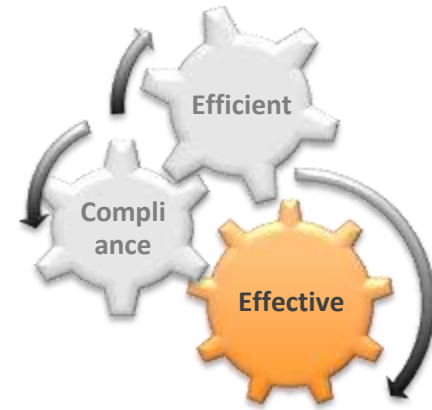


Goal 1 - Being consistently effective



CSF 2:

Processes are measured and appropriate corrective action is taken to address failure to achieve KPI targets

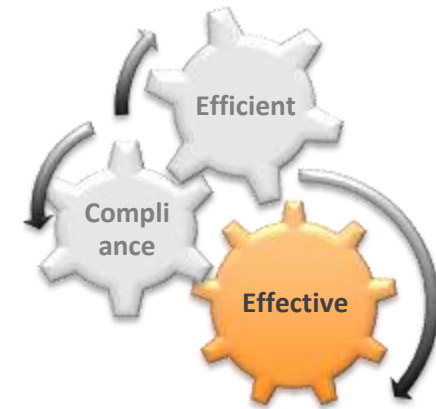


Goal 1 - Being consistently effective



CSF 2:

Processes are measured and appropriate corrective action is taken to address failure to achieve KPI targets

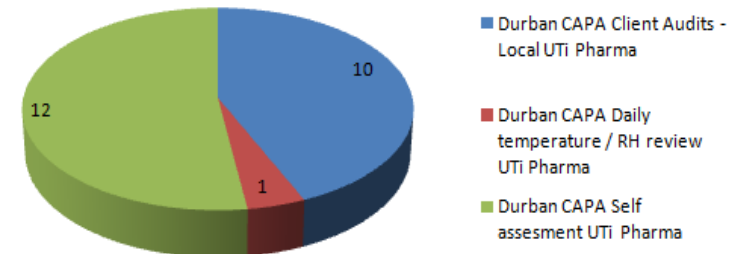


Count of Number				
Category	Action / Deviation source:	Action attributed to:	Total	
Durban CAPA	Calibration / Verification	Customer	1	
	Calibration / Verification Total		1	
	Client Audits - Local	Supplier / Service Provider UTi Pharma	10	
	Client Audits - Local Total		11	
	Daily temperature / RH review	UTi Pharma	1	
	Daily temperature / RH review Total		1	
	Self assesment	Supplier / Service Provider UTi Pharma	12	
	Self assesment Total		13	
Durban CAPA Total			26	
Grand Total			26	

Count of Number				
Category	Action / Deviation source:	Action attributed to:	Total	
Durban CAPA	Client Audits - Local	UTi Pharma	10	
	Client Audits - Local Total		10	
	Daily temperature / RH review	UTi Pharma	1	
	Daily temperature / RH review Total		1	
	Self assesment	UTi Pharma	12	
Self assesment Total		12		
Durban CAPA Total			23	
Grand Total			23	

Action sources attributed to UTi Pharma:

Durban
YTD: April 2011



2011 YTD Summary (UTi Pharma Durban):

Goal 1 - Being consistently effective



CSF 3:

Controlled implementation of process improvements (Changes) to prevent deviation from the quality results



Being consistently effective – Controlling change



CSF 4:

Controlled implementation of process improvements (Changes) to prevent deviation from the quality results

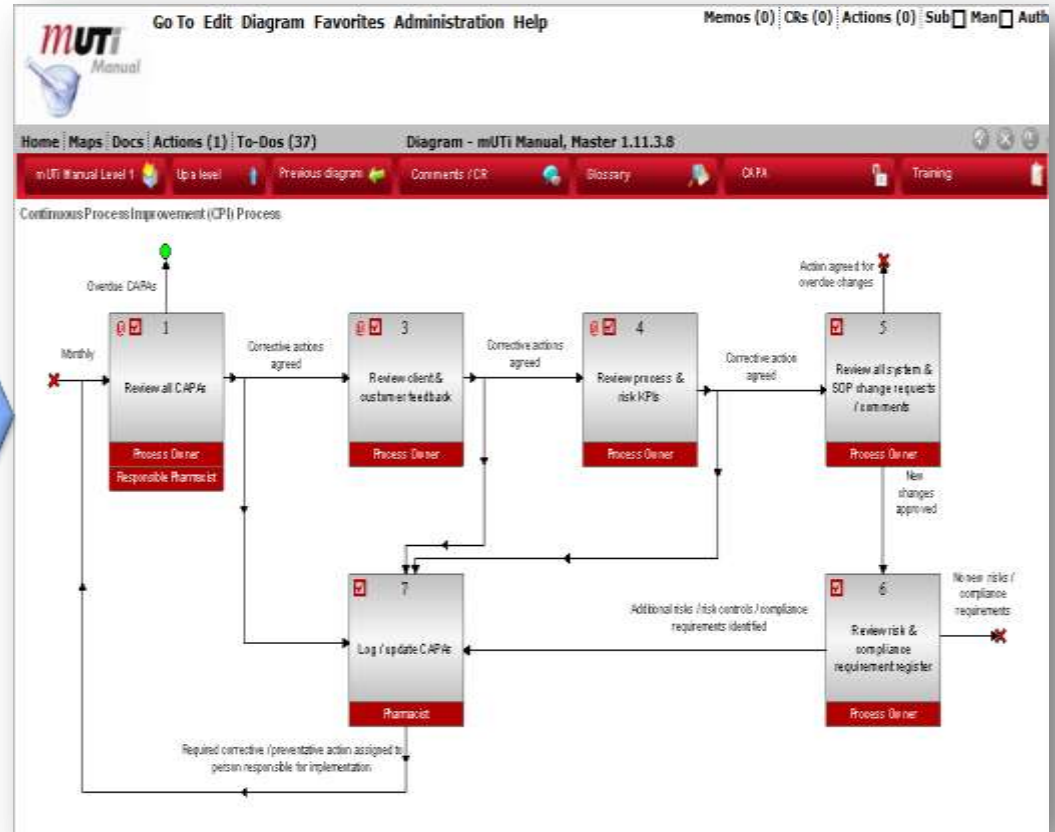
Planning Change Effectively

- Why are we changing?
- What do we expect to gain?
- What needs to change?
- Who will be affected?
- What do they need to do?

Goal 1 - Being consistently effective

Our Quality Review process inputs:

- KPI Results
- Customer Quality Complaints
- Risk Analysis
- CAPAs
- Audit & Self Assessment Findings

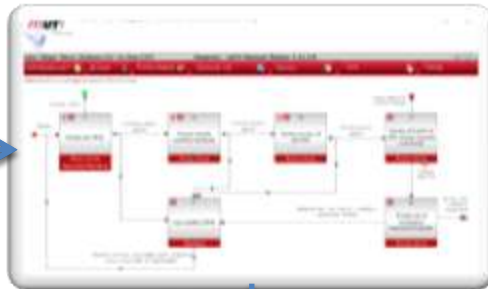


Goal 1 - Being consistently effective

Our BPM process

Quality Review Process

Monthly



CAPAs identified from quality review

New CAPAs logged



