Model actions on findings in a CAPA activity.

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First, a few definitions

What is a CAPA ?

A CAPA is *Corrective And Preventive Action.*

In other words, a set of actions to improve a process in an organisation in response to a problem.

It is a formal investigation into such defined problem or problems.

A CAPA can be initiated following an audit, inspection, customer complaint, quality problems, etc.

Corrective action is mandatory in ISO 13485:2016 (8.3, 8.5) and ISO 17025:2017 (7.10)

CAPAs are aimed to eliminate causes of nonconformities or other undesirable situations.

The needs for a CAPA can include…

- Internal or external audit or inspection
- Customer complaints
- Data from a post-market surveillance programme
- Negative quality trends (e.g. from statical process control data)
- Out of specification or out of expectation results
- Manufacturing or test equipment going out of specification
- Failure of manufacturing or test equipment
- Continuous improvement programme
- External factors (regulatory changes, new markets, etc.)

Note: this list is not exhaustive.

This presentation will cover…

This presentation will focus on:-

The interpretation of CAPAs supplied by a manufacturer in response to non-conformities found during an inspection by UNFPA.

The interpretation of CAPAs raised on a testing laboratory.

In many cases the same procedures will be followed.

Stages in a CAPA can include

Define the need for a CAPA

Obtain management sign-off for the work

Identify – accurately – the problem and the work to be done

Assemble the project team

Plan the work to be done

Carry out the work

Verify/validate the work as necessary

Carry out any training as necessary

Update documentation as necessary

Report

Acceptance of a CAPA

Acceptance of a CAPA will depend on the reason for raising the CAPA. For example

- if the CAPA has been raised to address non-conformities found during an audit, then generally the auditor will accept or reject the CAPA report.

- if the CAPA is the result of a customer complaint, then usually the Quality Director would approve it.

- if the CAPA seeks to correct negative quality trends, then again the Quality Director would be most likely to issue any approval.

Whatever the reasons for the CAPA, it should be accepted by senior management.

Identifying the problem

A clear, accurate and unambiguous definition of the problem is essential to a successful CAPA. You need to know what you are trying to fix.

If the problem is a non-conformity identified during an inspection of a manufacturer or a laboratory then it will usually be referenced to a clause in a standard (eg ISO 13485 or ISO 17025).

Otherwise it will be necessary to carry out more research to pin down the problem – for example root cause analysis, failure mode and effect analysis (FMEA), fault tree analysis (FTA), analysis of previous data and data trending or one of the other problem solving tools.

Following an inspection

Non-conformities identified during a UNFPA inspection or other audit will be communicated to the company or laboratory during the inspection.

The company will need to carry out CAPAs to correct any non-conformities.

UNFPA specify a time limit of 3 months for CAPAs to be completed, although this can be extended through negotiation in extreme cases.

CAPAs following an inspection or audit

As mentioned above, identify the problem as clearly as possible.

The inspector or auditor will have identified the non-conformity and may be able to help suggest remedial actions.

The problems could include:

- **not following the correct procedures in the relevant standards**
- **equipment not calibrated or validated**
- **equipment does not comply with the requirements**
- **incorrect document control.**

Once the problem is defined the CAPA can start.

“Not following the correct procedures”

This can be a particular problem in certain areas. For example commonly seen errors include:

Stability studies not carried out on product stored for the maximum time allowed between condom dipping and foiling, as required by ISO 4074:2015 .

Package integrity testing in ISO 4074:2015 requires a vacuum level of 20±5 kPa absolute pressure. This is frequently interpreted as a vacuum level of -20±5 kPa pressure.

The rolled water test for freedom from holes in ISO 4074:2015 requires that the condom is rolled through at least two *complete* revolutions.

“Not following the correct procedures”

CAPA actions:

- refer to the relevant standard or UNFPA guidelines

- ensure that the standard/guidelines are the current editions

- compare with the company SOPs and work instructions

- amend the SOPs/work instructions as necessary (follow document control procedures)

- train the relevant staff. Keep training and effectiveness of training records.

- if the stability study condoms are not correct the study must be re-started

Verified by submitting copies of SOPs/WIs, together with training records. A video of the amended procedure would also be helpful.

”Equipment not calibrated”

CAPA actions:

- calibrate the equipment. If calibrated externally, try to use a company accredited to ISO 17025. If calibrated internally, calibrate against a standard traceable to national or international standards.

- display a calibration sticker on the equipment.

- make sure the equipment identification and calibration date are displayed.

- ensure that the equipment is listed on the master calibration record.

- recalibrate at sensible intervals.

Verified by sending copies of the calibration certificates and photos showing the calibration sticker.

“Equipment not complying with requirements”

This can be a particular problem if the company or test laboratory does not fully understand the testing.

Common examples are:

- **the vacuum level in the pack seal integrity test not being correct**
- **the volume of water delivered in the freedom from holes test being incorrect**
- **the inflation length in the burst test being incorrect**

“Equipment not complying with requirements”

CAPA actions.

- refer to the relevant standard or guidelines

- thoroughly audit the equipment against the standard/guideline

- make the appropriate modifications

- verify or validate the changes

- update SOPS/work instructions if necessary (follow document control procedures)

- train the operators if necessary.

Verified with descriptions and photographs of the changes, validation reports, staff training records, copes of updated documents.

“Incorrect document control”

ISO 13485 and ISO 17025 have specific requirements for control of documents and records.

These include

- **ensuring that relevant documents are available at the point of use**
- **documents are readily retrievable**
- **ensuring that obsolete documents are not in use**
- **changes in documentation remain identifiable**

“Incorrect document control”

CAPA actions.

- **refer to the relevant standard or guidelines**
- **thoroughly audit the document(s) against the standard/guideline**
- **make the appropriate modifications**
- **update documents as necessary (follow document control procedures)**
- **train the operators if necessary.**

Verified with descriptions of the changes, validation reports, staff training records, copes of updated documents.

CAPA review

Review the CAPA thoroughly

- has the company understood the problem?

- has the action taken been appropriate?

- has the action taken been carried out correctly?

- are the actions taken supported by appropriate protocols, results, analysis of results etc?

- has the CAPA been signed off by an appropriate manager?

- is the CAPA supported by sufficient information to verify or validate the action taken?

If the answers are “yes”, approve the CAPA. If not, reject the CAPA or ask for further information. Give details why the CAPA has been rejected.

In summary

A CAPA is a systematic process to correct and/or prevent problems in manufacturing and testing.

It can be carried out in response to problems identified in an audit, customer complaints, negative quality trends, results outside of expectation, quality improvement programmes, etc.

Results from a CAPA must be verifiable and supported by as much evidence as possible.

Acceptance of a CAPA can only follow a thorough review of the actions taken, results generated and evidence supplied.

Thank you for your attention.

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