Review of Changes

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Introduction

A prequalified (PQ) condom manufacturer has been judged essentially at the time the PQ inspection was carried out

However, changes can take place at the company following the PQ inspection

These changes can take place for several reasons

Some Causes of Change

Continuous improvement (as required by ISO 13485 clause 8.5.1 and ISO 9001 clause 10.3)

Certifications expiring and needing renewal

New equipment being installed & validated

Formulation and process being changed

Changes in raw materials (cost saving? Product improvement?)

Some More Causes of Change

Customer complaints

Changes in senior management

Changes in regulatory requirements

Changes in site of manufacture

And many more.

Possible Effect of Change

These changes may well have an effect on product quality - sometimes deliberately, sometimes inadvertently

For this reason UNFPA demand that any PQ manufacturer reports any change for evaluation, together with the rationale for the change and supporting data

Evaluation of Changes

The data are passed to UNFPA experts for assessment

An estimate is made of the effect of the changes on product quality, and how this may affect the PQ status of the company

Any Changes to PQ Status?

Recommended changes to PQ status (maintain, maintain subject to conditions, suspend) are reported

A requirement for verification of the changes may be made, either immediately or at the next PQ inspection

Often further information will be requested of the manufacturer to allow a better assessment

Results for 2022

Responses from 35 companies (male condoms, female condoms and IUDs) were received

PQ for one company was suspended, as it is moving manufacturing sites

Six companies reported no changes

Questions?

Thank you for your attention