Caterina De Carlo, J Dev Drugs 2014, 3:3
http://dx.doi.org/10.4172/2329-6631.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Summit on
GMP, GCP & Quality Control
September 25-26, 2014 Valencia Convention Centre, Spain

The role of quality control in administering and documenting informed consent/assent process in a TB adolescent cohort study in Siaya county, Western Kenya

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The process validation approach, as described in EU-GMP guide part I, annex 15, is changing in order to be aligned to other sections of the EU-GMP guide part I, annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation and changes in manufacturing technology.

Exploring the current guideline document and the draft proposed, it is possible to know the difference:

- The retrospective validation approach becomes obsolete;
- The traditional validation approach (prospective and concurrent) survives;
- The continuous validation approach is born.

It is not important to discuss the abolition of retrospective validation approach, it was very old, and it was only a way to close the gap of validation activities for old processes. Likewise, the traditional validation approach is out of scope, all of validation professionals know it.

The main topic of this document is the continuous validation approach and the analysis regarding quality cost:

What? Process Analytical Technology and multivariate statistical process control. An alternative approach to the traditional process validation in which manufacturing process performance is continuously monitored and evaluated.

When? For products developed by a quality by design approach, where it has been scientifically established that routine process control provides a high degree of assurance of product quality.

How? The process verification system should be defined and there should be a science based control strategy for the required attributes for incoming materials, critical quality attributes and critical process parameters to confirm product realization. This should also include regular evaluation of the control strategy.

Why? Because it may be used as tool for knowing, measuring and controlling processes, because managing of deviations and recalls is expensive, also more than implementation of the proper quality system.

The right cost evaluation of quality must not leave out the cost of non-conformance resolution:

1. Evaluate cost of implementing the proper quality system;
2. Evaluate cost of managing deviation and recall;
3. Sum the results at the points 1 and 2, in order to obtain the total cost of quality.

At the optimum point:

- Optimum Total Cost of Quality;
- Optimum Cost of Implementing Quality;
- Acceptance level of non-conformance.

On the left Zone the system is under quality:

- Quality implementation is low cost;
- Managing non-conformance is high cost;
- Total Quality is high cost.
- On the right Zone the system is over quality:
- Quality implementation is high cost;
- Managing non-conformance is low cost;
- Total Quality is high cost.

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