



Abstract

## The unicist ontology of quality assurance

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Quality assurance is a characteristic that systems have, whether they include human action or not, to provide the accurate result to the point of being substituted by alternative systems in case of failure.

Nothing is absolutely certain by definition within the scope of science. When we refer to certainty we mean that there are at least three alternative plans in case of failure and that alternative processes have been designed to have a probability of failure of less than 0,01.

In order to assure this level of certainty it is necessary to count on a verification process in real conditions that ensure the result or output.

### Concept

The Quality Assurance concept implies that in the activity, which must bring about an added value, there is a Redundant Functionality and a Self-exclusion System within a framework of a Redundant Operative Method.

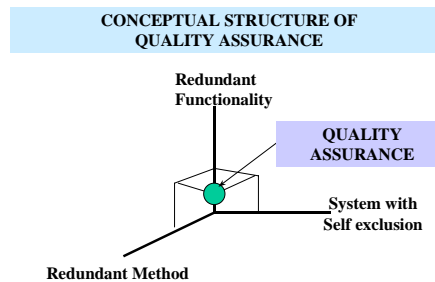
In order for knowledge to be certain, the basis for the use to produce elements, it is necessary to have been ‘redundant’ from different objective perspectives, be clear as to the scope of such knowledge (think and say “I don’t know” is to have a self-exclusion system that promotes certainty of what one knows), and count on a method that permits reaching a certain knowledge as of different points of view.

Quality assurance is of vital importance in the life sciences fields. In those fields in which the lack of quality is not a life or death, success or failure determinant, the possibility of conceiving a Quality Assurance process turns distant.

There is only quality assurance in those cultures and activities in which there is the attitude that things should be functionally right and certain as far as the value they add.

### Concept Development

The Quality Assurance concept is logically defines as:



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## Redundant Functionality

The purpose of quality assurance is to always have an alternative system to develop any activity. This purpose is related to the “minimum strategy”.

Every minimum strategy requires quality assurance in its development. That is why the redundant functionality carries the “Plan B” subconcept as an essential element, the definition that for whichever action there is an alternative in case of failure.

Furthermore, it has a redundant system and an “alarm” system, which sets Plan B in motion. There are as many plan Bs or alternative paths as possible within the systems cost restrictions.

The redundant functionality implies that there is a “default” alternative path for all failing process and if the self-repair has failed as well. The redundant functionality starts its full operation when the alternatives to the original system have been unable to repair the failure incurred into.

Total redundancy implies a greater cost that can only be considered when no alternative is left.

## System with Self-exclusion

The quality assurance procedure is the operation in work processes that has redundancies. These redundancies are partial and imply the substitution of elements in a process that can fail. There are industrial processes in which this is possible while there are others in which it is not.

In extreme cases, the system with self-exclusion implies a system with stops. A system with stops is, in case it fails, one that self-excludes from the “work” process. It is the “I don’t know” of a person when dealing with personal knowledge.

It has a control system that establishes when the stop mechanism is set in motion seeking to avoid that the said one acts, given that it implies the overall redundancy process startup.

The verbal function, that is, the active function of quality assurance seeks to develop the expected results with processes that include redundancies, a strict self-exclusion system from the system in case there is lack of safety in its activity.



## Redundant Method

The work method in quality assurance implies the startup of an alternative method as soon as the alarm system triggers the signal that the system has been unable to repair itself.

The repairing system is a function that needs to be ready to repair the process in real time. In turn, this repairing function has an alarm system that sets an alternative system in motion when this does not happen.

The method is completely objective; there is no possibility to generate subjective alternatives in light of changing situations. The redundant method is the homeostasis that assures Plan B's operability.

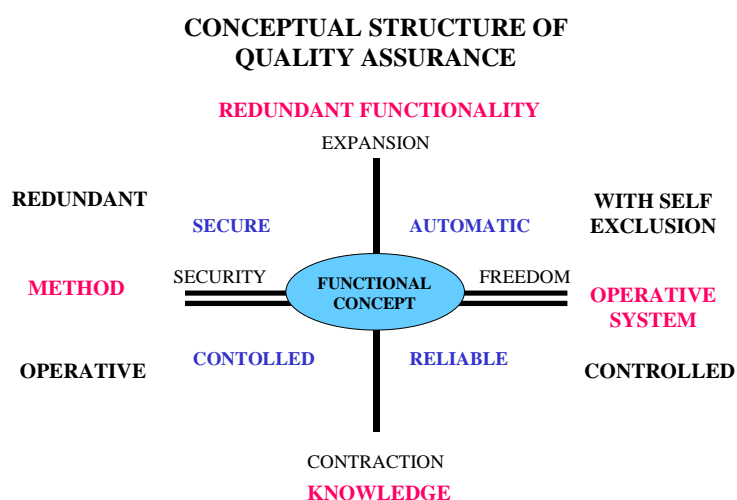
## Structural Segments of the Quality Assurance Concept

There are different ways to face Quality Assurance. In many cases quality control has been deemed synonymous to quality assurance. In fact, assurance itself enables that the system not be externally controlled. The control lies within its own system.

Complex processes pose the development of the quality assurance concept in all its forms. This means that automatic, secure, controlled and reliable aspects intervene in a complex system.

A complex system, by definition, implies the development of quality assurance that encompasses all the needs the system has.

The structural segments of the quality assurance concept are described as follows:



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## Reliable

These are the quality assurance processes based on the operative method that offers the operation security required. They use the external control to the process as a quality assurance method but emphasizing on the compliance of the operation method.

It is the most basic way to assure quality, through controlled operative methods, and appears included in all complex processes.

## Controlled

These are the quality assurance processes in which the operation revolves around control. They are the typical work processes of a high analytic, abstract level in which the possibility of error is high. In this case, they are processes that include a permanent control through parameters, points of control and/or validation of results.

The process is designed to comply with the specifications defined in the points of control. It is widely used in the industrial fields where 100% product reliability is required. These processes of external control to the process are based on the knowledge of the elements that determine their quality.

When incorporated to the process, they cease to be controlled processes to become secure processes.

## Secure

These are quality assurance processes in which the operation is being controlled by redundant methods with a self-exclusion system to the process or of the part that has “failed”. These are processes designed so that all the elements produced be subject to self elimination if they do not meet the expected specifications.

Their security lies in that they are mainly based on a system that sets an alternative process in motion to make results certain.

The “Secure” segment includes all controls and redundancies within the same process to assure results.

## Automatic

It is the process that, designed by objects, produces maximum quality assurance to generate added value. It is the way to develop “robots”, unmanned planes, complex system diagnosis methods, etc.

It is fundamentally based on a consecutive self-exclusion system, prior to self-repair, existence of processes with multiple redundancies in all critical processes and the existence of a stop system for emergency exits for the situation.

It is the highest expression of quality assurance and depicts as operational limit the system’s inability to adapt to unexpected situations.



## Conclusions

Quality assurance is the difference that makes a person, institution, work group, system, work or product reliable or not.

Without quality assurance there is no reliability in results within reality. The more objective the subject is the less complex the application of the quality assurance concept becomes. The more abstract, intangible or subjective the result, the more complex this concept management is.

As a final summary of the Quality Assurance process find listed below a synoptic description of elements which includes the Quality Assurance Functional Concept.

The taxonomy is the descriptive one according to order of presentation. However, it implies having a clear understanding of the concept seen as a unit given that the unified field it encompasses may only be apprehended as of this totalizing/integral idea.

Elements included in a Quality Assurance System

- 1) Plan “B”
- 2) Redundant Systems
- 3) Alarm System
- 4) Processes with redundancies
- 5) Stop System (stoppage/halt)
- 6) Control System
- 7) Self repairing/recovery System
- 8) Alternative Systems

The quality assurance concept is very hard to apprehend and internalize. In order to do so it is necessary to see the elements described above within oneself. It is only as of this that a quality assurance process can be developed.