# Tool Mania

## Innovation Quality Part 5

Quality tools or quality systems applied to innovation environments are frequently reported to have a catastrophic impact. Strangling creativity, tying researchers up in a corset of rules, wasting resources on filling pointless forms. All in all, a waste of time which would be much better invested in innovation activities. Even worse, at the end of the process there is usually no real benefit for the company, no economic value. Most of the time there seems to be no way for quality activities and innovation processes to co-exist in any fruitful way. One reason for this depressing outcome might be the confusion of quality tools and quality concepts.

### Quality Tools and Quality Concepts

A lot of quality tools, such as SOP Systems or Change Control Systems, originate in regulatory requirements. As a result, they tend to be very resource demanding and display a poor tolerability towards procedural flexibility. Focusing on critical process steps, aiming to prevent errors and process mistakes, quality tools are extremely process oriented, highly formalised, highly standardised and usually environment specific. In short, quality tools tend to be rather rigid corsets and do not fit well to the requirements of an innovation process.

*„Quality Tools - Rigid Corsets.“*

| TOOL | CONCEPT |
|---|---|
| Qualification System | Performance matches Requirements |
| SOP System | Reproducible Operations |
| Change Control System | Pre-Evaluate Impact of Changes |
| QA System | Minimise Mistakes |
| Data Integrity | Retrospective Analysis Possible |
| *Too complex.* | *Simple is possible.* |
| *Too resource demanding.* | *Quick and cheap are possible.* |
| *Not applicable to Innovation.* | *„Must have“ in Innovation.* |

Quality concepts on the other hand, even so aiming at prevention of low process performance as well, are less rigid and might be seen as the essence of a given quality tool. Quality concepts are not environment specific, not necessarily standardised and formalised and – if applied smartly – not necessarily a drain on resources. Quality concepts fit to the requirements of an innovation process and are both relevant and necessary.

## Innovation Unit's Tool Mania

When confronted with quality tools, innovation units usually tick off a long list of "not applicable" arguments. Most of the buzzwords on this list are based on hearsay since innovation units cherish their ignorance on finer details of formalised quality. Consequently, the tool is rejected – which must not be a bad idea - but the underlying concept is rejected as well – which is definitely a bad idea. Since most quality concepts apply to innovation as well, rejection due to tool mania easily leads to low performance of innovation processes.

*„Tool Mania 1 - Buzzword based Rejection."*

## Quality Unit's Tool Mania

The first choice of any quality unit tasked with innovation quality is the transfer of existing tools, e.g. from the manufacturing area, since the tools are known to perform, and the transfer seems easy and cost efficient. From the quality unit's perspective, the implementation of the tool is perceived as a value as such and sadly this view is frequently shared by management. Moving on, the quality unit leaves in its wake an innovation unit burdened with rule sets which are neither relevant nor feasible for daily operations. This kind of tool mania is a critical drain on resources and seriously impedes innovation.

*„Tool Mania 2 - System for System's Sake."*

## Tools versus Concepts – An Example

Equipment qualification done by manufacturing units tends to be a complex and resource demanding process, going through up to four consecutive qualification steps (DQ-IQ-OQ-PQ), nicely mixed with intermittent acceptance tests (FAT, SAT). Obviously, this process is a bit over the top of the requirements and possibilities of innovation units.

*„Equipment Performance needs to match Process Requirements."*

The quality concept however is highly applicable for innovation processes – equipment performance needs to match process requirements. And using this concept in an innovation environment is certainly feasible, since it just needs three steps, two of which should be done anyway, regardless of the qualification topic. First, the requirements of the innovation process need to be defined, e.g. in terms of accuracy, repeatability or robustness of results supposed to trigger process decisions and further innovation investments. Second, these requirements need to be linked to equipment output(s). Both steps should be an essential part of any innovation strategy since they prevent resource waste and low performance.

*„Three simple Steps."*

The only extra step of the "performance meets requirements" concept is a targeted performance check of equipment parameters relevant for equipment output. This targeted check can be done quick, e.g. via a black-box approach, and dirty, e.g. by just scribbling down the overall result in an equipment logbook instead of filling complex forms.

**How to do Do**

Applying quality concepts to real life is rather simple. Existing quality tools like SOP Systems, Qualification Systems or Change Control Systems can be used as an inspiration, a warehouse of ideas to select from. From there on, the underlying concept of these tools is identified and assessed with regard to the relevance for a given innovation process.

Those concepts being relevant should be implemented in a quick, dirty and cheap manner. Quick by going ahead without entering lengthy fundamental discussions. Dirty by avoiding investment of resources in unnecessary formalism or the beauty of documents. And cheap by preventing waste through always keeping the workload of future daily operations in mind.

More to the topic with a special emphasis on avoiding quality technocracy in one of the next issues.

*„Quick, Dirty and Cheap.“*