

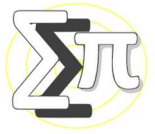
QUALITY RELEASE SUPPORT IN CHANGING ENVIRONMENTS

Monitoring of data-
characteristics and support on
quality release.

Empiriqation B.V. i.o.

Any considerations should be sent to: David.Hogeling@Empiriqation.nl

Interested in a demo or estimate? Call / WhatsApp: Content removed



Monitoring and Support by Empiriqation®

Improved daily experience

Can we make you, or someone else working on quality release in manufacturing, happy with back-to-basics quality management? Then this sounds probably familiar to you: the standards of the current system were originally fine but after new product versions there are considerations; data maintenance is overdue; new technical requirements are demanded; tighter goals and schedules; new people on board so “knowledge between the noses”ⁱ must be restored. Data integrity monitoring and support reduces these risks and mitigates incidents by the focus on knowledge and control over manufacturing, directly improving the daily experience of employees and the customerⁱⁱ.

SOLVING THE TRAFFIC JAM ON THE A16

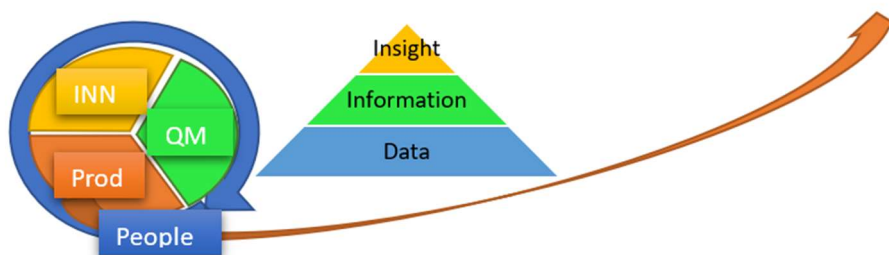
In June 2010, a blocked exit lane by trucks waiting at a production facility escalated to a traffic jam on the A16 for more than an hour. Although the mayhem was solved by fixing the bug in the software, the real cause was ignoring the guideline of a paper fallback. Integrity-by-design and the engagement with people and their observation skills is what makes up *critical thinking*: a top priority for safety and health for today and the future. From over more than 20 years of software solution projects, David Hogeling, founder of Empiriqation®, developed unique insights about manufacturing. He hopes to contribute to empirical sustainability for many more years by delivering solutions and by stepping-in on challenging moments.

BE CERTAIN OF WHAT YOU KNOW

The ability to show and reproduce evidence on demand in a transparent way about manufacturing lines, confirms that for instance food-products or medical devices are delivered to the best of modern science. Not because we like to question everything or fear what we don't know, but the advancing of science, technology and demands makes us stop from time-to-time, and review which of the procedures or products have to change and which ones are still good. Do you want to be a custodian of critical thinking to support your workplace?

✓ DECISION-MAKING BY DATA, INTEL AND KNOWLEDGE

Quality management (QM) is the workstream in manufacturing where decisions are madeⁱⁱⁱ. Depending on whether food, chemicals, high-tech or packaged goods are made, up to 1000 or more decisions per second are made (online or at/off-line quality assurance, QA), often to protect consumers' health and safety. These are called usage-decisions through tasks such as *control of production*, *recipe control* and *delivery & logistics*. By relying heavily on systems for efficiency, manufacturing companies risk the loss of the ability to change based on knowledge or intel. This despite the fact that the systems are adaptable. Producers of e.g. potato products or water rely on IT-departments to advance or to stay in business. From 2015 till 2023, maladministration^{iv}, late responds to changing demands and loss of operational efficiency are factors in cause number 1, 4 and 5 in the top 5 causes of bankruptcy.^v



Left: Schematic model to summarize the improvement of decision-making (orange arrow) in Innovate, QM and Prod/Make (blue arrow).

✓ NOT ALARMED AND NO INSIGHT

The networked architecture in the modern industry 4.0 reference model^{vi} emphasizes on *alarm management* and *monitoring & visualization*. The company management has a need-to-know about efficiency of operations. Also, when product lifecycles and supply chains aren't integrated in the decision-making of QA, the core-business of a company comes in danger. And if the company management isn't considering these alarms nor actively engaging in questioning the data and winning advice from custodians, already many red lights are passed. The factual nature of finance will lead to the inevitable consequences: higher costs by valuable stock pending for release, loss of turnover by late phase-in of new orders and finally the accountability of management by not knowing where there is a need-to-know.

✓ DATA QUALITY CHARACTERISTICS: SMART & EFFECTIVE

By the monitoring of at least 10 data-characteristics, alarms, insight and oversight can be obtained. These characteristics indicate where knowledge



gaps are, both on-demand and triggered well on time before efficiency is impacted or new orders are missed. This allows to take swift action in the production lines or sales. It also plays a role in the propagation of vision on sustainability through products and the supply chain. By investigating additional quality characteristics, both the current knowledge and the necessary advancements are covered within QM. These benefits endure in a culture where critical thinking is accepted and where custodians engage in regular reviews of data-quality and the evaluations of alarms. By application of industry 4.0 and GAMP5®^{vii} guidelines, countless customers can be monitored simultaneously 24x7, fully automated through the networked architecture.

MONITORING, PROBLEM-SOLVING AND ADVICE

Allow David Hogeling to advice on at least ten most common characteristics^{viii}, and their role in daily experience of manufacturing. Let us know your interest in a site-visit. The 24x7 monitoring tool can be introduced as well as how it is maintained in a networked architecture. Independent of tooling, the turn-key delivery of data-characteristics can be discussed or thoughts can be shared on how monitoring and support can propagate empirical sustainability at your site. David Hogeling is happy to arrange online meetings. Note that site travels above 200km (one-way) are subject to conditions.



Terms and references

ⁱ Source of term: Appreciative Inquiries of the 3.0 kind, Cees J. Hoogendijk.

ⁱⁱ Based on research by ADP in 2018.

ⁱⁱⁱ Source ISA.ORG, beyond the pyramid, From level 2 to level 3 and then to level 4 in MAKE.

^{iv} Based on quote "Management must master the basic internal skills—general and financial knowledge, control, communications, supervision of staff, and market development—or it will fail solely or primarily from the weight of these problems.", Statistics Canada - © Minister of Industry, 1997. Catalogue no. 61-525-XPE

^v Source Finom, 2023, top 5 causes of bankruptcy. <https://finom.co/nl-nl/glossary/faillissement/>

^{vi} Source ISA.ORG, beyond the pyramid, figure 5, 6 and 7,

^{vii} Source ISPE, Data-integrity by design, 2018.

^{viii} Source ISPE, Data-integrity by design, 2018, "ALCOA+".