Quality Metrics – Bane or Boon?
GMP Talk with Experts Claudia Pachl and Ruven Brandes

7 min reading time

by Dr. Sabine Paris

The FDA is currently pushing for quality metrics reporting. Are the authorities aiming at transparent factories and documentation? Is that the beginning of a data-collection obsession by the authorities? How are quality metrics and quality culture interrelated?

On 6th April at the LOUNGES 2016 trade show in Stuttgart, Thomas Peither spoke with the experts Claudia Pachl and Ruven Brandes in a GMP talk about this complex and highly topical subject. Please read these interesting questions and answers in our exclusive summary.

TP: Thomas Peither, Editor in Chief, Maas & Peither, GMP-Verlag, Schopfheim, Germany

CP: Claudia Pachl, Partner at Avantalion Consulting Group, Lucerne, Switzerland

RB: Ruven Brandes, Head of Engineering, Qualification, Cleaning Validation, WDT eG, Hanover, Germany

From left to right: Ruven Brandes, Claudia Pachl, Thomas Peither

TP: What is so complicated about quality metrics – shouldn't they have been available to us a long time ago?

CP: Yes, strictly speaking, we already have this type of metrics. Quality metrics that are regularly collected and evaluated already exist, even if their scope has been far too narrow up to now. Unfortunately, the metrics gathered are often not useful, or the results obtained are not put to good use.

RB: The data is already available. For example, we have information from CAPA and deviation management, as well as technical data on machines. The quality metrics can be calculated fairly easily from this. The challenge here is to meaningfully aggregate the data.

TP: Shouldn't this type of data be included in the Product Quality Review (PQR) or in the Annual Product Review (APR)?

RB: Yes, the data are generally included in the PQR and in the APR. They reside in the data base but usually are not further evaluated. This is partly because no one has been appointed yet to be responsible for determining the quality metrics.

CP: Before I collect data I should answer the following question: What are the meaningful quality metrics that can help me along in my process, my workflow, my quality philosophy?

TP: Why all this excitement about metrics? Everyone should have direct access to data such as the Lot Acceptance Rate proposed by the FDA.

CP: That could be due to a common attitude of irritation over regulative innovations that are basically not all that new and are merely being specified as requirements for the first time. There were similar reactions to Annex 15 of the EU-GMP Guide, which essentially contained nothing extraordinarily new.

The pharmaceutical manufacturer should have a deep-seated interest in keeping his product within specifications, having his process running smoothly and keeping critical steps under control. To this end he should define and evaluate quality metrics.

RB: Quality metrics make production measurable. However, not every member of senior management already places the measurability of productivity on equal footing with quality and product safety.

TP: The FDA would like to compare the metrics of different locations of a company.

RB: I am certain that many people will not necessarily want this transparency and comparability.

TP: But comparability would offer an incentive for improving quality. The question is: How can I improve? What basics do I need for this?

CP: A useful quality policy has to be established for the entire company. The quality policy is implemented in the company with the aid of defined quality objectives and quality metrics and with a practical understanding of quality. Many people have problems with this as it is easier to live with platitudes than to promote transparency and visibility and to work at improvement.

RB: Quality Assurance (QA) plays a key role. QA has to provide the impetus for collecting and working with quality metrics. Many QA departments, however, have not had the status assigned to them that is necessary for this.

TP: How can the quality of products actually be controlled if no quality metrics are available? What price do we pay nowadays for not calculating quality metrics?

RB: We are already paying the price for "non-quality" in the form of recalls, deviations and rejects. But continuous data collection and evaluation relating to this can surely be optimised. Then we could draw a well-founded conclusion about the actual cost of non-quality.

CP: Without metrics, I don't monitor critical steps or critical parameters! I can only monitor and control what I oversee and measure.

TP: The FDA is also planning to measure quality culture. In that case the degree of senior management involvement will surely be checked out. Are there any other aspects or important processes that have to be considered here?

RB: Knowledge Management plays an important role. By now it has become an explicit regulatory requirement that should be introduced first of all. Elusive quality culture becomes measurable through Knowledge Management. I can measure knowledge and the benefits gained from this knowledge.

TP: Knowledge Management is referenced in ICH Q10 as an enabler for the Pharmaceutical Quality System. Is this also the case in other sectors, such as DIN ISO?

RB: ISO 9001:2015 likewise calls for the establishment of Knowledge Management. Every company that wants certification pursuant to 9001:2015 has to introduce Knowledge Management. Especially smaller operations outside of the pharmaceutical industry have recognised the advantages, the meaningful quality behind it and are actively implementing the request. Only the pharmaceutical industry still finds this difficult to do.

CP: When speaking of quality culture, one cannot over-emphasize that this culture absolutely has to be lived by the highest-level leadership and by management. Employees cannot be expected to comply with regulations and SOPs and achieve best results if management does not set an example. But that requires dedication, effort and understanding.

RB: Quality culture rises and falls with the Management Review. Quality management should use this important tool more often to get the management involved, to determine the status and actually improve quality.

TP: PQR and APR are annual reports. Is this frequency adequate?

RB: The regulatory requirements are met by annual reporting. However, this does not indicate a reasonable quality culture with more in-depth process knowledge.

CP: The frequency depends on the size of business, the complexity of the processes and on error rates. If the processes are robust, the reporting interval can be more lax. Consistent data collection and evaluation are vitally important, as is trending.

TP: What department should take the lead in collecting and evaluating quality metrics?

CP: Ideally, the QA department should be responsible for this. QA should implement the system and create the framework conditions to enable all information to be aggregated. But QA cannot bear sole responsibility for content. The individual special divisions have to collect, evaluate and prepare the data and submit it to QA. What you have here is an obligation to provide data.

TP: Then QA would more likely have an advisory function. It would have to develop into a role of methodical competence in order to help the other departments to improve.

CP: The function of the QA department is viewed in quite different ways. For some it is purely formalistic. To me QA is a service sector within a company. It makes sense to take advantage of the competency of QA to support other departments in mastering their complex tasks. The important thing is that QA be authorised and accepted to do this.

TP: The request for quality metrics is still only a draft at the FDA. How do you see future development? How long will the implementation last?

RB: I am convinced that quality metrics will be introduced. Once Knowledge Management has been implemented, metrics will also come, resulting in process improvement and efficiency.

But this will certainly take at least 10 years. For example, implementation of the new requirements for qualification and validation has been ongoing for about 17 years. We have only now reached the point at which innovations are being implemented and introduced.

CP: The importance of quality metrics will continue to grow. We talked earlier about how the figures should already be available to a certain extent. In their own interests and with the objective of continuously improving quality, however, pharmaceutical manufacturers should act early and not wait until the final deadline for implementation has passed.

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