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The Big Debate

What will Quality Management in Life Sciences look like by 2025?

MERCK accenture Syneos Health

In November, visionaries from **Merck, Syneos Health** and **Accenture** joined **Generis** for a live video discussion of the latest trends influencing the way life sciences companies manage Quality – and what future lies ahead for the discipline. They considered what measures could be taken now to enable more efficient end-to-end processes – including the pre-empting and minimisation of Quality issues using AI/ machine learning technology.

Generis CEO James Kelleher chaired the proceedings, which included a live audience poll and questioned whether, long term, quality management might be needed at all.

On the panel were:

Dr. Heiner Niessen, Merck's Head of Application Technology Quality & Compliance

Peter Brandstetter, Accenture's Quality and Regulatory expert

James Man, Syneos Health's Quality subject expert and R&D Advisory Managing Director.

Highlights of the discussion follow below.

Challenging the status quo

Setting the scene, **Generis's James Kelleher** asked the panel to give their frank views of where the role of Quality is heading in the strictly regulated life sciences industry.

James Man (JM), Syneos Health: I like to think about Quality in quite a radical way. Could Quality be more embedded, so that improvements happen continuously; incrementally? Could we rethink the whole vision about what the function does, especially now we're moving towards a decentralised clinical trial way of working? Even take an industry-aligned view on things such as metrics for the board, etc. All of that is what interests me.

Peter Brandstetter (PB), Accenture: Whether it happens by 2025 or later, I think companies will reach a point where they don't need Quality Management and people working in Quality – especially once everything is digital. Fifty plus years ago, the main purpose was to implement processes and controls for manual work, to ensure the product going out of the door was the right quality. But when everything is automated, Quality Management loses its relevance.

James Kelleher (JK), Generis: Heiner, I gather you think the opposite – that Quality efforts will increase because there's now so much more to be measured; so much more data being captured?

Heiner Niessen (HN), Merck: Yes. Although for individual quality actions, there's no doubt that things will be faster and more digitalized. Yet the demands on Quality keep growing. More parameters are being measured and, in any case, Quality is not just about *product* parameters: it spans the whole supply chain. So the measures keep growing and becoming more diverse. Take a product's carbon dioxide footprint, which could well become a Quality parameter in future.

Drowning in data – but what's it all for?

JM: There's a tendency to collect more data just because it's available. That is, we're asking lots more questions – but are they the ***right*** questions? As ever, we're swimming in data – but not necessarily in insights. We have all of these flashing dashboards, but what is it we really care about? Laypeople may not understand the ins and outs of Quality Management, but they can readily appreciate the relative risk/benefits of the different COVID-19 vaccines. Part of the challenge is to determine what's really important - at a function level, a project level, even a company level.

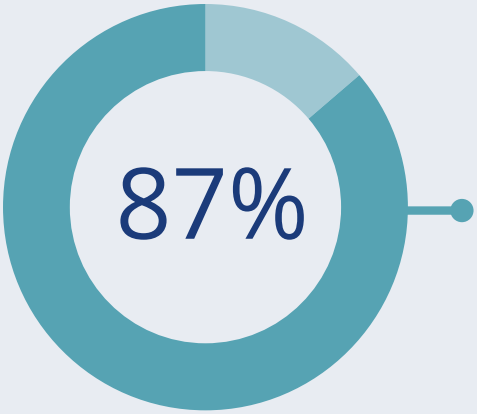
PB: I agree about expanding data volumes and multiplying parameters. All of this conspires to make the whole system more complex, which is why it's important to address the manual Quality effort. There is an opportunity here. The more we learn about the manufacturing process from all of this data, and about the context, the better we can ***predict*** quality – rather than leaving this until the end, and retrospectively testing and checking whether everything was created as it should have been. With more information and data about the product and the chemical processes, the biotechnology process, etc, whatever the complexity, the more we can start to predict what's coming and act earlier. For me, that's the goal. The priority must be to use all the data we have in the right way. Technology wise we have the means - it's just a matter of connecting all the different pieces.

HN: Working with suppliers or in a supply chain, in manufacturing of a regulated product, is a huge part of the Quality Management endeavour. Quality efforts don't stop at the company boundaries. Just capturing and collating all of this data, keeping it up to date and following up change requests across the supply chain is a significant undertaking.

JK: *Could smart automation help here? Would it be of benefit to capture all of this supply chain information in a structured way now, knowing that it might be needed at some point, for example by the regulators? Or would it generate too much noise to capture everything?*

HN: It wouldn't be a good strategy to gather everything you find on your way. But where there's probably still chance for improvement, with help from technology, is where information is coming from different sources. Perhaps it could be retrieved from a single source - which then includes information on the chain of custody, on the conditions during delivery, and so on. With improving digitalization, it's much easier to capture and track this information, right out into the real world.

Poll question 1
the current status of Quality initiatives



In the first spot poll of the live session, attendees were asked about the current status of quality initiatives in their organisation.

The vast majority – 87% - indicated that they had initiatives progressing at the current time.

People considerations: should Quality be blended into everyday operations?

JK: *What about the human aspects of Quality improvement, given that data and technology are just one part of the bigger picture?*

JM: Yes, ultimately it's humans who make decisions and promote change. Certainly today. They're informed by data though - as long as it's possible to turn the data into insights, enabling actual decisions and change of behaviour. Think of project teams back in the day: a study team from the 80s or 90s. Initially there would just be a scientific lead due to the medical interest in the scientific question. Then, as things grew, a clinical trial would have an operational lead, then Regulatory got involved, and Safety and Disclosure. As it scaled up, more skill sets were needed: people actually needed to sit, debate and make decisions together. So it wouldn't be beyond the realms of possibility to have a Quality person join that project in the future - someone sitting down with the team to fill out a supply oversight for the particular study; who could help think through the risks with a study, connecting with other causes, with other teams that are looking to benefit from all of that insight and data.

Right now, if you look at most life sciences companies and the way they're organised, there isn't a role of Chief Quality Officer – but perhaps there should be. Currently the Quality lead tends to be quite far down the organisation, which suggests that Quality isn't as important as some of the other elements. But if companies want to be more pre-emptive, for Compliance to be proactive and add value to the business, we need to make some structural changes - beginning with representation and project teams, going all the way to a Quality officer.

JK: *An anecdote from a recent customer audit touched on this: that the traditional approach involves a separate Quality division that sits somewhere and does its thing, perhaps with someone coming out occasionally to rap you on the knuckles, before retreating again. They were weighing up the possibility of embedding a Quality post in each project, even if the costs couldn't be recouped directly.*

HN: I would add that Quality is and will remain a continuous activity – I don't see the role disappearing. As long as you're developing new products or trying to improve certain aspects of your products, you will have Quality initiatives. If the activity levels remain the same, on the other hand, you'll probably be looking to lower the costs.

Human vs machine intelligence

JK: *What about Quality management linked to the use of artificial intelligence?*

PB: The technology clearly has huge potential. It's still early days though, especially in this regulated industry. Obviously, you need to ensure that if you're replacing a decision-making system with an AI tool, for instance, the quality of the decision is good. One way is to make the algorithms more transparent, and less 'black box' in nature. This will be important to convince the regulatory bodies that the technology is maturing.

JK: *Where is Merck with its thinking, here?*

HN: It's an important topic and we're seeing some limited representation in areas such as image analysis where it's quite advanced. As to real 'decision making', to date I'm not aware that we are using AI in this in this way. But, if we did, I think the Quality considerations would be similar to today. Either you train the human being, or you train the algorithm, so if it doesn't work the measures to take will be the same. But I agree that there needs to be clarity around what the algorithm is doing.

JM: There could be an opportunity with individualised/personalised medicine and Quality Management – to keep track of oversight and do this more cheaply/less manually? It might sound a bit 'Big Brother' but I'm thinking along the lines of a digital twin. Let's say I'm a mad scientist and doing an experiment, and I'm wearing Google Glass and it recalls previous activity and outcomes, and will flag up when current activity is diverging too much from original parameters, for example. But I'm just thinking out loud.

If AI can be applied as a learning tool, I see potential for collectively improving capability by identifying near misses and so on. In manufacturing there is more of a culture of celebrating this kind of thing, but in R&D we're a long way behind so it's a case of whether culturally we're willing to accept the technology within the workforce.

Adapting Quality to processes for personalised medicine

JK: *With the growing emphasis on personalised medicine, what is the impact on Quality Management?*

HN: With personalised medicine, you manufacture very low quantities of a product which applies to perhaps just one individual or a small group of people with a particular genetic background, say. Quality management then becomes a much bigger undertaking because you'll have as many quality control measures as you have personalised products.

JK: *Would that then strengthen the case for intelligent automation? To manage all of the additional tests and test protocols that will be needed?*

HN: That would complete the circle quite neatly. It's actually automation and machine learning that led us to the point of having personalised medicine, because at a biological level the complexity of the diseases we're trying to target with personalised medicine, the amount of data – be it the genetic code or other physiological parameters - is so enormous that it would be impossible for a human being to derive conclusions from it. Rather, it is AI and machine learning which makes the statistical connections that ultimately end up in a personalised medicine. So using the same technologies to help with the testing workload would make sense.

Poll question 2
cost optimisation in Quality

In the second spot poll of the live session, attendees were asked about the drive to optimise the cost of Quality management.

The desire to optimise costs was high: half of attendees said they expected the cost of Quality activity to keep rising.

Containing the rising costs of Quality Management

JK: *Should companies just accept that Quality costs will rise as data and parameters increase, or should they aim to be better at reducing effort and containing cost?*

PB: There is huge pressure on the industry to reduce the cost of medical drugs, so it follows that companies need to contain costs wherever possible. In personalised medicine, a single SKU can cost as much as USD 200,000-300,000. Whereas the cost of Quality wasn't really an issue before, the mindset has changed in the industry. Also, from a health insurance perspective, as outcome-based reimbursement becomes more established, the cost of Quality does become a factor. I know of many companies that are thinking about how they can reduce the cost of managing Quality.

JK: *Does anyone focus on the potential **business benefits** of Quality – for example in driving insights for future products, preventing recalls, ensuring the supply chain delivers as expected, and so on?*

JM: That's the Holy Grail and I think lots of companies are thinking about it, recognising that Quality is an underutilised competitive lever. Having said that, there's no company I know of that's really leading the way here. I think people are cautious about making some investments and decisions, and for now it's more business as usual – updating the QMS, putting that new CAPA management system in, etc. There's certainly more that can be done.

PB: It's something we tell our clients they should do more – learn from the font of information that is captured, to proactively improve processes, hone automation and reduce the effort expended on Quality rectification later in the cycle.

Making progress: next steps between now and 2025

JK: *What concrete steps could or should be taken by 2025, to move closer to where companies need to be?*

HN: At a corporate level, a huge topic is to connect individual quality systems across the value chain to enable seamless data transfer - from the first supplier of a single component up to the final end product, and even once it has been delivered to a given country. So you would have your CAPA system, your RIM system, your supplier RIM system all acting more or less as one system – creating the option to generate dossiers or reports according to need, or for a custom-made product. Merck sees a big advantage here and has initiatives to drive standard data exchange formats for exchanging Quality information at a system level, removing the need to send PDF files around and retype or scan information into each system. As well as saving time, this can significantly reduce errors.

PB: Yes, we need to be working with structured data that's exchangeable across company borders. Blockchain could help here, enabling a trusted chain of data, but the right foundations are needed and this is no small step. Big things don't change overnight - we need to break things down into smaller initiatives.

JK: *Do you see the 'document' going away: that we'll achieve that 'data exchange' Nirvana?*

JM: I don't think so. The way we access those documents and interact with them is here to stay. But we can and should connect Quality systems, and I think a Chief Quality Officer function will be important to make sense of everything and drive insights and decision making. The idea of calling down training in real time as needed – that kind of thing – has great value though. Also, I think embedding Quality people in the key R&D teams will happen. Achieve that, and you might be piloting more real-time data exchange with the regulators by 2025. That would be my prediction.

To watch or listen to the full debate, please visit us here:
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