The Big Debate: Will Quality Management Still Exist in 2025?

Late last year, visionaries from Merck, Syneos Health and Accenture took part in a live video debate on what now influences the way life sciences companies manage Quality – and what the future holds for the discipline, including the potential to pre-empt and minimise Quality issues using AI technology. Generis CEO James Kelleher chaired the proceedings, which included a live audience poll.

On the panel were:

- **Dr. Heiner Niessen, Head of Application Technology Quality & Compliance at Merck**
- **Peter Brandstetter, Quality and Regulatory expert at Accenture**
- **James Man, Quality subject expert and R&D Advisory Managing Director at Syneos Health.**

Challenging the Status quo

The panel began by giving their frank views of where the role of Quality is heading in life sciences.

James Man (JM), Syneos Health: I think about Quality in quite a radical way – e.g. could it be more embedded so that improvements happen incrementally; could we rethink the whole vision about what the function does, especially now we're moving towards decentralised clinical trials?

Peter Brandstetter (PB), Accenture: I think companies will reach a point where they don't need Quality Management or people working in Quality. When everything is digital and automated, Quality Management loses its relevance.

Heiner Niessen (HN), Merck: I disagree. The demands on Quality keep growing: more parameters are being measured and Quality spans the whole supply chain. In the future a product's carbon dioxide footprint might become a Quality parameter.

PB: Certainly the whole system is becoming increasingly complex, which is why it's important to address the manual Quality effort. There's 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 retrospectively checking whether everything was created as it should have been. 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: Quality efforts don't stop at the company boundaries, certainly. 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.

James Kelleher (JK), Generis: Could smart automation help here?

HN: Technology could certainly help manage information from different sources. With improving digitalisation, 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 a spot poll during the live debate attendees were asked about the current status of quality initiatives in their organisation. The vast majority – 87% – indicated that they had initiatives underway.

People Considerations: Should Quality be Blended Into Everyday Operations?

JK: What about the human aspects of Quality improvement?

JM: Ultimately people make decisions and promote change. They're informed by data though – as long as it's possible to turn the data into decision-supporting insights.

Think of project teams back in the day. First there would only be a scientific lead. As things grew, a clinical trial would have an operational lead; then Regulatory got involved, and Safety and Disclosure – more people needed to sit, debate and make decisions together. It wouldn't be beyond the realms of possibility to have a Quality person there now too – to help think through the risks with a study.

Right now, there isn't typically a role of Chief Quality Officer – but perhaps there should be. If companies want to be more pre-emptive, and for Compliance to add value to the business, we need to make some structural changes – beginning with representation.

JK: A recent customer audit touched on this. They were weighing up the possibility of embedding a Quality post in each project, even if costs couldn't be recouped directly.

Human vs Machine Intelligence

JK: What about Quality management linked to the use of artificial intelligence? Where is Merck with all of this?

HN: We're seeing some limited re-presentation in areas such as image analysis where use of AI is 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. There has 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? Along the lines of a digital twin. Let's say I'm doing an experiment and wearing Google Glass, which recalls previous activity and outcomes and will flag up when current activity is diverging too much from original parameters, for example.

If AI can be applied as a learning tool, I do 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 perhaps more 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 are the implications for Quality Management?

HN: Here, you're manufacturing very low quantities of a product which applies to perhaps just one individual or a small group of people. 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. 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, 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 become better at reducing effort and containing cost?

PB: With huge pressure on the industry to reduce the cost of medical drugs, companies do need to contain costs wherever possible. Whereas the cost of Quality wasn't really an issue before, that mindset has changed with personalised medicine. Also, from a health insurance perspective, as outcome-based reimbursement becomes more established, the cost of Quality does become a factor.

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 lots of companies recognise that Quality is an underutilised competitive lever. But I don't know of any company that's really leading the way here. People are cautious about investing currently: it's more a case of business as usual – updating the QMS, putting in that new CAPA management system, etc. There's certainly more that can be done.

Next Steps Between Now and 2025

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

HN: At a corporate level, a big one is to connect individual quality systems across the value chain to enable seamless data transfer. So you would have your CAPA system, your RIM system, your supplier RIM system all acting more or less as one system. 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/scan information into each system.

PB: I agree that 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. We need to break things down into smaller initiatives.

JK: Do you see the 'document' going away?

JM: No. The way we access and interact with them is here to stay. But we should connect Quality systems, and a Chief Quality Officer function will be important. 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.

Dr. Heiner Niessen

Dr. Heiner Niessen, Head of Application Technology Quality & Compliance – Merck. After leaving Academia with a PhD in Molecular Biology & Biophysics, I joined the Silicon Valley Biotech Company Applied Biosystems and assumed various roles from IT expert through Sales and Project Manager in laboratory information management. Later I moved to the German Biotech company QIAGEN as Alliance manager responsible for quality and supply for industry customers. In 2017 I joined Merck KGaA Darmstadt, since 2019 in the role of Head of Application Technology Quality & Compliance.

Peter Brandstetter

Peter Brandstetter is a Senior Manager for Technology Consulting at Accenture in Zurich, Switzerland. A respected authority in IT-enabled transformation in life sciences, he has more than two decades' experience of solving complex IT challenges for pharmaceutical companies globally – gained across senior life sciences consulting/IT roles including Life Science Central Region Lead at CSC, Senior Managing Consultant for GBS Life Sciences at IBM, and Senior Manager at PwC. Peter specializes in quality management and quality assurance in manufacturing and R&D, enterprise content management, and R&D (clinical data management, pre-clinical, R&D Lab, R&D collaboration and project management), as well as computer validation.

James Kelleher

James Kelleher, CEO, Generis. After graduating from Cambridge University, James initially pursued a career as an opera and symphonic conductor, before turning the closely related field of content management in Life Sciences, initially working at GSK before setting up Generis. For the last two decades he has focused on Regulatory and Quality within Life Sciences, working with customers such as Bayer, Merck KGaA, Pfizer, BMS, Gilead, AstraZeneca and Otsuka on a range of implementations across these disciplines.

James Man

James Man,Director, R&D Advisory, Syneos Health Consulting. With over 20 years' experience in the pharmaceutical and life sciences industries, James Man, Director, R&D Advisory, Syneos Health Consulting, has led a wide variety of projects across R&D during his 14 years as a management consultant. Recent areas of specific interest include supporting a large global biopharmaceutical design and implement a clinical lab QMS and a small biotech build a modular QMS as it starts to get ready for clinical trials. James is experienced in leading transformational projects in Clinical Development, Medical Affairs and R&D Operations He excels in facilitation, communication, change alignment and stakeholder buy-in around operating model design, process reengineering, governance, patient centricity and performance management. He has authored several white papers including 'Enhancing productivity in bio-pharmaceutical R&D'. James holds a PhD from the University of Bristol.