CONCERNS AND PRIORITIES: TRACEABILITY

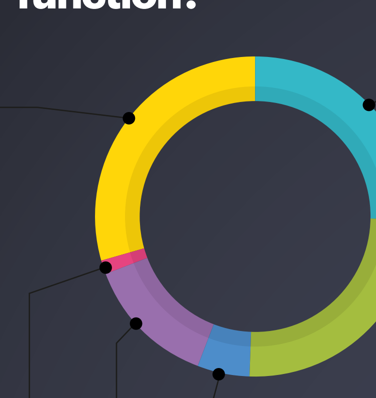
TRACEABILITY IN OPERATION 2017

AHEAD OF THE **TRACEABILITY IN OPERATION FORUM 2017** WE CONDUCTED SOME MARKET RESEARCH TO PINPOINT THE CONCERNS AND PRIORITIES OF THOSE IN THE MORE MATURE PHASES OF SERIALISATION.

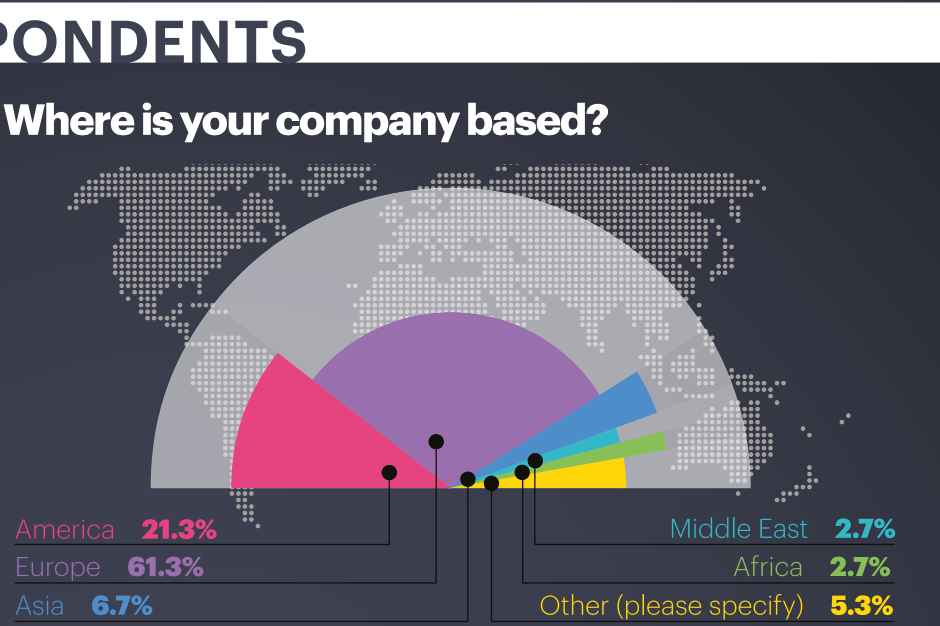
Commentary supplied by Pasi Kemppainen, Executive Consultant, Pharma Serialization and Traceability.

ABOUT THE RESPONDENTS

What is your company's function?



Where is your company based?



What regions do you operate within?

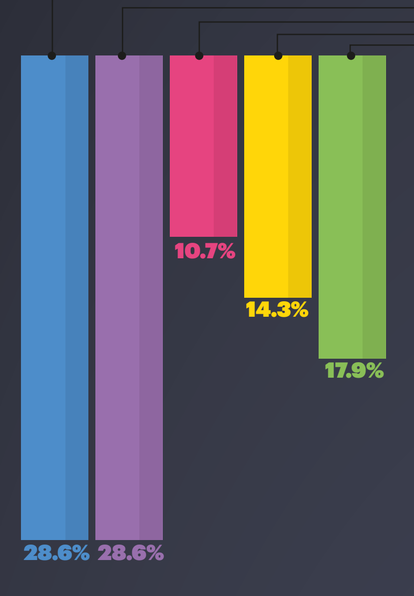
"It is no surprise that the majority of the companies are based and operating in Europe. The small percentage for the rest of the world and relatively high 'Other' answers could be explained with globally operating pharma companies that are headquartered in Europe.

"As serialisation and traceability implementation in the regulated scope is, to the most extent, entirely new to the industry, there is understandably a lot of inexperience, unknowns and uncertainty with actually comprehending what is really required to comply with different markets. In addition, the regulation can change relatively quickly as we have already seen in China and Russia.

"In addition, it is already clear that starting in 2019 after the biggest pharma markets, covering more than 80% of the global pharma business, will be enforcing serialisation and traceability, the most of the smaller and especially developing countries will be following as the investments have been already done by then. This concerns especially countries in Latin America, South-East Asia, Middle East and Northern Africa. However, this can lead to a quickly emerging global patchwork of local implementations and regulative requirements, putting the production flexibility and collaboration with the supply chain network as the key priorities.

STATE OF PLAY

How has the implementation of your track and trace project impacted your core production cycle so far?

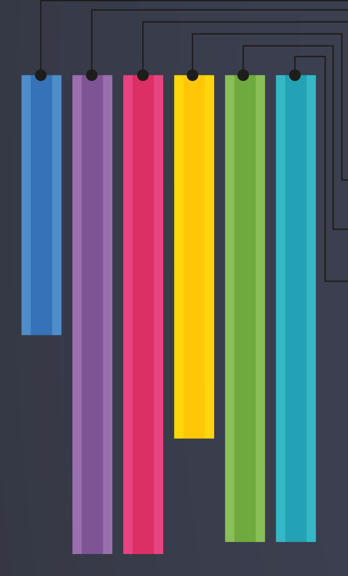


"Only third of the companies seem to be able to keep the production cycle on an acceptable level. At the same time every fourth company says that the implementation will have tangible impact on the innovation rate and productivity, and even become a main priority. This can be due to that the serialization and traceability implementation is seen to mainly focus on packaging line retrofitting, which is regular and well-known maintenance projecting for pharma manufacturers.

"However, the end-to-end implementation will also require new manufacturing and enterprise IT systems – and respective systems and data integration – which is especially new for the small and mid-size pharma companies. The true devil is in the implementation details and internal collaboration, and how to mitigate the execution risks and costs during, and more importantly, after the implementation.

"Clearly, many companies have first taken the shortest and seemingly the cheapest route in implementation and are now facing challenges in getting end-to-end implementation done without impact on the core production cycle."

How would you rate the operational efficiency of your track and trace system?

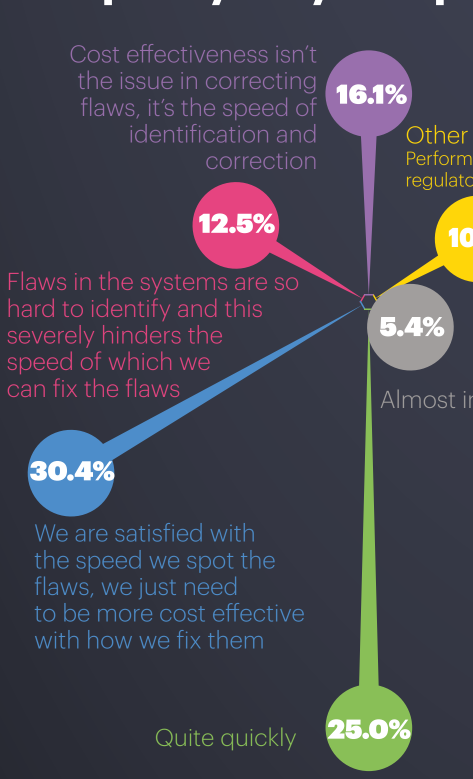


"Most of the companies are behind the current operational efficiency, which has been expected. The efficiency decrease after the implementation ramp-up can substantially increase the production costs especially in the longer term. The efficiency will not only affect the total line, capacity but can also require upgrading existing equipment with new and more expensive equipment, after the implementation.

"When combined with the potential requirement for the aggregation, this can lead to changing from the manual packaging processes into more automated solutions. This, in turn, can create additional efficiency and cost concerns.

"Therefore, manufacturers should start re-thinking how they run can run the production cost-effectively also in the future. This calls for new innovation both in processes and systems enabling fundamentally data-driven finished pharma manufacturing."

When a flaw is identified within your system, how quickly are you capable of rectifying?



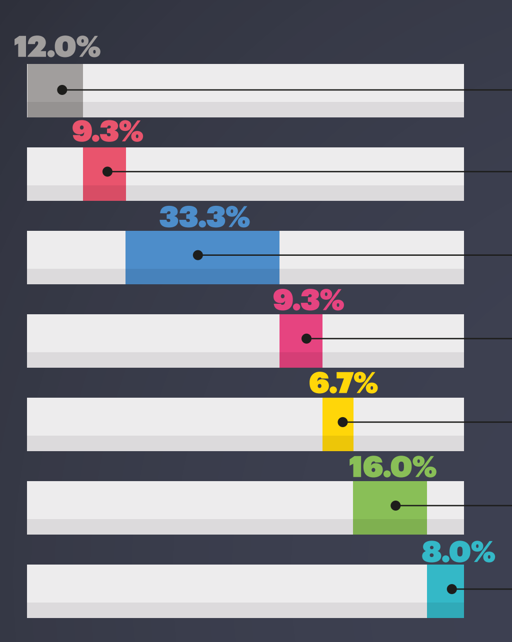
"Obviously, the companies should be certain that they can isolate and correct the problems that they identify in the production.

"This is expected as we dealing with regulatory approved facilities for medicine packaging where all systems and processes need to be fully validated before accepted in the production.

"The true difference between the implementations is the cost-effectiveness and production flexibility where still more than half of the companies are responding having tangible problems. In addition, it is important to understand that only parts of the costs will materialize during rectifying, and mitigating the root causes proactively is essential, as the problems tend to accumulate over time with production delays and additional efficiency related costs."

CONCERNS

What is your main concern for 2017



"The priority at the moment is getting the packaging line functionality and efficiency on the required operational level. However, it is good to see that companies are already planning and working on the capabilities beyond the packaging line print and verify implementations such as developing software management and getting the master data harmonized.

"In serialization and traceability projects there are always risks with late stage changes in the solution requirements and specifications or rescheduled production planning might escalate into substantial increases in the total costs and especially in the readiness timetable. The larger and more distributed a company is, in terms of organisation and geography, the more costs will be associated with the operational overhead due to the unclear governance with the responsibilities leading to a longer project implementation time.

"Additional on-going concern is the CMO/CPO readiness. Many MAHs are completely dependent on them delivering serialization on timetable and with competitive cost. Delays and high costs will not only affect CMO/CPO own businesses but more importantly in their customer businesses."

PRIORITIES

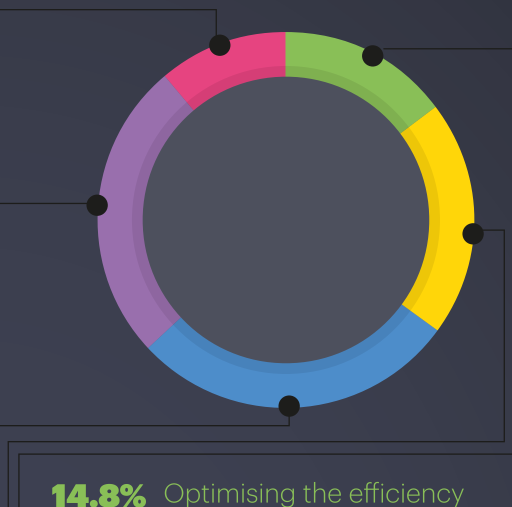
How would you rate your ability to meet the 2019 FMD deadline?

"Interestingly, as it is less than 24 months to go for the EU FMD deadline, almost half of the respondents feel that they are either making the deadline just in time, or in jeopardy not making it. Being just in time or needing to speed up with the implementation with no timetable buffer for mitigating the problems is a very high business risk. Given that the serialisation and traceability projects have tendency of being late or get delayed due to other business priorities, it means that there could be a tangible risk for the product shortage in the EU market.

"Many pharma companies seem to still think that there is an unlimited delivery capacity from vendors, and the later implementation would end up in lower costs, which is not the case. Especially, if CMOs and CPOs will be late with their projects, the risk will be affecting multiple MAHs at the same time. Unfortunately, many of the late respondents could be small and mid-size companies whose capability to investing upfront and mitigating the product supply problems is usually not very good.

"MAHs might also end up needing to build expensive buffer stock prior to the deadline just to meet the market needs, and still continue investing heavily in getting ready as soon as possible after the deadline. This means that those CMO/CPOs and MAHs who will be ready on timetable will actually gain market advantage."

What areas do you see your traceability system progressing towards?



There has been already a lot of discussion of serialization and traceability value beyond compliance in product supply and patient care.

However, before getting to realizing the additional value, there are a lot of operational and implementation level challenges to be solved. Therefore, it is obvious that the most of the companies are currently focusing on getting the integration, compliance and data management implemented most cost-effective and operationally efficient way.

What hasn't been fully realized yet is that these changes and new capabilities are leading to industrial internet of things or Industry 4.0 implementations in finished pharma manufacturing, integrating the operations technologies at the packaging sites with manufacturing and enterprise information technologies across the supply chain. This should lead to more productive and cost-efficient pharma manufacturing and streamlined supply chain operations improving the business performance in the longer term.