



Pharma's Fantastic Four — what to watch out for over the coming 12 months in pharma

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What to watch out for over the coming 12 months that should have an impact on the pharma landscape, according to some industry leaders...

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As we are now (just about) settling back into our everyday routines, it's time to look towards the potential trends we may expect over the coming months. In this prediction feature, we put forward some questions to a few industry leaders to discern what they believe should be on our radars for the year ahead and have come up with a list of our 'Fantastic Four' for the pharma industry.

1. Technology tangent

It's no surprise that technology will have a certain amount of influence in the future but as we move further into 2018 what technological advances and trends can we expect to witness in the pharma sector.

For Daniel Piekarz, SVP DataArt Solutions, Healthcare & Life Sciences practice leader, blockchain will be of interest to many more hospitals and pharma companies. "We expect to start seeing more real-world solutions being piloted leveraging blockchain," he said. "The moonshot being a longitudinal view of patient data that can be used to incentivise the patient to do things, like make healthier choices."

This view of assisting the patient and helping with patient adherence marries well with technological advancements, particularly in the wearable space. The array of new technologies available to pharma has the potential to truly transform the clinical trial space, according to Dr Andrew Rut, CEO and founder of MyMeds&Me.

"Technology will be a catalyst to the transformation of clinical trials," he asserted. "Implementing truly real-time data observation, capture and collection, systemised processing and analysis, significantly improves the quality and efficiency of clinical studies and technology is emerging as the catalyst that drives these new efficiencies for the benefit of clinical trials and people's lives."

Manufacturing is also set for a change through the adoption of wireless monitoring technology. “As the demand for high potency drugs increases and the biotechnology sector continues to flourish, the industry will look to technological advances to drive future change in manufacturing facilities,” explained Michael Avraam, global product manager at ChargePoint Technology. “Incorporating wireless monitoring technology will allow operators to receive vital equipment performance data as well as generating an audit trail; allowing for maintenance, health and safety and compliance teams to make informed decisions to proactively manage their maintenance programmes.”

2. Excelling in efficiency

Various factors are converging within pharma, meaning there is more need to increase efficiencies across the board. An ageing population, more demand from the end user and governments to reduce drug prices, along with increasing pressure to reduce the time to market, to name but a few.

“With the drive for demand and rising cost pressures there has to be manufacturing solutions that are more effective,” stressed Marianna D’Onghia – I Holland marketing assistant. “What we are seeing is an increased need for efficient monitoring processes and management systems which allow manufacturers to undertake in-depth scrutiny of tablet production. During 2017 we saw an increased interest in software and technology that effectively manages tablet production and we see this continuing in 2018.”

“Pharmaceutical companies are facing a lot of pressure to reduce the costs of medicines for the end user and they’re looking for ways to reduce both costs and time to market by improving efficiencies throughout the supply chain,” added Mark Quick, executive vice president — Corporate Development, Recipharm. “As a result, many companies are seeking to automate certain processes to reduce errors and increase throughput.”

Avraam concurred with Quick, explaining that in many drug manufacturing facilities automated systems are already in operation. “This is likely to increase rapidly as the potential for more efficient integration of processes and Industry 4.0 are fully realised,” he said.

Besides automating processes in the manufacturing space, technology may have another role to play in improving efficiencies. “Further opportunities are presented by the prospect of incorporating smartphone technology to enable more direct patient engagement,” explained Jean-Marie Aulnette, vice president of EMEA sales, TraceLink. “This could lead to the first of its kind in patient data collection and advance the efficiency of the healthcare industry in an unprecedented way.”

3. Serious about serialisation

Prior to serialisation regulations there was extremely limited communication between manufacturers and the end users. As the deadlines for these regulations get ever nearer, we are approaching a time when this disconnect may be bridged, however, it is imperative, now more than ever, that companies get on top of their preparations for this regulatory implementation.

“2018 must remain track and trace focused,” asserted Aulnette. “The regulations cannot be avoided and if companies do not comply in time, their days will be numbered. This year will be a ‘survival of the fittest’ situation with regards to compliance.”

In agreement with this sentiment, Quick added: “Those who haven’t prioritised developing a serialisation solution in 2017 (and many haven’t) are now in a race against time to ensure compliance ahead of the respective deadlines. Serialisation is a huge task and having underestimated the challenge in 2017 it’s important that companies adopt a proactive approach to these regulations this year.”

Obviously, these changes will be impactful on pharma on a global scale and as Quick emphasizes, it will be important to quickly mitigate the effects of serialisation so that it doesn’t impact too heavily on efficiency.

“With the recent US implementation of the Drug Supply Chain Security Act (DSCSA) regulations in November 2017, European companies should look ‘across the pond’ for advice, guidance and support with the tricky and at times onerous task of serialisation,” Aulnette commented.

“What is clear is that serialisation and new regulatory requirements across the globe will continue to be key market drivers over the next year, shaping the sector landscape,” he continued. “The gap across the industry regarding serialisation readiness needs to be closed, otherwise companies are going to be left behind in February 2019.”

4. Market movements

Market trends, growth, expansions, acquisitions and developing sectors are always on the agenda when considering future possibilities. As we are witnessing an increase in the need for industry to adjust to new regulatory requirements, there will undoubtedly be a corresponding change to certain aspects of the pharma market, one in particular is anticipated to be the growth of the outsourcing sector.

“Outsourcing, in particular, will continue to grow over 2018,” said Aulnette. “Finding the right outsourcing partner with the necessary serialisation capabilities will be an increasing trend over the next 12 months.”

“It is likely that, given the time constraints and the cost implications, we will see more and more companies look to well-prepared outsourcing partners to cater for their serialisation requirements,” agreed Quick. “The introduction of new serialisation regulations and the increasing demand for new, automated technologies is driving companies to take a more innovative approach to development and manufacturing. This combined with ever-increasing pressures to reduce costs across the board is driving companies to consolidate and collaborate with other members of the supply chain.”

It isn't only outsourcing that is predicted to experience growth. With more interest in personalised medicine and biologics, this too should drive an increase in merger and acquisition activity.

“The pharmaceutical industry is seeing huge demand in oncological and immune-suppressant therapies, which is fuelling the increase in drug manufacturing using high potency active pharmaceutical ingredients (HPAPIs),” Avraam explained. “This has serious implications throughout the supply chain, however the result for manufacturers is a growing need to look at more innovative containment strategies to meet high potency handling requirements.”

From I Holland's perspective, there will be continued expansion in oral solid dosage forms, with a particular emphasis on the emerging markets. “The requirement for solid dosage continues to grow,” stated D'Onghia. “We have seen this specifically within Latin America. This region is the ‘fastest ageing in the world, and in 2055 there will be 130 million more Latin Americans over 60 than there are today’* this means a growing demand in medicine and over the counter products like solid dosage forms.”

These developing markets are being driven to comply with good manufacturing practices to ensure their products are compliant and can be marketing on a global scale. To this end, investment is required to enable facility upgrades, noted D'Onghia.

Original article can be found here: <https://www.epmmagazine.com/opinion/parmas-fantastic-four-the-year-ahead-2018/>