Look and learn

*It's good to keep on top of industry trends and the pharma sector is no exception.
Lu Rahman looks at some of the key trends likely to be feature significantly in 2015*

2014 in the pharma sector was dominated by mergers & acquisitions – actual and speculative. Heading into 2015, it looks likely that trend will continue to dominate the pharma space. Add to this the need for the industry to continue its push on innovation and the picture for the year ahead looks very interesting indeed.

As always, innovation is key and 2015 looks likely to continue this trend which is vital to the sector. There has been much discussion of late of the role that digital health, the cloud and digital medicine have to bring to the sector and many pharma companies are exploring the benefits this can bring.

One company that is embracing the digital future is Novartis which has launched the 'Trials of the Future' initiative to digitally connect and aggregate medical device data during clinical trials.

Teaming up with Qualcomm Life, the pharma group says it aims to "leverage health care technology to improve the experience of clinical trial participants and patients using Novartis products, and provide connectivity with future products marketed by Novartis".

*Clouded house:
Jen Goldsmith, Veeva Vault,
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pharma in the year ahead*

Novartis is just one example of the pharma sector exploring digital possibilities as it opens up ways to potentially revolutionise the way many businesses operate internally and with external partners and customers.

Jen Goldsmith, VP of Veeva Vault, Veeva Systems comments: "There seems no end to the cloud's ability to enable progress, and content management is no exception. For decades, life sciences companies have been struggling to establish a single source of the truth – the Holy Grail of content management – across all functional areas including therapeutic areas, regional affiliates, and investigator sites worldwide. Though many have tried, no technology provider has been able to fully deliver on this promise without sacrificing business efficiency or compliance. Instead, diverse teams were historically served by isolated solutions that didn't interact, forcing manual document handoffs that created gross inefficiencies and compliance risk."

According to Goldsmith, the cloud, in contrast, has the power to unite these groups without a single compromise – regulatory teams share content with marketing; Europe with North America; investigator sites with clinical departments.

"In the cloud, it's no longer an 'either/or' decision – as in either a centralised content repository that supports content sharing and corporate control but adds enormous complexity or a decentralised solution that meets local or department requirements but limits content reuse and collaboration. The cloud bridges content gaps across all lines-of-business and geographic regions to balance global harmonisation with local autonomy. In the near future, a reliable, single source of the truth will live in the cloud for universal sharing, yet also reflect unique business processes and compliance requirements for the best of both worlds," she says.

While pharma explores new ways of working, accessing and recording information, there are some trends from 2014 that look likely to remain going forward. Innovation is of course crucial but 2015 looks set to marry this with financial caution as companies look to keep a close eye on spend. At the start of the year, Flemming Ornskov, chief executive of Shire, told the Financial Times that 2015 is likely to see more dealmaking as pharma companies increase their efforts to find growth and efficiency savings.

"I think you are going to continue to see consolidation" he told the newspaper, highlighting the continued need for scale, efficiency and innovation that is driving current "deal frenzy".

Last year Shire made an attempt to buy US firm AbbVie for £32 billion but the deal fell through. More recently, the company has been in the news for its decision to purchase US group NPS Pharmaceuticals for £4 billion in a bid to strengthen its position in the rare disease medicine field. According to Ornskov, it will be the companies whose treatments are able to 'change the trajectory of diseases' that will be able to flourish going forward.

Come together: Adam Moorhouse, Onyx Scientific, believes that on the CRO side, we will see the consolidation of the past few years across the industry

Adam Moorhouse, director of US business development, West Coast at Onyx Scientific, says there are some trends that look likely to continue into 2015. He believes that on the CRO side, we will see the consolidation of the past few years across the industry.

"In large pharma and the larger biotechs, there is a move towards re-evaluation of current CRO/CMO partnership, or a more strategic organisation of CRO/CMO partnerships respectively. Circumstantial evidence of this includes the attendance at numerous outsourcing shows of increasing numbers of representatives from said companies. Easy to spot as those companies which were previously closed shops find their employees swamped by eager CRO/CMO staffers… Given the often protracted nature of the evaluation, short-listing and due diligence applied to the assessment of new suppliers, it seems likely that this process (and the new partnerships formed as a result of it) will be of significance in 2015. Perhaps the time is right for CRO/CMOs to poach a new big player before they cosy up into hibernation with their new strategic partners," he says.

Moorhouse says it seems safe to assume that the consolidation in the CRO/CMO space will continue, given the continued perceived importance by much of the industry of suppliers providing increased integration of services.

"This pattern matches the movements within big pharma of a move towards forming more strategic partnerships with CRO/CMOs, vendor consolidation and also the trend of pharma reducing fixed assets and peering outward for approaches to finding innovation (biotechs and partnerships) and maximising profits (increased mergers & acquisitions), in the face of the patent cliff free-fall, from which no-one has yet landed," he adds.

View point: According to Sven Stegemann, Capsugel, quality will be crucial in 2015

Sven Stegemann, director of pharmaceutical development at Capsugel, is looking at quality during 2015 and believes this will be have a significant contribution to play.

"A decade of cost-cutting in pharmaceutical development and manufacturing yielded some unintended consequences for many companies in 2014, as the quality of their products failed to meet established standards," he says.

According to Stegemann, some of these consequences resulted in manufacturing sites being shuttered or banned from import into the US by the Food and Drug Administration (FDA) due to serious violations in Good Manufacturing Practices (GMP).

"For example, high levels of chromium were found in gelatin capsules, jeopardising product safety and creating detrimental legal issues for companies. And, just recently, hundreds of product licenses were withdrawn by European regulators due to falsified clinical trial data generated by a contractor. Aside from the direct legal and financial impact for the companies involved, the damage to the reputation of the overall pharmaceutical industry is potentially enormous," he adds.

Stegemann says that as every customer is also a vendor, just looking at costs at the supply level is no longer a sustainable approach, without seriously addressing product quality and supply chain security.

"Future enhancements in manufacturing efficiency designed to manage overall costs require a combination of innovative formulation, lean manufacturing platforms and high-performance components utilising the opportunities derived from QbD, PAT, six sigma and continuous manufacturing. The industry has to increasingly recognise that credible and trusted suppliers are essential partners to achieving these objectives and that quality is a 'value' rather than a 'cost'" he says.

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TRUSTED
QUALITY
VALUE