

CPhI predictions for 2022: high manufacturing demand to constrain global ingredients, partnering options and available CDMO capacity

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CPhI Worldwide releases its beginning of year pharma market predictions for 2022 combining research from over 350 pharma executives and expert views from 10 CPhI contributors.

The findings suggest that there will be 30+ FDA new drug approvals in the next year, more than five commercial COVID vaccines – resulting in a production squeeze at CDMOs and consequentially higher margins and profits for supply side companies – with mRNA, advanced therapies and biologics seeing the fastest growth rates. Overall, the findings suggest a very robust and prosperous year ahead for the contract services industry.

Dan Stanton – Editor at BioProcess Insider – commenting in the report on the consequential impact for CDMOs added, “With the race to develop and manufacture vaccines in their billions, the pandemic has put immense pressure on the global manufacturing capacity and stretched capacity for equipment and consumables further, with vials and single use components, filters and bags particularly affected.”

In fact, the wider industry expects CDMO capacity to continue to be constrained throughout 2022 for biologics (54%), advanced therapies (46%), and API (44%), with 70% of respondents also stating there is a ‘global shortage of CMC personal’ that could run for the next two years and potentially slow down development timelines.

It is anticipated that the first half of 2022 pharma will see continued higher prices, limited availability, and delayed deliveries for many raw materials and therefore a continuation of the dynamic supply chain issues prevalent in 2021 according to Stephan Schmidinger, Partner at Kemiex.

One of many key positive developments rapidly gaining traction according to Manjit Singh, Chair of the Pharmaceutical Supply Chain Initiative (PSCI), is the global rise of sustainable sourcing and he forecasts 2022 will see an acceleration of transparency and sustainability strategies. In a further boost for patients and sustainability, Yasemin Bettina Karanis, Senior Consultant Thought Leadership at IQVIA, predicts home-administration will continue to increase, and the challenge for device manufacturer’s will be how best to demonstrate the value and impact of their new devices. For example, she added this might be in

the “form of quantifying the carbon footprint of self-administration versus travelling to a hospital or demonstrating improved adherence and patient experience.”

Significantly, the industry expects continued high levels of approvals by the FDA with 29% predicting the FDA will approve 21-30 new drug applications in 2022, 35% expecting 31-50 NDAs, and 15% suggesting there could be a record 50+ approvals in the year ahead. Perhaps unsurprisingly, given the validation the technology has revived via the approvals of both Moderna and Pfizer vaccines, 65% believe mRNA technologies will be the biggest investment opportunities in 2022 followed by cell and gene therapies (45%) and biologics (43%).

Looking at biologics in particular, Stanton’s view is that pragmatic and agile approaches to supply chain problems will need to continue into 2022 as the global crisis continues into a third year. “More than 30 vaccines and therapies have been approved (or been granted Emergency Use Authorization) for COVID-19, and with much of the world still needing a first and second vaccine dose, not to mention the rollout of boosters, the pressure on the supply chain will not abate,” he adds.

In fact, 25% of the industry believes there could be as many as 10+ new novel Covid vaccine approvals in 2022 – with the majority (45%) expecting 5-10, and 29% 1-5 approvals.

2022 could also bring about significant regulatory changes as the EU embarks upon its once in every 20-years pharmaceutical policy revisions, with Adrian van den Hoven, Director General of Medicines for Europe suggesting that Covid has ‘sprung’ European policy makers into action to address many long-standing issues.

“The pharmaceutical industry made some outstanding progress in 2021 in how it managed to speed up time to market and eke out efficiencies along the supply chain in order to meet the huge demand for Covid vaccines,” said Tara Dougal, Head of Content and Insights, Pharma, Informa Markets. “The CPhI Pharma Trends 2022 Report not only addresses some of the major tensions and obstacles that the industry will face in 2022 but also the innovative solutions that it is developing to overcome them.”