COVID-19 IMPACT ON BIOPROCESSING

Accelerating Trends - Long-term Impact of Novel Coronavirus-19 on Biomanufacturing and Bioprocess Supply Chain

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Introduction

The Covid-19 pandemic is adversely affecting nearly all global industries and social functions. The biopharmaceutical industry and bioprocessing stand out as something of an exception. Because of the urgent demand for treatments, vaccines and assays, the pharmaceutical and biotech industries are experiencing disruptive, often chaotic, increased demands on its resources. This has begun to catalyze and accelerate a number of significant changes, including many preexisting trends.

For this research, we interviewed 10 major biopharmaceutical industry senior bioprocessing decision-makers, and 11 with bioprocessing suppliers in the US and Europe. In addition, we interviewed 5 biopharmaceutical manufacturer and supplier executives in China, which has had a head start on dealing with the near-term adverse impacts of the pandemic on its domestic industry.

We found that this 'essential' industry is experiencing systemic changes. Even before the crisis, the industry had been undergoing significant, steady advances. Having seen healthy, consistent 12% annual growth [1] for at least the past 20 years, the biopharmaceutical industry and its bioprocessing sector have evolved and matured relatively rapidly. A benefit of this period of rapid growth has been that the industry has learned to be flexible, and to adapt quickly to change. 'Flexibility' has become a major consideration in facility design, and the selection of technologies, equipment and CMOs. This industry adaptability is already helping the industry re-tool for rapid development and production of pandemic vaccines, therapeutics, equipment and diagnostics; while also responding to changes that this worldwide mobilization of resources will bring to the industry. As one respondent remarked, *"Not much has really changed. The industry has been part of the pandemic and biodefense response for decades."*

Overall, the pandemic is changing many of the trends affecting bioprocessing and the biopharmaceutical industry. Near-term impacts have tended to be the result of increased activity, while strategic shifts mostly involve accelerating ongoing trends that have hampered productivity. Recovery from the pandemic will bring some significant changes to the biopharmaceutical industry and its bioprocessing sector in the long-term.

We need to keep in mind that the pre-pandemic R&D and products manufacturing being done by the industry continues to be essential, and life-saving, and it cannot generally be put on hold. Prioritization is a new fact-of-life for the industry, including suppliers broadly implementing policies favoring pandemic-related projects, which are going to the head of the line. The pandemic has forced some non-related projects to take a back seat, which may in the long-term, have consequences for those illnesses and companies. However, a major finding from our research, is that the pandemic has primarily accelerated existing trends, many of which are likely to become the norm, post-Covid.

Methodology

In May 2020, BioPlan launched a study to determine the pandemic's effects on the bioprocessing industry. Twenty high-level US and EU executives and managers were interviewed – 10 with suppliers (of bioprocessing equipment and CDMO services) and 11 with biopharmaceutical companies, along with 5 executives with Chinese companies, to discuss:

- How has Covid-19 affected daily operations?
- What is being done in response?
- What will be the long-term effects of the pandemic on bioprocessing?
- How should the industry respond?
- Concerns or fears as we come out of the pandemic?
- What will be the "new normal," what will have changed?

Pandemic-related Trends

Some pandemic-related changes or trends with long term, strategic implications include:

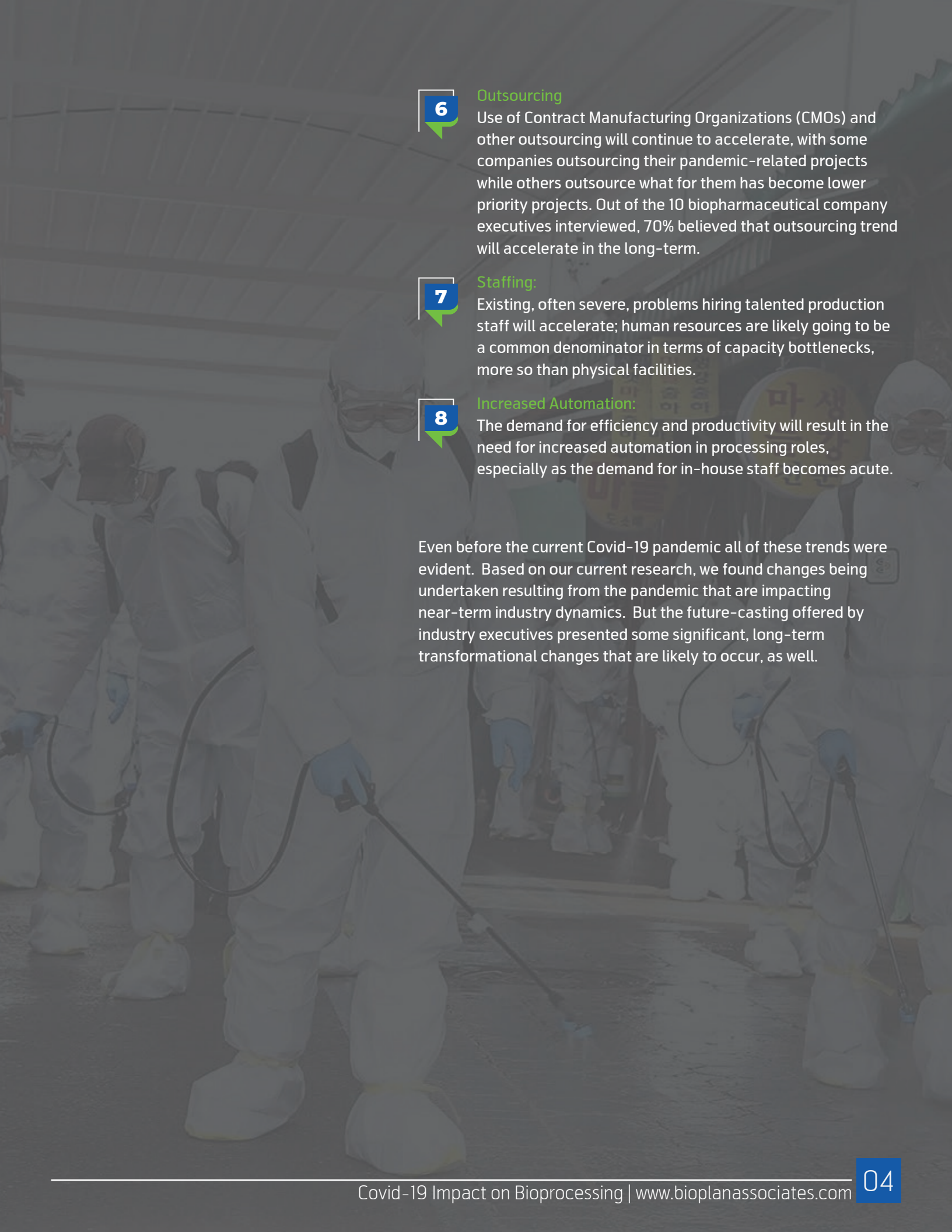
1. **Bioprocessing will rapidly accelerate globally:**
By mid-May, more than 215 novel and repurposed therapies were in the pipeline for Covid-19, with investment already of billions of dollars from organizations such as CEPI (Coalition for Epidemic Preparedness Innovations), Melinda and Gates Foundation, and leading biopharmaceutical companies. Additional billions will be rapidly invested in pandemic vaccines and therapeutics, much of this for very large scale commercial manufacturing. Expect this investment to boost those bioprocessing technologies that enhance efficiency and productivity at large scales.

2. **Supply chain strengthening:**
Expect greater emphasis on secure, robust supplies, including backup sources. Greater transparency in supply chains and coordination among all those in the supply chain and customer will be needed.

3. **Single-use systems:**
The trend for single-use-based commercial manufacturing (and also adoption of modular process lines) will rapidly accelerate, including pandemic products manufactured by scaling-out rather than scaling-up (producing using more process lines and facilities, rather than in larger volumes).

4. **Process intensification:**
There will be more emphasis on doing bioprocessing faster, with smaller facilities, fewer staff, more cost-effective, etc.

5. **Regionalization:**
More bioprocessing is likely to be done in more places, including more outside the major hubs such as Boston and San Francisco. This globalization will accelerate with more multi-site facilities internationally. More facilities have been coming online to serve regional markets, including China, and the pandemic will accelerate the trend toward supply chain and bioprocessing facilities' diffusion worldwide.



6 **Outsourcing**
Use of Contract Manufacturing Organizations (CMOs) and other outsourcing will continue to accelerate, with some companies outsourcing their pandemic-related projects while others outsource what for them has become lower priority projects. Out of the 10 biopharmaceutical company executives interviewed, 70% believed that outsourcing trend will accelerate in the long-term.

7 **Staffing:**
Existing, often severe, problems hiring talented production staff will accelerate; human resources are likely going to be a common denominator in terms of capacity bottlenecks, more so than physical facilities.

8 **Increased Automation:**
The demand for efficiency and productivity will result in the need for increased automation in processing roles, especially as the demand for in-house staff becomes acute.

Even before the current Covid-19 pandemic all of these trends were evident. Based on our current research, we found changes being undertaken resulting from the pandemic that are impacting near-term industry dynamics. But the future-casting offered by industry executives presented some significant, long-term transformational changes that are likely to occur, as well.

Industry Views of Long-term Effects

The Table below summarizes the responses of US and European suppliers and biopharma who were interviewed for their perspectives on the long-term effects of the Covid-19 pandemic.

Table 1: Interviewees' Perspectives Regarding the Long-term Effects of the Covid-19 Pandemic

Suppliers		Biopharma	
Cited Perspective	Frequency (%)	Cited Perspective	Frequency (%)
Increased funding	64	More outsourcing	70
Expansion in SUS manufacturing capacity	64	Changes in supply chain	60
More Regionalization	45	SUS supply crunch	50
Need for digital solutions	36	More Regionalization	50
SUS supply crunch	36	Increased business	50
More need for contingency planning	27	More need for contingency planning	40
Delays/problems in CTs and CROs	18	Regulatory changes	40
Response In response to this crisis, 82% of interviewed suppliers and 50% of biopharmaceutical respondents cited that expansion and higher investment in R&D would be a go-to strategy. More than 30% of both supplier and biopharma respondents additionally chose collaborations and partnerships as a long-term measure.		Expansion in SUS manufacturing capacity	30
		Need for digital solutions/automation	30
		Expert staffing shortage	30
		Increased funding	20
		Delays/problems in non-Covid CTs and CROs	20

Clearly, the impact on the industry is already broad reaching and strategic. The biopharma companies are likely to plan for greater outsourcing, supply chain management, and greater regionalization. While the suppliers are expecting increased funding (and investment), and expansion of their single-use technologies, as well as greater regionalization.

Near-term Impacts

Overall, in the near term there is increasing R&D and manufacturing and shifting of resources towards pandemic response. The bioprocessing sector in the near-term is experiencing operational and staffing problems, often related to increased activity or adapting to social distancing. Most bioprocessing-related industrial activities are considered 'essential' and are continuing largely unaffected in terms of operations and output, while many are planning to ramp-up R&D and manufacturing. While there are many near-term changes in onsite staff management, broader business plans are generally not affected in the near-term.

The table below highlights the bioprocessing-related critical attributes that were considered relevant by interviewees (suppliers and biopharma executives) in responding to the Covid-19 pandemic.

Table 2: Effect of Covid-19 Response on Daily Bioprocessing Operations

Bioprocessing Operation	Frequency of Responses Indicating Optimism	Frequency of Responses Indicating Worry	Frequency of Responses that were Neutral
Operations running at full capacity	86	14	0
No current shortage of supplies	86	5	10
R&D continuing at the same pace	67	0	33
Non-production related work has moved to home/off-site	57	19	24
Ramping up production	48	0	52
Stocking up supplies	29	0	71
Filling of orders being prioritized	24	0	76
Anything related to Covid19 is top priority	19	5	76
Inquiries are coming in	19	5	76

Overall, the pandemic is changing many of the trends affecting bioprocessing and the biopharmaceutical industry. Near-term impacts have tended to be the result of increased activity, while strategic shifts mostly involve accelerating ongoing trends that have hampered productivity. Recovery from the pandemic will bring some significant changes to the biopharmaceutical industry and its bioprocessing sector in the long-term.

As expected, many companies, including developers and suppliers of hardware and services, are increasing their pandemic-related R&D and manufacturing. Suppliers are anticipating and planning for increased business as companies and governments start to rapidly develop, test and deploy pandemic-related vaccines, therapeutics and diagnostics. There has also been demand for increased short-term stocking-up on supplies, with many facilities planning to store more supplies on-site and seek back-up sources for supplies and services.

Healthcare segments generally tend to be less sensitive to economic stress. We found that some suppliers, particularly companies not primarily within or serving the pharmaceutical industry, are reporting significant loss of sales and related cut-backs. Those companies that are decreasing or delaying expenditures tend to be those more diversified with more non-bioprocessing-related businesses, and smaller companies. In the longer term, the industry driver, biopharmaceutical sales, will remain largely unaffected, with patients still needing these therapies.

The general expectation is that there will be relatively minimal adverse near-term economic impact from the pandemic and its aftermath on the bioprocessing sector. Most companies are continuing with their long-term capital-intensive expansions and mergers/acquisitions, with many accelerating their plans.

Biopharmaceutical-related facilities, equipment suppliers, CMOs, CROs and R&D/developer companies are considered "essential," and have continued operations with only minimal initial disruptions, most of which have been associated with management of operations staff during this crisis. Many are now planning on how to ramp-up their activities. There are many examples of selfless work, but this is not sustainable. Many essential companies, including developers and suppliers of hardware and services, are maximizing their manufacturing capacity utilization, with more business expected as pandemic-related R&D and manufacturing rapidly increases for some.

Most non-R&D and non-manufacturing jobs, such as sales, some technical and regulatory and other support operations, are now being done virtually from home. With the (bio)pharmaceutical industry long seeing benefits from large centralized facilities and encouraging staff interactions, it will be interested to see the extent to which, how fast, the industry eventually moves back to this prior 'normal' when effective vaccines, therapeutics and diagnostics become available

Areas where near-term impacts are being felt include:

- Bioprocess Staffing: Bioprocessing facilities report they have already adapted well to pandemic-related staff disruptions and challenges. Non-essential staff working from home are reported to be doing well. Inside facilities, many companies have adjusted work shifts and limited movement of staff within facilities, to keep groups isolated from infection. But this reduces the interaction among staff that has long been considered important in this industry. Staff management adaptations today will potentially have long-term effects, but many of these 'wartime' changes will likely be abandoned after the crisis is over, e.g., when effective vaccines become available.

- Supply Chains: Supply chains have proven reasonably robust and deliveries of bioprocessing-related supplies manufacturing and services have continued largely unaffected worldwide. In certain situations, manufacturing is being ramped-up in response to increased demand. At present, neither equipment nor biologics manufacturers report any significant supply chain issues, as their suppliers continue essential operations. Access to information and supply chain transparency has become more critical. Deliveries of supplies of goods and services to biopharmaceutical developer, services and supplies companies have largely continued unaffected. Upstream suppliers have continued deliveries, although some minor disruptions are expected in coming months, mostly involving commodity-type products, such as

solvents and reagents. The sector's specialized logistics companies report having adapted, including continuing deliveries to and from China and other countries during shut-downs.

- Demand for Supplies/Services: Service providers, CDOs and CROs, are seeing an increase in inquiries and orders, mostly pandemic vaccine- or therapeutics-related. Many suppliers of both equipment and services have begun increasing their activities in response to this increase, and to projected demand. There has been limited short-term stocking-up on supplies.

- R&D/pipelines: Overall, developer R&D and pipelines are expected to change little, other than adding more pandemic- and infectious disease-related R&D, while some other projects are delayed or dropped. The 'inertia' built into bio/pharma pipeline projects makes it difficult to pivot on projects quickly, so current pipelines are not expected to change much in the near-term, other than new vaccine and therapeutics projects.

- Disaster Planning: Essentially all companies are working aggressively to upgrade their contingency and disaster planning. This now will include scenarios where numbers of critical staff are not working for periods of time. Worst case scenarios are no longer confined to fires, earthquakes, floods, blackouts, IT hacking, etc. These concerns will extend into the next year, as many decision-makers are worried about staffing challenges this winter, with the annual influenza epidemic overlapping the Covid-19 pandemic. Many facilities are stockpiling more PPE supplies as well.

What do Suppliers and Biopharma Say About Near-term Impact on Bioprocessing:

- "It is too early to tell if there will be a slowdown."
- "We normally stock up for 60 days manufacturing inventory. We are ramping this up to 80 days supply."
- "Companies will see disruptions and lose money with their ongoing trials."
- "We are working to avoid any supply shortages."
- "We are making effort to stock more (supplies), are ordering more, particularly essentials."
- "We will have to wait and see if there will be shortages of higher-level staff applying and recruiting."

The near-term conclusions are that business for this sector is continuing, sometimes expanding, despite the cutting-back of marketing, sales and certain non-essential efforts in some companies. Sales reps are not making visits, conference exhibitions have been cancelled or turned into virtual meetings. It is possible that some of these business-related shifts may have long-term effects on how business is done, with more virtual meetings, and online events in the future. Overall, industry suppliers of goods and services are experiencing or expect increases in sales, while some companies will see a downturn in revenue in the later quarters of FY2020. But most suppliers are seeing, and expecting increased revenue, with an increasing number of pandemic and other infectious disease orders and projects already beginning to come in. Major players - Big Pharma and leading supplier companies such as Thermo Fisher, Sartorius, Pfizer, Merck, GSK, Roche and others - are investing millions or even billions of dollars in R&D, stockpiling of supplies, and the anticipated expansions. These expenditures are trickling down and supporting other suppliers to the industry.

CDMOs/CROs may face challenges as some prospective non-pandemic-related projects are postponed or canceled, while those with viral vaccines-related services see increased business. This may presage mid-term challenges for the sales pipeline of some service suppliers, particularly those not supporting pandemic-related R&D or manufacturing. But with bioprocessing CMOs overall having as much as a year's backlog of projects, CMOs are insulated from many of the short-term revenue disruptions; while more pandemic-related work at some CMOs will displace other project to other CMOs. Bioprocessing equipment suppliers report a similar response, with some slowing of orders but newer pandemic-related inquiries and orders coming in, with an overall increase in business.

The "New Normal," What Will Change, Long-term?

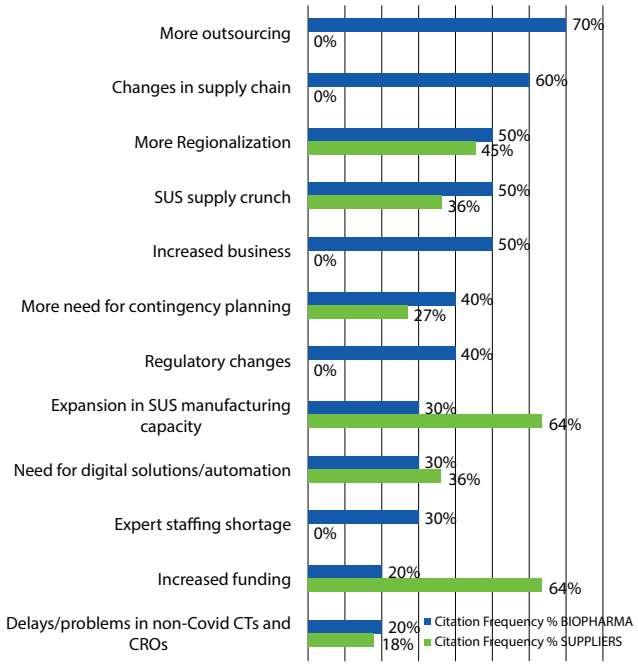
The 21 US/EU interviewees we asked regarding long-term changes for bioprocessing due to Covid-19 provided critical insights. Different aspects were cited by suppliers and biopharma company experts. A quantitative summary of their responses is shown below. Biopharma company respondents indicated they expect the new normal to include:

- More outsourcing
- Changes in supply chains and
- More regionalization.

Suppliers to the industry primarily expect to see:

- Greater expansion of single-use technologies
- More sales/revenue, and
- More regionalization.

Fig 1: Long-term Effects of Covid-19 on Bioprocessing

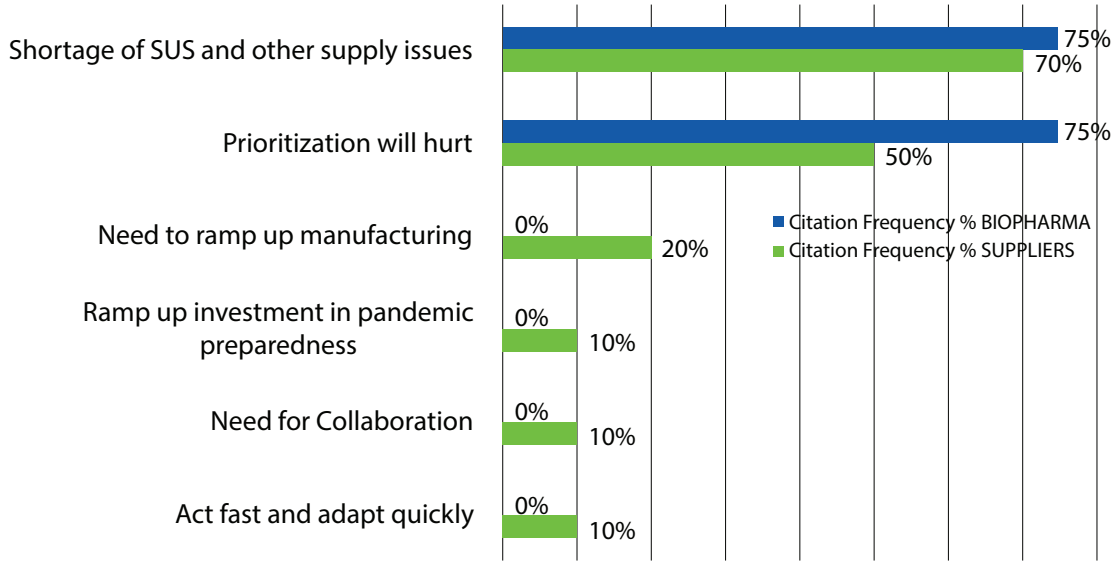


While more difficult for our interviewees to predict, based on how the industry is responding to the Covid-19 pandemic, we project that 'Post-Covid', there will be a number of fundamental changes resulting from responding to the pandemic. Many of these, such as the increase in the number of global facilities, were trending prior to the crisis due to regional growth, the need for redundant production, and preferences for smaller and flexible facilities. But the added pressures of responding to the pandemic will move up the timelines and magnitude of change. The Covid-19 pandemic appears to be a catalyst for acceleration of existing and emerging trends in the industry.

Fears to Be Addressed

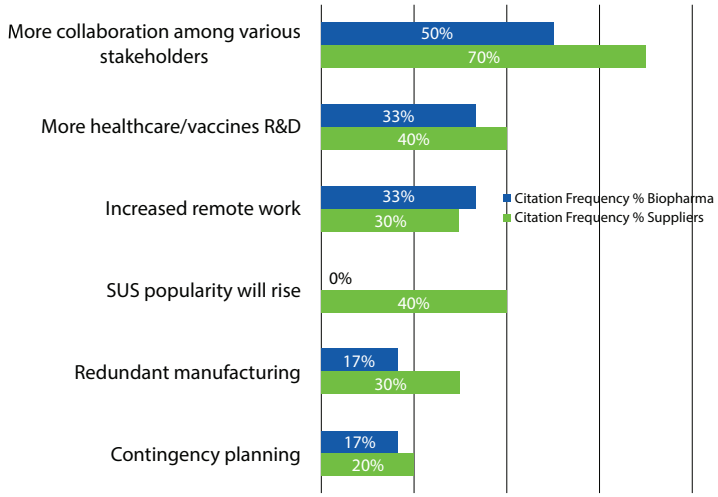
The interview results below report some of the key fears, options for their resolution and the expected "new normal" for the bioprocessing industry that were cited by the interviewees. Worsening shortage of single-use technologies and is a key fear that will require resolution. Already there are long wait times for many single-use supplies, and these will likely lengthen (for non-pandemic response-related projects).

Fig 2: Key Fears and Resolutions in Bioprocessing Post Covid-19



In the future, respondents, both biopharma company and suppliers, expect to see a different 'new normal'. Changes include collaborations among stake-holders are likely to increase. Today, as the world works through this crisis, collaborations are seen as indispensable. This includes cross-company, cross-industry, with governments, and multi-nationally. There is a clear sense that we are all in this together, and that the current situation may be well be defining our relationships in the future. If any positive outcome results from this pandemic, it may be the recognition that working together is essential today, and this will likely carry out into the future. Many also foresee practical benefits, including improved public perceptions of the (bio)pharmaceutical industry.

Figure 3: "New Normal" in Bioprocessing Post Covid-19



Long-term Effects on the Industry

Below we summarize our findings and other assessments of where the industry is likely heading as a result of the Covid-19 crisis.

- More Facilities: Even at this early point in the crisis, we see that there will easily be $15-20 billion or more invested in new pandemic-related vaccines and therapeutics by governments and philanthropies, e.g., the Gate's and Wellcome Foundations. Likely half or more of this funding will go to new manufacturing facilities. Already, multiple vaccine developers are preparing to rapidly develop capacity for production of billions of doses/year, often 'at risk,' building facilities even before clinical trial results are available.

- More Bioprocessing: All interviewees agreed that bioprocessing and related supplies and support activities will increase. This will include major significant rapid increases in pandemic-related R&D and manufacturing by companies and governments. Not unexpected, the bioprocessing sector will grow as a result of this crisis. Much of this will be in the form of preparedness for future pandemic and biodefense challenges.

- More Pandemic-related R&D and Manufacturing: Many companies and governments will be pursuing pandemic- and infectious diseases-related R&D and manufacturing, including $billions already being planned as new investments in pandemic vaccines development and facilities in coming years. This may result in shortages including for single-use systems (SUS) supplies and experienced staff.

- More Supply Chain Oversight: The pandemic will result in more product, supplies and services companies exercising more control over their supply chains, including reaching further upstream to more suppliers. Having control of supply chains will be even more critical to maintain access to needed supplies. This will also be required to support product quality, regulatory documentation, and patient safety. Companies will be pressing suppliers (and their suppliers, on up the supply chain) for more information; and organizing this will be a challenge. Because there are relatively few suppliers of bioprocessing goods and services, there may be a need to centrally compile and facilitate access to product and regulatory documentation and information, at least regarding commonly used equipment and reagents.

- Prioritization of Supplies and Services: Prioritization of outsourced projects and supplies orders will be part of the "new normal" after the pandemic subsides. Orders for pandemic-related supplies and outsourcing already are receiving priority, going to the head of the line. There will be losers and winners in terms of wait times for supplies and services.

- Single-use vs. Stainless Steel: There will be more single-use systems (SUS) new process lines and facilities. Most expect that pandemic-related new facilities will largely use SUS due to its flexibility which will be needed, combined with SUS speed and much lower capital investment. Longer-term, this flexibility will improve the responses to future pandemics and health crises. Due to the speed, cost and flexibility benefits of SUS, most pandemic-related new facilities and process lines are expected to be SUS-based, and many of them will likely be of modular construction. New stainless steel facilities will also be constructed, after pandemic-related products show long-term utility, or where there is government funding.

- More Modular facilities: Many new pandemic-related vaccines and biotherapeutics facilities will likely be modular. Modular units, along with SUS, will facilitate rapid cloning of facilities worldwide. Modular facilities manufacturers are already experiencing high demand, and this is likely to continue. This trend has been accelerating for at least 5 years; the crisis will precipitate more rapid expansion.

- Single-use (and Other) Shortages: Because pandemic-related bioprocessing process lines and facilities are or will generally be SUS-based, suppliers are concerned about future shortages. Already, there is a worldwide shortage of some of the key high-purity polymers, causing increasing lead times. Suppliers are concerned that the uptick in pandemic-related vaccines and therapeutics development and, particularly, related manufacturing will result in shortages of SUS supplies. In the future, this is likely to result in greater investment in SUS supply chains and supply chain security. Most pandemic-related vaccines and therapeutics manufacturing efforts will be scale-up or -out at unprecedented world-class scales. Assuming just two or three pandemic-related vaccines or biotherapeutics enter the market, each will likely require manufacture of 100s of millions, if not a billions, doses/year. This will require multiple facilities. For example vaccines manufacturing could involve 4,000 SUS bioreactors/year with total output of 8 million L of culture media/year.

- More Regionalization/Decentralization: More new facilities, including vaccines-related and for bioprocessing supplies, will be located internationally, with emphasis on regional manufacturing and distribution of both supplies and biopharmaceuticals. This is now seen as essential to deal with any future pandemics. For example, suppliers expect to build more equipment capacity in the U.S. for the U.S. market, in China for the Chinese market, etc. Biopharmaceutical manufacturing itself will likely be more internationally disseminated to increase flexibility and manufacturing redundancy.

- Faster R&D and Speed-to-Market: The pandemic is showing that (bio)pharmaceutical R&D needs to be more streamlined. New ways of doing product testing, including clinical trials, and more rapid approval options from regulatory agencies are needed to speed-up product development. Needs include faster ways of identifying and designing candidate vaccines and therapeutics, their testing in clinical trials, and manufacturing. Suppliers recognize they will need to move their new products through R&D and beta testing faster.

- More Collaboration: Those in the industry recognize the need for more collaboration and communication among bioprocessing professionals and companies/facilities at all levels. This already includes pandemic-related developer companies banding together to perform vaccine or therapeutics R&D and manufacturing. And suppliers are initiating more communications and sharing of information with fellow suppliers, including SUS suppliers within industry trade organizations, BPSA and BPOG. On a global level, the unprecedented R&D efforts for development of life-saving medicines will result in significant growth in scientific collaborations as the early successes from the crisis response bear fruit.

- No stopping in Mergers & Acquisitions (M&As): The biopharma and suppliers in the industry are not halting their plans for mergers and acquisitions just yet. Millions of dollars are pledged to be spent on M&A activities in 2020, which will contribute to the growth of this industry. Some M&A activity in the midst of this crisis include, Novavax acquiring Praha Vaccines for $167 million; Roche - Stratos Genomics; Merck – Themis; Shionogi – Tetra Therapeutics; and others.

IMPACT OF COVID-19 ON CHINA'S BIOPROCESSING INDUSTRY

As in US and EU, few significant impacts on operations.

Domestic Chinese suppliers do not offer an adequate alternative due to quality constraints.

Near-term:

- Sales and clinical research is impacted.
- Greater M&A likely.
- Staffing may become easier due to consolidation.

Long-term:

- NMPA likely to make policy changes which would enable faster development of vaccines, and potentially other biologics.
- China will adopt reforms towards a more transparent and market-oriented segment.

- Better Inventory Management: The need for better inventory management is becoming obvious. Before the crisis, delays in obtaining required equipment for biologics production were a challenge. Today, avoiding delays is a critical mission. Bioprocessing facilities are likely to maintain more inventory of more needed supplies; pandemic and other vaccines and therapeutics will likely be stockpiled by governments and countries' biodefense programs; and vendors will improve their inventory systems to minimize the impact of future challenges and crises. Stockpiling by governments will likely increase as national security is recognized as being impacted by the ability to respond to pandemics and other health threats.

- More Investment: The private and public sector will increase investments in pandemic- and other infectious diseases-related R&D and manufacturing. Already, BioPlan is tracking well over $10 billion in projected new pandemic-related vaccines and therapeutics development efforts, with much or even most this likely to go towards bioprocessing. For example, Pfizer and BARDA, the U.S. biodefense agency, are "at risk," even before trials start, investing ~$1 billion in vaccine development and manufacturing facility construction.

- More Staffing Difficulties: Chronic staffing challenges have plagued the industry for 15 years. These will now be exacerbated by the expected increase in bioprocessing for pandemic-related products. Hiring challenges and shortages of staff with expertise and experience (documented in BioPlan's annual survey) will accelerate. Pandemic R&D and manufacturing will compete for limited staff with the rapidly growing cellular and gene therapies sectors, as new facilities come online. Expect bioprocessing expertise and even technicians to be increasingly in short supply, with recruiting more difficult and salaries increasing.

Shipping Delays: Adverse effects on shipping are being already experienced by many suppliers. Shipments are being held up by customs and these delays are expected to increase.

More Automation: Related to the staffing difficulties, the preferences to decrease onsite staff, and process intensification, there will be increasing investments in automation; along with automation for process improvements and cost reductions. There will also be increased use of automated screening systems, process modeling, etc. – anything that reduces need for staff.

Impact of Covid-19 on China's Bioprocessing and Biopharm Industries

China has been dealing with the impact of Covid-19 longer, since mid-January, when it began lock-downs and closures. This ~2-month lead time compared to most other countries provides us with early insights into how the biopharma industry there has fared, and how it is adapting. We interviewed five Chinese biopharmaceutical company executives regarding the impact of the current crisis on their bio-production. As with Western facilities, those in China do not appear to be significantly affected by the pandemic. Companies have stockpiled supplies to ensure at least several months of bioprocessing. Most facilities did not stop operations, and the consensus is that in the future, better inventory management will ensure smoother operations in the event of future disruptions.

- Inventory and Supply Chains in China: At present, domestic Chinese suppliers of bioprocessing equipment and reagents are not considered an acceptable alternative to Western suppliers. The challenge is product reliability and suitability for biopharma. Critical consumables and reagents, including single use supplies and R&D reagents, must be imported as the quality of domestic products today is not sufficient. If the pandemic lasts, the supply chain from overseas suppliers became a major challenge. If this occurs, end-users would necessarily shift to domestic vendors with validation packages. But for this to happen, the Chinese regulatory authority, National Medical Products Administration, (NMPA) would need to make regulatory shifts that would streamline acceptance of such products from domestic vendors.

  According to our earlier studies[2], prior to the pandemic, the shift toward more use of domestic Chinese bioprocessing consumables acceptance has been a slow trend. As with other preexisting trends, the pandemic may accelerate the shift towards more use of domestic supplies. Ensuring domestic resources are available in the event of future crises may be a long-term strategic outcome.

- Short-term Impacts in China: In-person sales/marketing and clinical research are two areas that have virtually stopped completely during the early crisis period. Early stage R&D projects do not seem to be affected much. Companies, of course, also cancelled non-critical business and meetings, and this is likely to cool down growth of the monoclonal antibodies-dominated bioprocessing sector in China. This is basically accelerating an existing trend in China, where recent very rapid growth in the mAb segment was creating overcapacity. As a result, industry observers expect greater M&A in the field, as weaker competitors stumble in the market. This may also reduce existing staffing challenges in bioprocessing and operations, making recruiting of talented, experienced staff easier.

- Long-term Impacts in China: Interviewees expressed major concerns about de-coupling/de-globalization between China and the West. They worry that the current trade issues, coupled with pandemic-related political tensions, will make technology transfer, investment, staff recruitment overseas, financing, and partnerships more difficult for China's emerging domestic biopharma industry. However, industry insiders expect that the Chinese government and private sector executives will prioritize public-health related products, and the NMPA is likely to make policy changes which would enable faster development of vaccines, and potentially other biologics. For example, the current policies do not allow contract manufacturing of vaccines. Problems persist that most of the vaccine makers with production capacity do not have R&D capability and vice-versa. To address potential threats from future pandemic and health crises, China will likely adopt policies that will help reduce supply chain risks and improve collaborations.

Conclusions

Changes in the bio/pharmaceutical industry are being accelerated and catalyzed by the responses to the current Covid-19 pandemic. Although suppliers have proven themselves rather robust in their dealing with the pandemic, and business is continuing generally uninterrupted, there will be significant changes. Ongoing and accelerating trends will result in changes including improved strategies to moderate future pandemics and supply disruptions, development of collaborative relationships in R&D and among suppliers, and the implementation of more rapid, flexible, and modular production processes to speed products to the market. Along with much rapid expansion in bioprocessing capacity, these changes will affect manufacturing long after the current crisis resolves.

About BioPlan

BioPlan Associates, Inc. is a biotechnology, pharmaceutical and healthcare strategy and market information company headquartered in Rockville, MD. We deliver market strategy and research services so our clients can make more effective business decisions. Since 1989, we have provided market analysis and strategic assessments in biotech/biopharma, along with custom studies and strategic analyses, databases, quantitative and qualitative research, and white papers. Our strategy recommendations are used for new technology decisions, market development, due diligence, and acquisitions

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