DARE TO BE DIFFERENT:
It’s time to revamp collaboration in life sciences contract manufacturing

Accenture Life Sciences
Patient Inspired. Outcomes Driven.
MANAGING A COMPLEX LIFE SCIENCES SUPPLY CHAIN

The life sciences industry is in a state of transition as it shifts toward complex biopharmaceuticals and highly personalized medical therapies and devices.

This shift is driving increased complexity in supply chain operations. Companies now manage smaller production batches, right down to the level of individual patients, while shortening fulfillment times from order to delivery. They must also ensure extremely precise product handling due to the variability and temperature sensitivity of new products. And while the faster product approvals seen in the industry are, of course, positive, they also mean less time to optimize manufacturing processes for complex products.

All this adds even more pressure to life sciences companies that are already stretched by increasing product price pressures, the need to deliver outcome-based reimbursement, regulatory uncertainty around new therapies, and a legacy of inefficient collaboration in supply chain operations.

To find out more about how life sciences companies are working with their contract manufacturers to address challenges within today’s increasingly decentralized and complex supply chains, Accenture surveyed senior executives from various functions across 105 pharmaceutical, medical device and contract manufacturing companies (see Figure 1). Our goal: to understand where the pain points are in the supply chain—and how better collaboration can solve them.

STATE OF TRANSITION: INDUSTRY GROWTH DRIVERS

New Science is expected to drive 54% of industry revenue growth from 2017-2022. New Science involves a new mechanism, modality or indication for treating patients that serve an unmet need (for example, CAR-T cell therapy) and may include a technology companion or simply involve the technology on its own. Biologics and digital health are also expected to grow faster than traditional pharma. The biologics industry has an expected CAGR of 8.3% from 2016 to 2022, compared to a CAGR of only 3.1% for small molecule pharmaceuticals. In 2017, biologics accounted for 12% of all life sciences sales, and by 2022 that number is expected to grow to over 16% ($268B). New treatment discoveries are leading the growth, accounting for 77% of biologics sales. Similarly, the digital health market has an expected CAGR of 28% from 2018 to 2024. Growth in the digital health market is led by smart gadgets, IOT enablement, and mHealth apps.
One in five brand owners (manufacturers) now work with over 100 external partners.

Respondents told us that 44 percent of their manufacturing volume is now externalized, and a third said they outsource more than half of their manufacturing activity. Complex product portfolios (from small molecules to biologics, solid oral dose to drug device combinations) require a complex portfolio of specialized external manufacturers. In fact, every single company we spoke to confirmed that they work with Contract Manufacturing Organizations (CMOs), Contract Packaging Organizations (CPOs), and/or Contract Development and Manufacturing Organizations (CDMOs).

We Found:

Companies are lacking visibility, control, and standardization.

More than 60 percent of respondents told us they struggle to get real-time inventory or manufacturing visibility. Close to 40 percent said they lack control over product quality. And 58 percent said a lack of process and technology standardization is leading to operational complexity. Collaboration between manufacturers and partners is beset by inefficient manual processes, a lack of standardization, and poor visibility into manufacturing operations. Simply put, this can’t provide the agility and efficiency needed to manage an ever more complex life sciences supply chain.

To solve these pain points, pharmaceutical and medical device companies must reshape the way they collaborate with their contract manufacturers.

Organizations have an opportunity to use digital technologies to build more connected, data driven, and intelligent supply chain networks. Coupled with process improvements, this will give them real-time visibility and insights into operational data, as well as support fast and accurate cross-enterprise decision making with limited manual effort. By creating these digitized Intelligent Supply Chain networks, life sciences companies will be able to improve operational effectiveness, drive cost efficiencies and better serve their patients.6

In this report, we dive into the key findings of our research, explaining where companies are facing collaboration challenges—and where they’re looking to make improvements. We also share Accenture’s view on how organizations should transform their externally managed manufacturing with advanced digital technologies.
KEY FINDINGS

01 Externalized manufacturing will keep expanding...

Contract manufacturing is deeply embedded in the life sciences industry—and growing at speed. The CMO market is outpacing the broader industry and is expected to show a 7.6 percent CAGR between 2016 and 2025 (compared with 6.0 percent for life sciences as a whole). This growth reflects the extra efficiency and capacity that CMOs offer, as well as their support for global expansion.

According to our survey, 91 percent of biopharma and medical device company respondents plan to expand their use of CMOs, CPOs and CDMOs over the next three years. In response, 78 percent of CMO survey respondents say they intend to increase capacity over that period as they expand their technology platforms and specialized services. Increasingly, those CMOs also say they are working with life sciences companies who fully outsource their manufacturing, including growing numbers of smaller asset-light market entrants.

What CMOs are Saying

CMO respondents indicated that overall, they are expanding their operations and capacities in response to industry growth. This expansion is occurring geographically as well as into different therapeutic and service therapeutic areas and services. Our findings confirm that they are expanding equally across new or existing geographic locations. In addition, they are bolstering manufacturing capacities with new manufacturing technologies. Figures 2 and 3 outline key areas where Pharmaceutical and Medical Device CMOs are looking to expand their capabilities in the next three years.
CMO Areas of Expansion Within the Next 3 years:

**PHARMA/BIOPHARMA**

- **API Production**: 79%
- **Packaging**: 71%
- **Formulation**: 67%
- **Development**: 67%

Figure 2

**MEDICAL DEVICE**

- **Diabetes**: 86%
- **Diagnostics**: 71%
- **Cardiology, Orthopedics, Radiology**: 57%
- **Imaging, Surgery, Nephrology**: 43%
- **Pediatrics, Respiratory, Dental, Vision**: 29%
- **Neurotechnology**: 14%

Figure 3
What Brand Owners are Saying

Brand owners plan to increase their use of CMOs in the next three years across a variety of therapeutic areas in response to CMO capacity expansion (Figures 4 and 5 below).

### PHARMA/BIOPHARMA

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Currently Leveraging</th>
<th>Planning to Leverage in the Next 3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lungs/Respiratory</td>
<td>77%</td>
<td>13%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>70%</td>
<td>23%</td>
</tr>
<tr>
<td>Oncology</td>
<td>70%</td>
<td>20%</td>
</tr>
<tr>
<td>Migraine</td>
<td>67%</td>
<td>20%</td>
</tr>
<tr>
<td>Brain</td>
<td>63%</td>
<td>23%</td>
</tr>
<tr>
<td>Neurodegenerative conditions</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Immunotherapy</td>
<td>60%</td>
<td>30%</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>50%</td>
<td>37%</td>
</tr>
<tr>
<td>Genetics</td>
<td>50%</td>
<td>30%</td>
</tr>
<tr>
<td>Dermatology</td>
<td>47%</td>
<td>27%</td>
</tr>
</tbody>
</table>

### MEDICAL DEVICE

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Currently Leveraging</th>
<th>Planning to Leverage in the Next 3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Care/Patient Monitoring</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>80%</td>
<td>12%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>64%</td>
<td>20%</td>
</tr>
<tr>
<td>Orthopaedics</td>
<td>64%</td>
<td>16%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>60%</td>
<td>24%</td>
</tr>
<tr>
<td>Surgery</td>
<td>60%</td>
<td>20%</td>
</tr>
<tr>
<td>Paediatrics</td>
<td>56%</td>
<td>12%</td>
</tr>
<tr>
<td>Imaging</td>
<td>56%</td>
<td>20%</td>
</tr>
<tr>
<td>Vision</td>
<td>52%</td>
<td>20%</td>
</tr>
<tr>
<td>Dental</td>
<td>52%</td>
<td>20%</td>
</tr>
<tr>
<td>Radiology</td>
<td>48%</td>
<td>20%</td>
</tr>
<tr>
<td>Neurotechnology</td>
<td>40%</td>
<td>32%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>40%</td>
<td>28%</td>
</tr>
<tr>
<td>Nephrology</td>
<td>28%</td>
<td>36%</td>
</tr>
</tbody>
</table>
Complex therapies require a different supply chain

Consider how complex and personalized therapies such as bispecific antibodies, antibody drug conjugates, oligonucleotides, and chimeric antigen receptor-T (CAR-T) cell therapy, are making supply chains much more challenging to manage. For instance, CAR-T cell production requires companies to track patients’ T-cells at every step from the apheresis center, through the manufacturing facility, to the clinical site for infusion. These time-critical precision therapies are often a last resort for the patient, and it’s vital for companies to plan, schedule, manufacture, and deliver the product to the correct individual (maintaining the chain of identity) at the necessary speed and quality. That requires collaboration with contract manufacturers and other ecosystem partners on a whole new level.

The manufacturing process for biologics is complex. To ensure product consistency, quality, and purity, manufacturers must capture large amounts of data over the process lifecycle (monitored in terms of Critical Process Parameters or CPPs). In addition, regulators are prepared to grant faster approvals to drugs and devices that show promise in treating life-threatening disease and addressing unmet medical needs. But for life sciences companies, this means they must develop stable manufacturing processes much faster, while ensuring they sustain knowledge management and risk mitigation all the way across R&D, process development, tech transfer, and production.

In addition, regulators are prepared to grant faster approvals to drugs and devices that show promise in treating life-threatening disease and addressing unmet medical needs. But for life sciences companies, this potentially puts product development and manufacturing on a collision course. Companies must develop stable manufacturing processes much faster, while ensuring they sustain knowledge management and risk mitigation all the way across R&D, process development, tech transfer, and production.
With these increasing industry complexities, both life sciences brand owners and their external partners face similar challenges in their collaborations. This can be an opportunity to jointly address these operational challenges as outlined below from our survey (see Figure 6).

**Operational challenges for brand owners and CMOs requiring increased collaboration**

**Respondents experiencing operational challenge**

<table>
<thead>
<tr>
<th>Operational Challenge</th>
<th>Brand Owner</th>
<th>CMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of visibility or control over Product Quality</td>
<td>67%</td>
<td></td>
</tr>
<tr>
<td>Lack of visibility into Manufacturing Operations or missed SLAs</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td>Ineffective capacity management</td>
<td>38%</td>
<td>54%</td>
</tr>
<tr>
<td>Lack of inventory visibility</td>
<td>36%</td>
<td></td>
</tr>
<tr>
<td>Lack of IT capabilities</td>
<td>33%</td>
<td>34%</td>
</tr>
<tr>
<td>Delays in Tech Transfer and New Product Launch</td>
<td>31%</td>
<td>46%</td>
</tr>
<tr>
<td>Misalignment of interpreting global regulations</td>
<td>29%</td>
<td>32%</td>
</tr>
<tr>
<td>Misalignment and lack of &quot;single source of truth&quot; for KPIs</td>
<td>27%</td>
<td>40%</td>
</tr>
</tbody>
</table>

**Figure 6**
The Risk of Ineffective Collaboration During Tech Transfers

Too many organizations still rely on laborious manual processes for collecting, storing, and sharing critical supply chain and manufacturing data. The result is unnecessary complexity and operational inefficiency.

Consider the process of getting regulatory approval for CMC (chemistry, manufacturing and control) changes, such as scale up, intensification, or the tech transfer of a process from one CMO to another. International Council for Harmonization quality guidelines (ICHQ8-11) are designed to support and encourage companies to invest in process improvement and flexibility while emphasizing the importance of a deep understanding of both critical process parameters (CPPs) and the product’s critical quality attributes (CQAs), as well as managing risk and knowledge across the lifecycle.

This is difficult to achieve without a strong process for exchanging data and knowledge between CMOs and their customers, particularly for complex drugs where the original process development was entirely managed by the CMO who may have developed tacit knowledge of the process (and the CPP/CQA correlations). If this knowledge isn’t comprehensively captured, curated, analyzed, and shared with the client, the risk associated with changing the process will be very high, especially for complex products with large numbers of CQAs.

The risk associated with CMC changes is potentially highest when the transfer of complex datasets and knowledge occurs between different organizations (sponsor and CMO). A failure to ensure strong collaboration and knowledge sharing between a pharma company and its CMOs can therefore have real long-term impacts, limiting the efficiency gains that can be realized across a product’s lifecycle, creating business continuity planning (BCP) risks for the pharma company from sole-source production, and leading to a poor relationship between a CMO and its “captive” clients.
Companies recognize the need to improve collaboration with technology...

Our survey reveals ample opportunity to improve supplier–manufacturer relationships. Respondents realize the importance of digital capabilities in enabling collaboration to address operational challenges (see Figures 7 and 8).

Respondents also indicate they are experimenting with technologies like the Internet of Things (IoT), cloud-based collaboration platforms, big data analytics, and artificial intelligence. Their expected results include greater supply chain visibility, traceability, and operational efficiency—as well as increased control over product quality, reduced manual effort, and faster delivery to patients.

Digital capabilities currently in use or with planned implementation in the next 3 years

### BRAND OWNERS

<table>
<thead>
<tr>
<th>Technology</th>
<th>Currently using</th>
<th>Planning to implement in the next 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cybersecurity</td>
<td>80%</td>
<td>15%</td>
</tr>
<tr>
<td>IoT (Internet of Things)</td>
<td>76%</td>
<td>20%</td>
</tr>
<tr>
<td>Cloud Collaboration Platforms</td>
<td>73%</td>
<td>27%</td>
</tr>
<tr>
<td>Big Data/Analytics</td>
<td>67%</td>
<td>24%</td>
</tr>
<tr>
<td>Control Towers</td>
<td>64%</td>
<td>35%</td>
</tr>
<tr>
<td>Additive Manufacturing Technologies</td>
<td>64%</td>
<td>35%</td>
</tr>
<tr>
<td>AR (Augmented Reality)/VR (Virtual Reality)</td>
<td>53%</td>
<td>35%</td>
</tr>
<tr>
<td>RPA (Robotic Process Automation)/AI/Machine Learning</td>
<td>45%</td>
<td>42%</td>
</tr>
</tbody>
</table>

### CMOs

<table>
<thead>
<tr>
<th>Technology</th>
<th>Currently using</th>
<th>Planning to implement in the next 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cybersecurity</td>
<td>76%</td>
<td>20%</td>
</tr>
<tr>
<td>Cloud Collaboration Platforms</td>
<td>74%</td>
<td>26%</td>
</tr>
<tr>
<td>IoT (Internet of Things)</td>
<td>66%</td>
<td>30%</td>
</tr>
<tr>
<td>Big Data/Analytics</td>
<td>62%</td>
<td>30%</td>
</tr>
<tr>
<td>Additive Manufacturing Technologies</td>
<td>52%</td>
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<tr>
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</tr>
<tr>
<td>RPA (Robotic Process Automation)/AI/Machine Learning</td>
<td>30%</td>
<td>54%</td>
</tr>
</tbody>
</table>
There are several process areas—product development, tech transfer, manufacturing/quality, and planning—where companies are looking to standardize and improve their collaboration with their contract manufacturers and packagers. Both brand owners and CMOs expect digital capabilities will deliver benefits that help them address existing operational challenges.

**Top 3 areas where CMOs and Brand Owners wish to improve collaboration**

**QUALITY / MANUFACTURING:**
Address lack of visibility into quality and manufacturing data to improve product quality

**DEVELOPMENT:**
Accelerate new product launch to increase speed to market with first-time quality

**PLANNING:**
Improve capacity management and scheduling to enhance operational efficiency and product lifecycle management

**Top 3 benefits expected from digital collaboration**

**IMPROVED PRODUCT QUALITY**

**IMPROVED VISIBILITY / REDUCED VARIABILITY**

**IMPROVED COST COMPETITIVENESS**
COLLABORATE NOW: REAL-WORLD EXAMPLES

Pharmaceutical, biotech, and medical device companies and their contract manufacturers know they must improve the way they collaborate with each other. In everything from product development to capacity management, there are real-world examples which show how digital technology can solve some of the biggest collaboration pain points brand owners and CMOs say they’re currently facing.
Consider the challenges of medical device manufacturing today. As more software is embedded in smart connected devices, product development cycle-times and costs are increasing. Manufacturers and their CMOs struggle to collaborate effectively on simultaneous hardware and software development.

Offering accelerated, hyper-personalized, and agile product design and development, digital collaboration platforms such as Dassault’s 3DExperience can facilitate the development of complex medical devices by multiple partners simultaneously, leading to increased product quality.

Osstem Implant improved product quality and drove better tracking and product management by using 3DExperience License to Cure for Medical Device to connect previously disparate processes and data (bills of material, device master records, management of certification documents and UDIs, document versioning, requirements management, quality control, and management of environmental substances). This concept can be integrated with external partners to drive similar results.

Traditionally, tech transfer to CMOs uses documented Standard Operating Procedures (SOPs) and work instructions followed by frequent on-site visits by experts. But product and process complexities are making this increasingly difficult. Multiple iterations are often required for CMOs to reproduce the desired results from the analytical methods provided by the sponsor. The result is longer lead times and higher costs.

Accenture has conducted a series of pilots to showcase how connected worker technologies such as augmented or virtual reality (AR/VR) can streamline tech transfers. AR devices (such as smart glasses) can be used to:

- Deliver interactive audio-visual SOPs to technicians,
- Help ensure SOP adherence and maintain an audit trail for compliance and issue resolution,
- Facilitate over-the-shoulder coaching of CMO technicians to reduce training times and costly on-site visits.
Manufacturing

In pharma manufacturing, it is critical to understand, monitor and control raw material and manufacturing process variability across the value chain from suppliers to patients to ensure proactive management of product quality.

Life sciences manufacturers and CMOs can use cloud-based data exchange solutions (such as Microsoft Azure) with standard formats and visualization capabilities to use for manufacturing visibility and analytics to deliver the safest and most effective drugs possible.

Amgen successfully used analytics and supplier data to proactively identify variability issues before they become a larger problem impacting product quality. To address the key challenge of a lack of a standard file format for seamless data exchange with raw materials suppliers, Amgen leveraged both an industry forum and standards organization. Since the data exchange with suppliers was established, Amgen has used artificial intelligence tools to drive predictive statistical process control models that anticipate issues or identify improvement opportunities with suppliers. This has led to a potential reduction in variability and increased product quality.9

Quality Management

Quality testing and batch release accounts for anything from 30 to 70 percent of manufacturing lead time mainly due to reasons like manual processes, disconnected instruments, and non-standard paper-based documentation and control procedures. Greater regulatory scrutiny and data integrity risks have led to the development of separate point solutions for regulated and non-regulated environments, increasing the complexity of leading managing quality processes with external partners.

A cloud-based quality management solution (such as Veeva Vault, Delmia, or Trackwise) can streamline processes for deviations, lab investigations, customer complaints, internal and external audits, change controls, CAPAs, and proactive quality management initiatives. For repetitive tests (such as environment testing), artificial intelligence (AI) supported by Robotic Process Automation (RPA) can allow lab scientists to work by exception and focus on improving predictability.
Supply Chain Planning and Capacity Management

Manual information sharing across forecasts, inventory, production capacity, and engineering changes drives slow response times and leads to operational inefficiencies.

Cloud-based supply chain collaboration platforms (such as SAP Ariba SC Collaboration, E2Open, and Oracle SC Management Cloud) can be used to manage non-linear and externalized supply chains effectively. These platforms help companies standardize processes across multiple suppliers and access supply chain information in close to real time. They also enable business processes like integrated sales and operations and supplier managed inventory (SMI).

A global medical device company adopted the SAP Ariba and SAP Integrated Business Planning (IBP) solutions to integrate their supply chain planning and manufacturing activities with their CMOs, optimize SMI processes and improve overall operational productivity through transaction automation. Business goals enabled by the solution included end-to-end supply chain visibility, improved productivity, and reduced variability in demand and supply.11

Gilead has deployed Veeva Vault QualityDocs to achieve real-time visibility in quality processes and GxP documents across their large network of CMOs and contract testing labs. Gilead can push documents such as quality manuals, master batch records, and standard operating procedures out to external partners. Gilead quickly receives confirmation when changes have been implemented and also receives back executed batch records plus the related quality documents. As a result, Gilead has seen an up to 30% reduction in their batch record review cycle time.10
LET’S GET STARTED:
A new era of CMO collaboration

A perfect storm of enhanced patient-centricity, more complex products and services, accelerated product approvals, and growing regulatory challenges is bringing unprecedented challenges to an already multifaceted life sciences supply chain. Managing this shift successfully now calls for a new era of collaboration between life sciences companies and their suppliers.

There are four key steps for companies to take, encompassing everything from the initial business case right through to the continuous improvement of CMO partnerships:

01 **Start with a top-down approach.** Identify a C-level sponsor to drive the innovation and change agenda and build strong leadership engagement from functions across the organization. Define the business case and map out a roadmap with the company’s overall vision and strategy. Establish a strong change management plan both internally and with suppliers.

02 **Define a collaborative roadmap to pilot, then scale.** Join forces with key partners to define a joint implementation roadmap. Then define the technology platforms that can best support and connect the organizations’ people, processes, and assets, driving patient value while targeting operational improvement. Operationalize the processes and technologies on a small scale. Implement the learnings and make improvements to the model – then scale throughout the supplier portfolio.

03 **Co-invest on strategic innovation and share the value.** Avoid the trap of misaligned objectives, whether in controlling costs or building niche capabilities. Ensure the business case and supporting technologies deliver and demonstrate value to both parties, keeping in mind that it’s not a zero-sum game.

04 **Continuously measure and improve.** Define the right governance structure, ensuring operations are sustainable. Measure established KPIs and enable continuous improvement. Embed the idea of collaboration into the DNA of both the company and each of its suppliers.

Above all, today’s leaders must completely rethink how they operate. Existing processes just cannot handle the level of smart collaboration required. Only by reexamining the entire approach, segmenting and tailoring supplier relationships, aligning incentives, and co-investing in digital technologies and product innovations can life sciences companies truly meet today’s market needs. The ultimate goal? To deliver real patient value with a supply chain transformation powered by collaboration and continuous improvement.
Sources

1. 49 NMEs approved by FDA through Nov 8, 2018, the highest ever. https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm592464.htm

2. Accenture analysis, data provided by Evaluate Pharma


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