



TOP 7 PHARMACEUTICAL INDUSTRY TRENDS IN 2021

Maximizing market success and lowering liability through
validation and compliance



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INTRODUCTION

The pandemic has wrought enormous changes in our world, and perhaps no industry has been greater affected than life sciences in general and pharmaceuticals in particular. COVID-19 has forced pharma companies to rethink how they do business to become more efficient and stay on top in a highly competitive environment. These are challenging times, no doubt, but it's an era that also offers significant opportunity in a changing landscape.

In this eBook, you'll discover some of the key trends within the pharmaceutical industry for 2021:

- #1:** Technological innovation increases in importance.
- #2:** Compliancy takes center stage.
- #3:** Collaboration among (and within) enterprises rises.
- #4:** Contract manufacturing flourishes.
- #5:** Small-scale manufacturing plays a large role.
- #6:** Organizations see renewed focus on culture and reputation.
- #7:** The world is moving quickly – and pharma companies continue to adapt.

With these trends in mind, we'll then explore Meridian Cloud for Life Sciences, a strategic business application for engineering information management, and provide a vision for helping your pharmaceutical organization maximize market success and lower liability through validation and compliance.

“Leaders of pharma companies are in the midst of unprecedented change... Pharma companies are up against a fresh set of challenges even as the pandemic has spurred adoption of technologies and other innovations to support virtual work and other functions.”

– Deloitte Insights¹

² <https://www2.deloitte.com/xe/en/insights/industry/life-sciences/pharmaceutical-industry-trends.html>

#1: TECHNOLOGICAL INNOVATION INCREASES IN IMPORTANCE

Digital transformation has been a priority for pharmaceutical companies for some years now, but the pandemic has kicked those efforts into overdrive. Almost overnight, companies had to upgrade their systems, revamp their supply chains, facilitate remote work, improve their business models, communicate more effectively with clients and more – all while many were under extreme pressure to research, manufacture and distribute life-saving vaccines. COVID-19 shone a spotlight on the importance of technological innovation in life sciences organizations, a journey that in many cases was shortened from years to mere weeks. It's a journey that requires a clear strategy with a system of people and technology that are aligned to the mission of delivering more value, more efficiently.

A critical part of achieving this transformation is putting modern digital software and systems into place. New technologies such as artificial intelligence will make an impact, but updating existing processes with current, comprehensive and centralized systems will arguably convey even greater benefits by ensuring that information is accessible and up to date. A single source of truth, where files are stored in one repository rather than on individual hard drives or department servers, means everyone who needs the information to execute their work has access to it. And confidence in accurate information means lowering the risk of accidents caused by incorrect procedures, delays due to wrong parts being ordered, and confidentiality and security breaches as a result of improper external party access.

“In a short time, COVID-19 has increased our dependency on technology and companies are actively investigating this digital transformation. In developing digital strategies, the focus must be on increasing efficiency while minimizing risk.”

– Pharmacy Times, Together Beyond COVID-19: A Look at the Future of the Pharmaceutical Industry

AMONG HEALTHCARE ORGANIZATIONS²

74%

Of companies sped up their digital transformation due to the pandemic

6

The number of years digital communications strategies have been accelerated by

59%

of companies lack a fully defined digital strategy



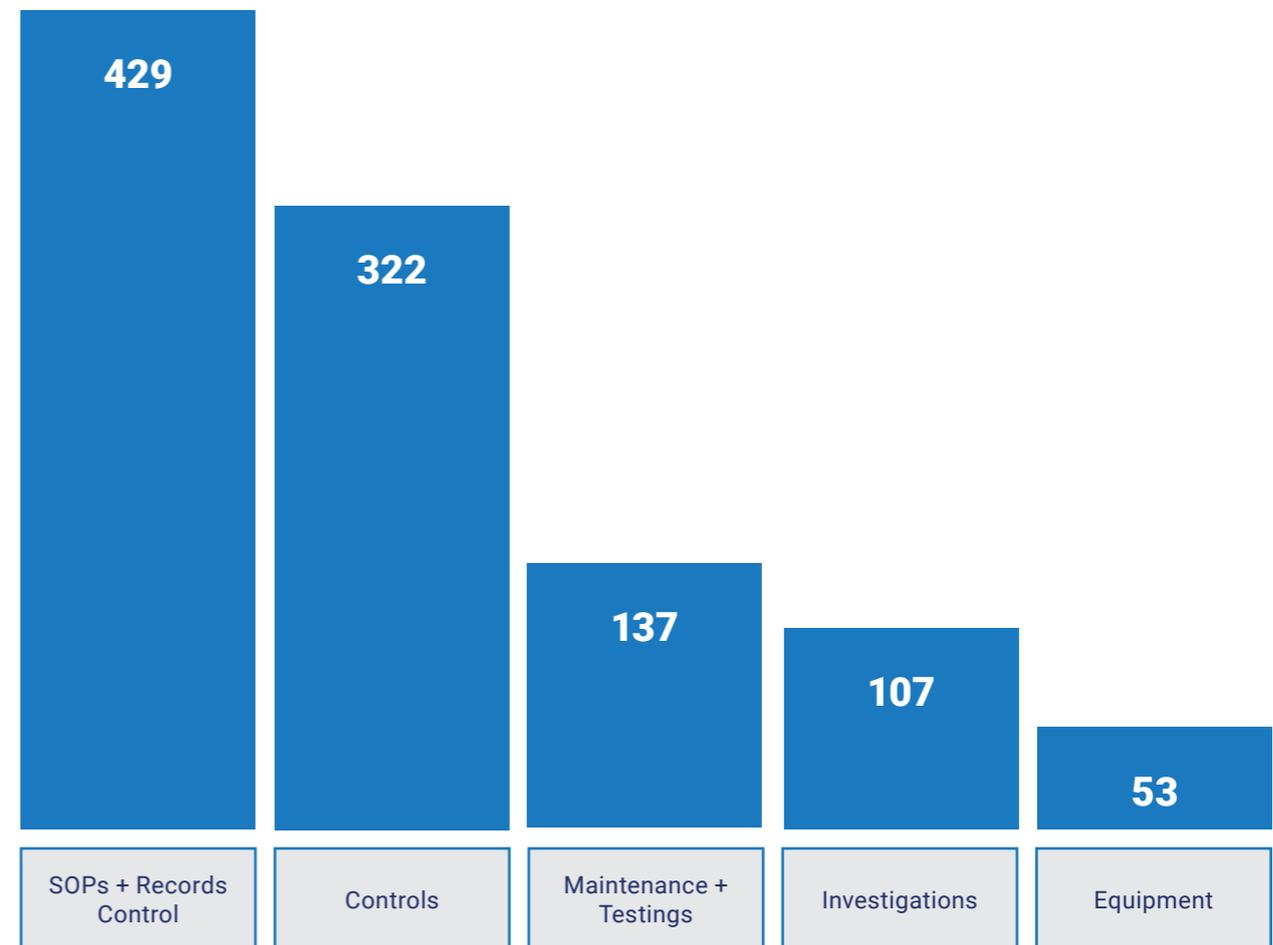
² <https://pharmaphorum.com/digital/the-acceleration-of-pharmas-digital-transformation/>

#2: COMPLIANCE TAKES CENTER STAGE

In a highly regulated industry, compliance is mandatory. Fail to meet governmental or industry regulations, and you risk a range of penalties, from the relatively minor – such as additional inspections, lost production time or un-sellable products – to more major costs such as recalls, plant shutdowns and company fines.

Pharmaceutical professionals have long worried over receiving the dreaded “FDA 483 letter,” but compliance issues increasingly have become more top of mind since the release of the 2020 draft for the revision of Annex 1 of the EU GMP Guide to Good Manufacturing Practice. EMA Annex 1 contains multiple revisions compared to the 2017 draft, and manufacturers have raised concerns over its emphasis on outdated technologies rather today’s more automated environments, its application to the areas of validation, and its “inadequate consideration of global regulations.”³ The exact wording of the revision is yet to be finalized, but in the meantime, companies are adopting tools designed to manage the requirements of compliance and fully integrating them into how they do business.

Tools and systems such as Meridian Cloud for Life Sciences help pharmaceutical organizations comply with the requirements of FDA 21 CFR Part 11 and EU GMP Annex 11 by managing the as-built master documents, controlling engineering project management and integrating connectivity with authoring tools and maintenance management systems. By providing the technical controls to support CFR 21 Part 11 compliancy in a pre-validated template solution, Meridian Cloud for Life Sciences can help cut down on SOPs and records control violations, the leading cause of FDA 483 violations for pharmaceutical companies.



LEADING CATEGORIES OF 483 OBSERVATIONS ON PHARMA IN 2018

<https://www.qualio.com/blog/compliance-issues-in-pharmaceutical-industry>

³ <https://www.pharmamanufacturing.com/articles/2021/top-pharma-industry-predictions-for-2021/>

#3: COLLABORATION AMONG (AND WITHIN) ENTERPRISES RISES

Even before the pandemic hit, collaboration among pharmaceutical and other life sciences organizations was growing. As patents expire and regulations tighten, big pharma is shifting from an environment of competition to one of collaboration, where companies are working with universities, biotech labs, government agencies and “rivals” to overcome industry challenges. For example, Pfizer partnered with IBM to further promising research leading to new therapies,⁴ while Novartis is providing its drug inclisiran to the UK National Health Service for a clinical trial in atherosclerotic cardiovascular disease patients.⁵ Internal collaboration is increasing as well, as organizations break down information silos among teams and departments and enhance efficiency by integrating engineering, maintenance, operations and other systems.

>2x

The rate at which academic-industry collaborations rose in 2012-2016, with more than half of those in life sciences⁶

10%

Predicted growth in outsourcing research activities to academic and private contract research organizations from 2019-2022⁷

>80%

Bio-pharma enterprises reporting increased alliance activity⁸

⁴ <https://www.technologynetworks.com/drug-discovery/articles/the-importance-of-collaboration-in-the-pharmaceutical-industry-299095>

⁵ <https://www.europeanpharmaceuticalreview.com/article/111557/five-of-the-most-recent-pharma-collaborations-in-2020/>

⁶ <https://www.inova-software.com/collaboration-in-pharma-the-new-normal/>

⁷ <https://www.biopharmatrend.com/post/30-pharma-rd-outsourcing-is-on-the-rise/>

⁸ <https://info.vantagepartners.com/insights/the-perils-and-promise-of-strategic-partnering-with-cros>



#4: CONTRACT MANUFACTURING FLOURISHES

Contract manufacturing is poised to take off. Given the rapid growth of the pharmaceutical industry as a whole and the pressures pharma companies face to meet regulatory requirements while improving profitability, analysts predict that contract manufacturing organizations (CMOs) will increasingly step in to meet those needs. CMOs tend to have modern processes and technologies – which can be invaluable in proving compliance – and as they consolidate, they boost profitability in a highly competitive market.

But outsourcing data makes the information flow extremely complex, as major changes can involve thousands of documents and dozens of external parties. Key to this outsourcing of systems and services is the ability of pharmaceutical companies to streamline the qualification and validation of contract manufacturers. Pharmaceutical companies use EDM systems like Meridian Cloud for Life Sciences to smooth the exchange of documentation with external parties and identify and fix data inconsistencies before they become an issue.



THE GLOBAL PHARMACEUTICAL CONTRACT MANUFACTURING MARKET⁹

6.6%

Compound annual growth rate from 2018 through 2023

\$162.1B

Expected market size in 2025

47.8%

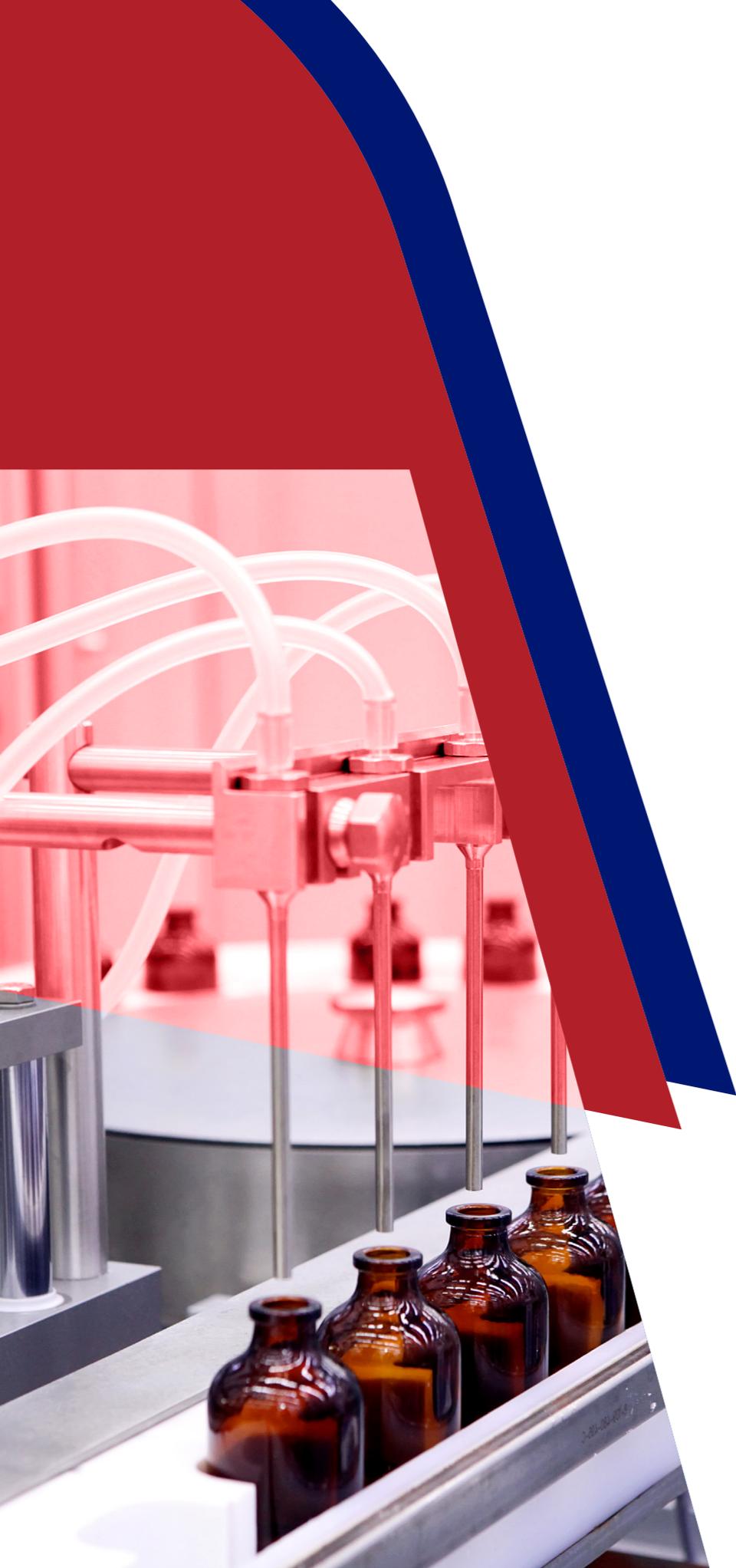
Increase in market size from 2019 to 2025

“Contract development and manufacturing organisations, just like the big pharma organisations, will need to improve speed, increase efficiencies and expand globally and outsourcing services and production will likely be a key enabler. Being flexible in this way will make organisations more competitive in the long run.”¹⁰

– Chris Lawson, Orientation Marketing

⁹ <https://www.reportlinker.com/p05778451/Pharmaceutical-Contract-Manufacturing-CMO-Market-Growth-Trends-and-Forecast.html>

¹⁰ <https://www.orientation.agency/insights/pharma-marketing-trends-from-2020-to-2021>



#5: SMALL-SCALE MANUFACTURING PLAYS A LARGE ROLE

Clearly, the COVID-19 pandemic had an extraordinary impact on the pharmaceutical industry, and the effects will carry far into the future. One area that is being upended is manufacturing, where small-scale manufacturing is taking on greater importance than before as the need for rapid vaccine rollout expands into new continents, countries and regions, who desire greater control over production but lack large production infrastructure. Rather than an environment in which a few industry giants control production, we will see the collaboration and cooperation extending into other markets. In addition, the growth of niche medicines has engendered the rise of smaller-scale facilities.

This reliance on small-scale manufacturing means that pharma companies will need to quickly deploy and adopt standards and processes across various smaller plants. Engineering Information Management systems provide a variety of benefits for these companies, including the ability to:

ENHANCE COMMUNICATION AMONG TEAMS

Teams save time by finding key asset information faster, all departments have the same view of official documentation, and users gain access to communication tools such as comment and editing capabilities.

ENSURE FULL CONTROL OF ENGINEERING CONTENT

Version control and change management are preserved in a safe and secure environment, while individuals are guaranteed to be working on the most current documentation.

STREAMLINE AUDITS WITH REDUCED RISK OF NONCOMPLIANCE

Audit trails that show what has changed, by who and when enable compliance with life science specific regulations to avoid costly fines and speed time to market.

DELIVER QUALITY DOCUMENTATION WITHOUT DELAY

Reduce search time for engineering information from hours to minutes as you avoid production delays due to inaccurate information.

Small-Scale Manufacturing Will Grow

“Disruptive technologies such as cell and gene therapy will challenge the status quo and drive the industry towards rapidly deployed facilities, with smaller scale, modular and portable plants becoming increasingly utilized. This will aid the speed to market, further diversify the manufacturing footprint globally and increase the desire for real-time supply chain management and planning.”

– Joe Haugh, CEO, Zenith Technologies, a Cognizant Company¹¹

¹¹ <https://www.pharmamanufacturing.com/articles/2021/top-pharma-industry-predictions-for-2021/>



#6: ORGANIZATIONS SEE RENEWED FOCUS ON REPUTATION AND CULTURE

For an industry long plagued by reputation woes – for example, a 2019 Gallup study found that pharmaceuticals ranked dead last in Americans’ eyes among 25 sectors, pushing it below the oft-maligned federal government¹² – the pandemic has shone a spotlight on the public perception of pharma companies. And many in the industry are seeing this as an opportunity to bolster their image, with a renewed focus on how they can drive public perception and boost trust.

“The COVID-19 pandemic is a really interesting time, with contradicting consequences: for one, the public is listening, watching and reading – paying more attention to pharma and drug development than perhaps ever before,” Caliber’s Chief Executive Officer, Shahar Silbershatz, told European Pharmaceutical Review’s Hannah Balfour in an interview. “This provides a great opportunity for companies to redefine what they stand for.”¹³

In addition to focusing on their external reputations, companies are also turning their gaze inward, considering ways in which they can improve their

standing among their employees. Modern employees not only want to work for companies that clearly align with their values and that they can be proud of,¹⁴ but these tech-savvy individuals want tools that allow them to be efficient and productive. The technologies, software and systems they use must help them save time, better communicate and collaborate, and streamline access to the information they need to do their jobs. Advanced software helps companies attract – and keep – top talent.

“What do your employees really want from the tech they use on the job? From choosing devices, to picking apps, to opting for voice over text, employees look for options that help them do their best work... Today’s workforce is curious about technology, and ready to invest time in learning.”¹⁵ – PwC

¹² <https://news.gallup.com/poll/266060/big-pharma-sinks-bottom-industry-rankings.aspx>

¹³ <https://www.europeanpharmaceuticalreview.com/article/132222/has-covid-19-changed-public-perception-of-pharmaceutical-companies/>

¹⁴ <https://www.fastcompany.com/90538157/this-is-the-thing-employees-want-most-from-their-employers>

¹⁵ <https://www.pwc.com/us/en/services/consulting/library/consumer-intelligence-series/tech-at-work.html>

#7: THE WORLD MOVES QUICKLY – AND PHARMA COMPANIES CONTINUE TO ADAPT

There's no question we're in unprecedented times, and 2020 was a tumultuous year. But the pharmaceutical industry has shown its resilience by adapting to unforeseen circumstances. From new therapeutic research to supply chain adjustments to regulatory accommodations, the industry responded with modernization and innovation.

These demands will be ongoing throughout the wake of the pandemic and beyond, however.

To keep up with this altered landscape, pharma companies are going to continue adapting – often in ways that we cannot even imagine today. It will take a combination of people, processes and technology to achieve success.

Here at Accruent, we're dedicated to providing the software and systems that will make that adaptation possible. Our mission is to fundamentally change the way you use data to run your built environment. By delivering data-led

intelligence, we can transform the way your people and systems work together and help you drive business forward. Tools like Meridian Cloud for Life Sciences will help keep your pharmaceutical business running by allowing you to master asset management, promote workplace efficiency and meet strict compliance requirements.



CONCLUSION

Ask yourself: Is your pharmaceutical company keeping up with the global needs of 2021 and beyond?

- ✓ Do you rely on outdated hardware, software and infrastructure?
- ✓ Are information silos creating walls between departments and teams?
- ✓ Is employee productivity hampered by unwieldy processes?
- ✓ Do you struggle to meet regulatory requirements?
- ✓ Are external parties, contractors and collaborators challenged by access to critical data?
- ✓ Could system maintenance costs be lowered with online administration and configuration?
- ✓ Do you lack confidence in your engineering data integrity?

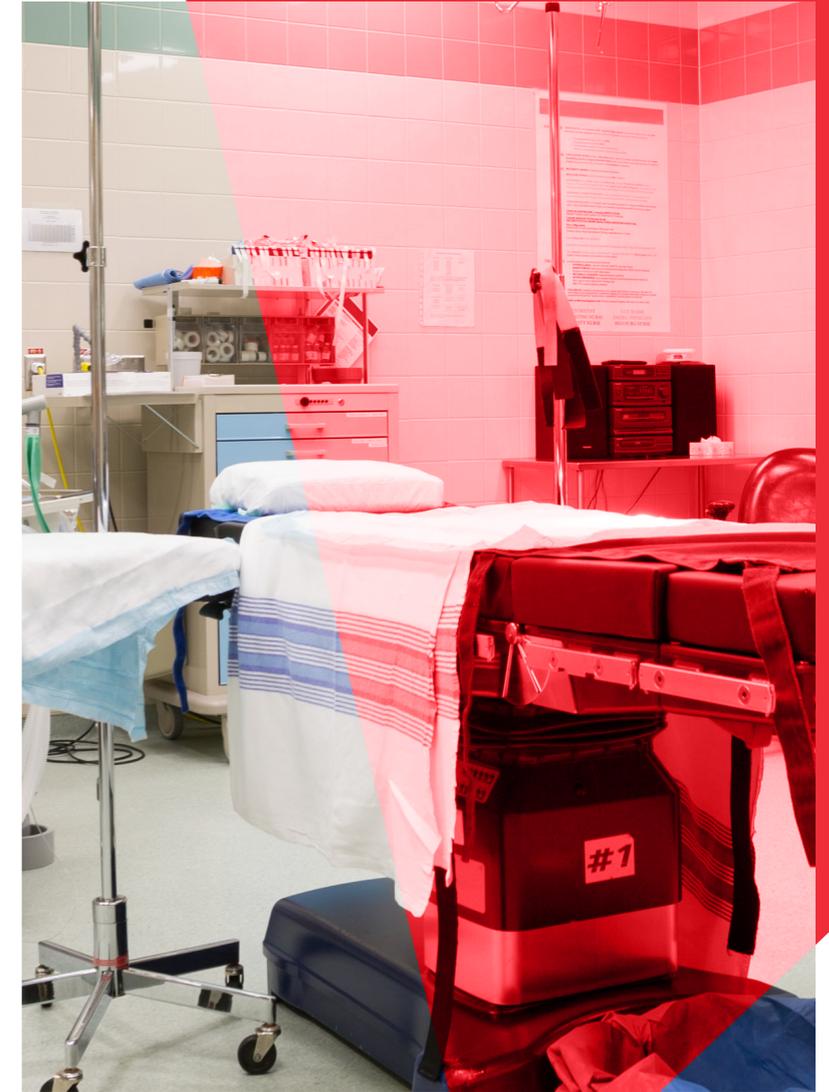
If you've answered "yes" to any of these questions, you may be missing out on crucial opportunities drive greater value for your business.

To learn more about how you can improve operational excellence and lower total cost of ownership, visit [here](#).

CONTACT FOR A DEMO

Accruent, LLC

sales@accruent.com | www.accruent.com | 512-512-5125





ABOUT MERIDIAN CLOUD FOR LIFE SCIENCES

Accruent's Meridian Cloud for Life Sciences provides a best-of-class engineering document management solution for the world's largest life sciences enterprises that manage their facility engineering content in the cloud. Encompassing engineering change management, release management and handover management, Meridian Cloud for Life Sciences empowers both new projects and renovations.

\$1.5T

In Assets Managed

500M

Documents Tracked

300K+

Users

Used by **8** of the **10**
largest pharmaceutical
companies in the world

By establishing a single source of truth for all asset information, Meridian Cloud for Life Sciences helps facilities ensure plant safety and compliance, enable disparate teams to share engineering information securely and reliably, and demonstrate effective change control procedures for all engineering documentation.

With Meridian Cloud for Life Sciences, you:

1. PRESERVE ENGINEERING DATA QUALITY.

Identify and fix data inconsistencies before they can become an issue. Meridian Cloud for Life Sciences helps you maintain the quality, accuracy and completeness of data and metadata by working in a unified system. Manual data entry and redundant data are eliminated, while controlled releases prevent users from working on an incorrect version.

2. ENSURE EFFECTIVE CONTROL AND CHANGE MANAGEMENT.

Entire teams will stay on track with access to released engineering information. Meridian Cloud for Life Sciences makes it easy to keep as-built master data up to date while you manage change processes in dedicated project areas, where it allows you to quickly run through review and approval workflows based on your organizational needs.

3. UTILIZE CAD INFORMATION WITHOUT USING CAD SYSTEMS.

Generic content management systems can't handle engineering drawings, references, models and constantly changing engineering data. Meridian Cloud for Life Sciences' purpose-built engineering information management software supports out-of-the box CAD integrations to ensure accurate engineering information exchange, allowing users to easily store, manage, render and visualize engineering content.

4. REDUCE THE COST OF HANDOVER.

Shorten project turnaround through controlled and automated engineering information handover processes among Engineering, Operations and Maintenance teams, and smoothly manage exchange of engineering documentation with external contractors.

"By creating a single source of up-to-date information that removes silos and integrates with our EAM solution, Meridian has helped us reduce maintenance errors by 50% and save \$20,000 annually in unnecessary rework."

— Willy Baten, Information Specialist, Radboud University Medical Center



ABOUT ACCRUENT

At Accruent, we know the built environment better than anyone. We are setting new expectations for how data can fundamentally change the way you run your built environment and empower your people and systems work together more seamlessly for greater ROI.

10K+
Customers

150
Countries Served

5.3T+
Square Feet Managed

500M+
Work Orders Managed

The built environment is all around you. Today, it is saddled with more systems to manage, more regulations to follow and higher expectations from your workforce than ever before. But within this mosaic of connected infrastructures and integrated workflows is endless opportunity.

Accruent helps you look below the surface to unlock the value hidden in your complex systems and endless data points and gain deeper insight into your organization. We offer intelligent solutions that are intuitive, seamlessly integrate with your existing systems and workflows, and not only deliver the results promised, but also illuminate possibilities that you couldn't see before – so you can achieve results that you never knew were possible.

Accruent is the world's leading provider of intelligent solutions for the built environment, spanning real estate, integrated technology systems, and the physical and digital assets they connect. Accruent continues to set new expectations for how organizations can use data to transform the way they manage their facilities and assets and is transforming the way people and systems work together.