A ROAD MAP FOR ADDRESSING QUALITY AND MANUFACTURING CHALLENGES IN LIFE SCIENCES:

MOVING BEYOND REGULATORY BURDENS TO ENABLE NEW COLLABORATIVE MODELS FOR GROWTH

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TABLE OF CONTENTS

A Road Map for Addressing Quality and Manufacturing Challenges in Life Sciences:
Moving Beyond Regulatory Burdens to Enable new Collaborative Models for Growth

Section 1

EXECUTIVE SUMMARY

Executive Summary

The life sciences industry faces many challenges coming from all directions, and the most immediate and pressing are external. Due to the inextricable connection between the industry's products and public health, life sciences companies are subject to increasingly strict regulatory measures, which are only poised to tighten in the future.

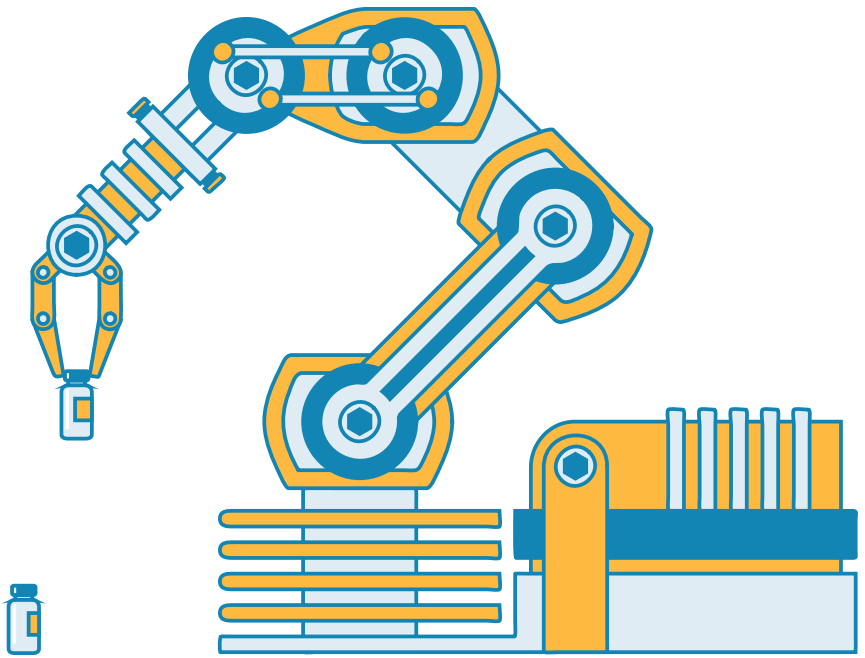
Additionally, the face of the life sciences industry/pharmaceuticals is in the midst of a broad transformation as healthcare adapts to growing world populations and standards of living, a move toward more personalized medicine, and a growing number of dispersed suppliers. Put simply, the systems and processes life sciences have used to manage production and quality up until now are inadequate. But in this daunting operational climate is opportunity.

Today, leading life sciences companies are greatly enhancing operational capacity and achieving business value through the adoption of next-generation Enterprise Quality Management Software (EQMS) and Manufacturing Operations Management (MOM) software, along with formal processes to better manage quality and build the end-to-end traceability capabilities that have become so vital for compliance.

This eBook dives deep into life science challenges and how leading organizations are approaching them.

Specifically, it addresses:

- How rising world populations and standards of living are increasing spending on healthcare
- Pressures of cGMP regulations from FDA and other regulatory bodies.
- Organization for approaching quality holistically rather than "as a department"
- Real-world examples of leading life science companies' responses to regulation issues
- Benchmark data on how EQMS and MOM applications correlate to improvements in On-Time Complete Shipments (OTCS), New Product Introduction (NPI), and Products in Compliance (PiC)
- Recommended actions

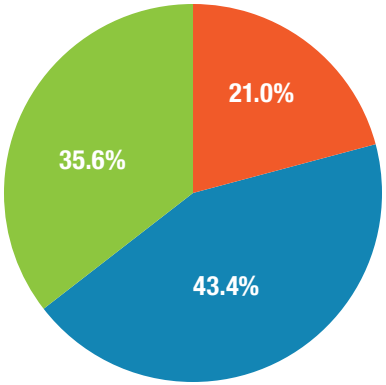


Section 2

RESEARCH DEMOGRAPHICS

Research Demographics: Quality Management

The 2012-2013 LNS Research Quality Management Survey has been completed by over 500 executives and other senior leaders, hailing from companies large and small across a range of industries and locations. The survey questions drill down into the challenges and opportunities that companies face, strategic objectives data, and the most important goals currently being pursued around quality. As seen in the demographic information listed above, more than half of the respondents were from discrete manufacturing industries. A majority of the participants, 51.5%, were from North America, with 41.2% from Europe. And nearly half, 43.4%, were from medium-sized companies, with 35.6% and 21% from small and large companies, respectively.



COLOR BY COMPANY REVENUE

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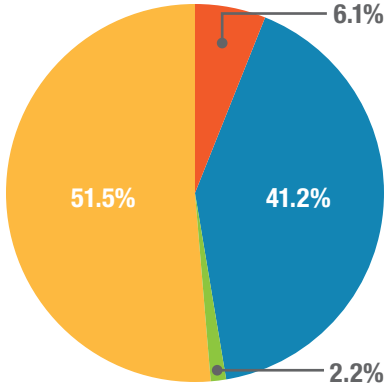
- MEDIUM: $250MM–$1BB
- SMALL: $0–$250M



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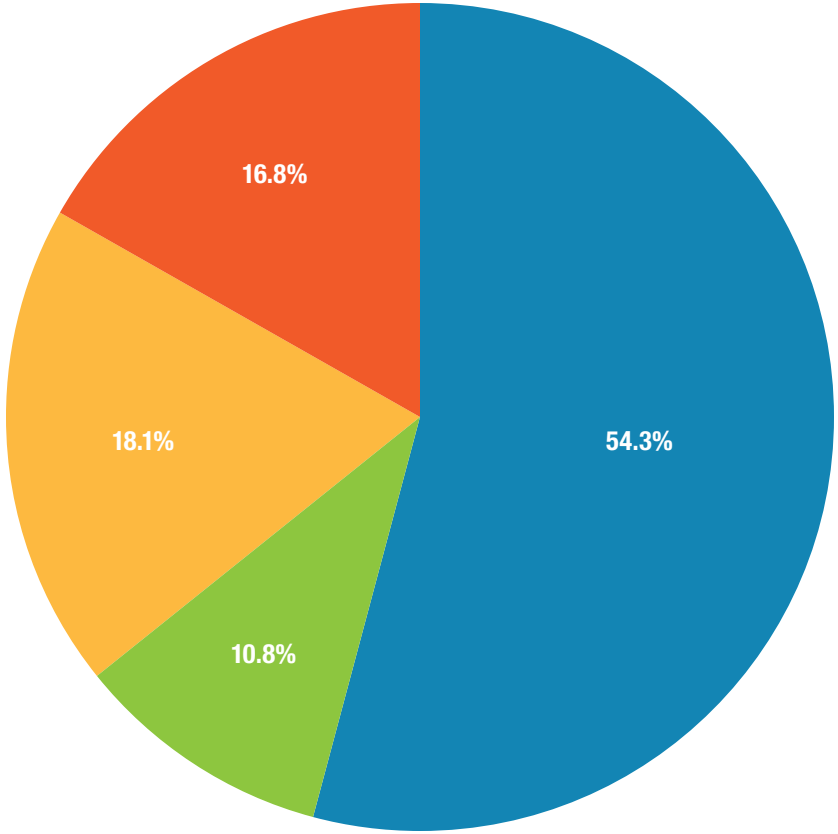
- EUROPE
- MIDDLE EAST/AFRICA
- NORTH AMERICA

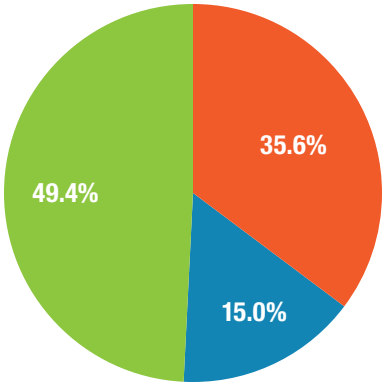


COLOR BY INDUSTRY

- DISCRETE MAN
- F&B / CPG
- LIFE SCIENCES
- PROCESS MAN

Research Demographics: Manufacturing Operations Management

The pie charts above provide background demographic information on the LNS Research MOM survey participants. As shown, the results depict a diverse set of Respondents. There were 60% from the discrete manufacturing industries, 10% from process manufacturing, 16% from food & beverage/consumer packaged Goods, and 13% from life sciences. Nearly 65% of the executives surveyed were from Small to Medium businesses, with 35.6% from Companies with revenue greater than $1 billion. Geographically, North American companies composed 44% of respondents; 32% were from Europe, 12% from the Asia/Pacific region, and 11% were from the rest of the world.



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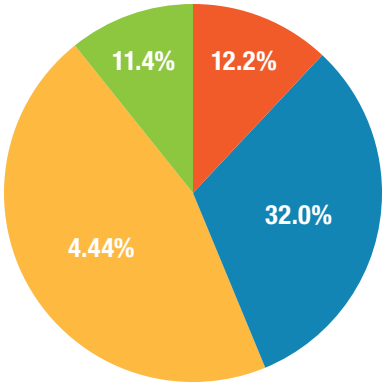

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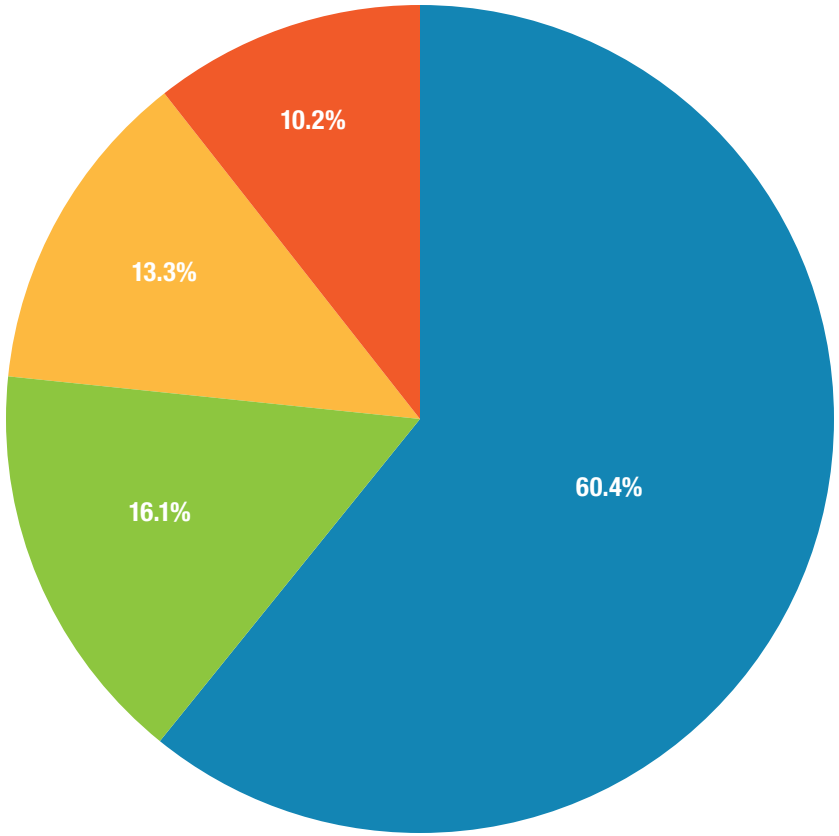

COLOR BY INDUSTRY

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- F&B / CPG
- LIFE SCIENCES
- PROCESS MAN

Section 3

LIFE SCIENCES MEGATRENDS

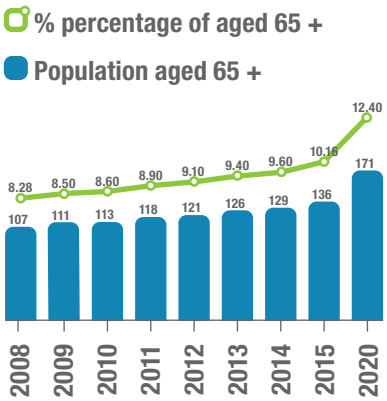
World Population and Economic Growth

As the global population continues to grow the world faces unprecedented challenges in healthcare. As life expectancy increases, predictions for the proportion of the population over 65 approach or exceed 10% globally, 20% in Western Europe and 27% in Japan by 2017. In parallel, the number of high-income households is on the rise with more than 500 million households earning over $25,000. Over half of this growth comes from Asia. As a result, the average increase in global spending on healthcare is expected to rise an average of 5.3% (4.4% per head) through 2017.

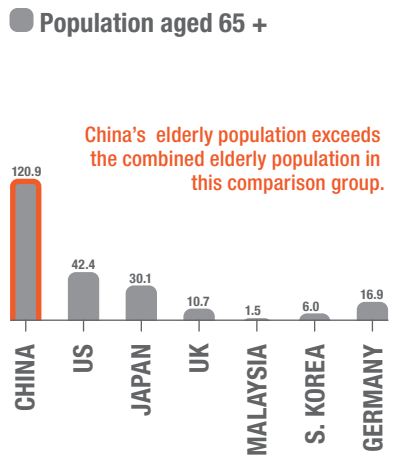
Despite pressure to reduce healthcare costs, sector expansion is predicted, driven by treatment advancements and government initiatives as an aging population creates an increase of incidences of chronic ailments that are expensive to treat.

China's Aging Population vs. Global Comparison Group

Aging population in China (2008–2020F)



Comparison of population 65+ Number in Million (2012)

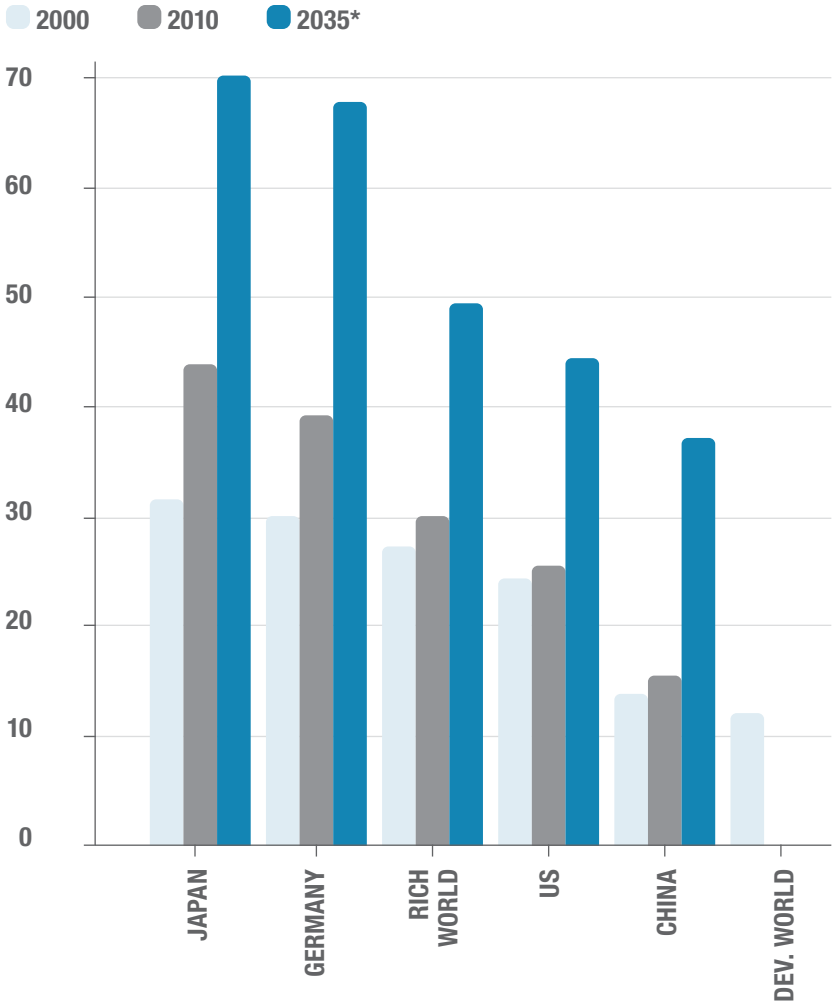


Reference: *http://www.economist.com/news/briefing/21601248-generation-old-people-about-change-global-economy-they-will-not-all-do-so*

Reference: *https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/dttl-lshc-2014-global-health-care-sector-report.pdf*

The Big Shift

Old-age dependency, population aged 65 and over per 100 people aged 25–64



Personalized Medicine: A Trend on the Horizon

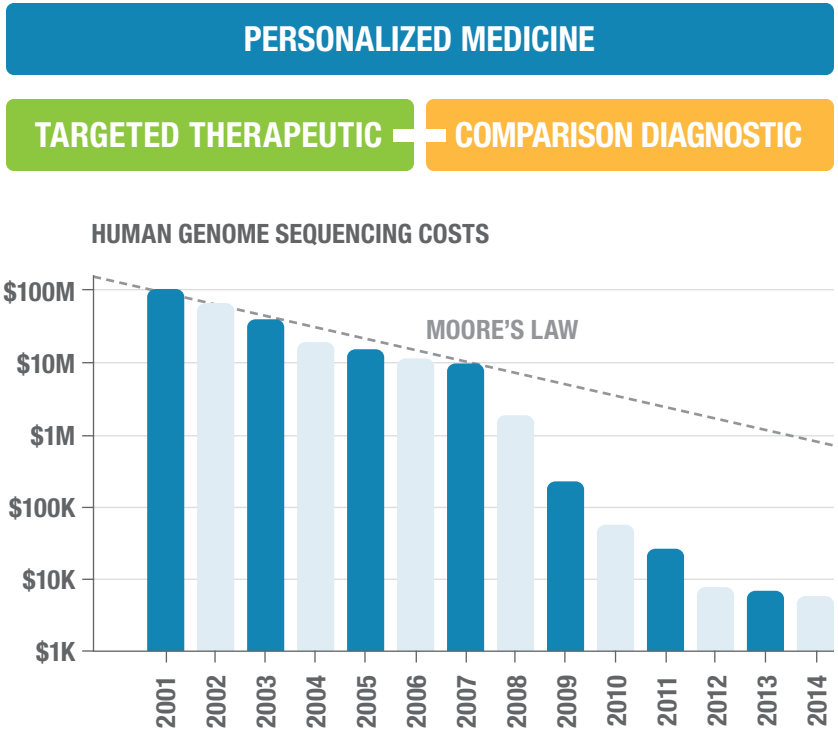
Personalized medicine is the ubiquitous term to describe the potential for treatments specifically tailored for an individual patient based on their individual genotype (genetic characteristics). Since its beginnings in the 1990s, this field has slowly gained momentum to present day, where some say that global healthcare is on the cusp of this reality while others assert that the time has already arrived (FDA). Nevertheless, at present only 102 pharmaceuticals have an "associated" biomarker to date (GENReports:Market&Tech Analysis, Produced by Enal Razvi,Ph.D.©2014).

As acceptance increases and costs for genomic sequencing are reduced the market has experienced growth. For example, costs have plummeted in the last six years and the "$1,000 Genome" is on the near horizon. A vast change from the $100M cost less than 15 years ago.

A substantial share of current growth is expected to be generated by cancer companion diagnostics. It is clear though that based on cancer care costs alone the companion diagnostics market is attractive.

One critical element for personalized medicine is the speed of new in vitro companion diagnostic (IVD) devices to market where these are required for the safe and effective use in personalized therapies. Organizations with mature EQMS solutions have demonstrated improved NPI.

One impact on the life sciences sector as emphasis on personalized medicine takes hold is the potential for fewer blockbuster drugs making it to market. The gap between R&D spend in pharma and drug approvals by the FDA (known as the innovation gap) is indicative of the need ahead for different, streamlined manufacturing models while enhancing traceability. The success of this will rely heavily on technology.



Other advances that will play into the overall picture of personalized medicine include devices designed to be capable of monitoring and processing individual health characteristics and the traceability of these products. As monitoring devices become pervasive a new wave of individual patient data will feed the Big Data landscape, increasing the demand and opportunity for analysis service and resulting diagnoses.

Reference:*(NHGRI) http://www.genome.gov/sequencingcosts/*

Life Sciences Industry Regulatory Burden

New challenges have placed and continue to place enormous pressures on improving quality management and manufacturing traceability. Regulatory burdens and rising customer demands are two notable examples that have changed the industry landscape over the past several years.

FDA Director of the Center for Drug Evaluation and Research (CDRH), Janet Woodcock, stated in October 2014 that, "Quality is the underpinning of everything we do, and it is imperative that we have a drug quality program as robust as those programs we presently have for drug efficacy and drug safety."

Adding complexity, the FDA places special focus on the global nature of manufacturing and raw materials sourced from outside the U.S.

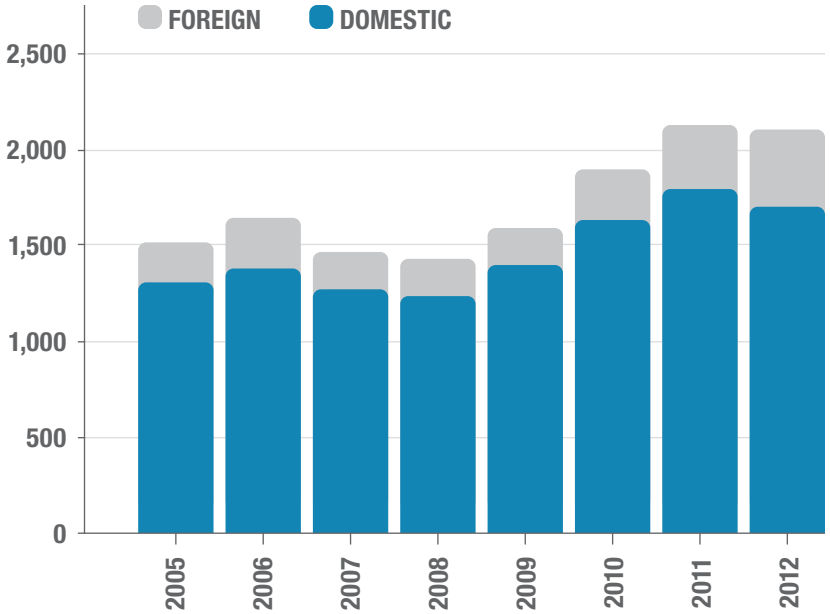
The number of quality system inspections has been generally increasing in recent years. Between 2005 and 2012, FDA's routine Quality Systems Regulations (QSR) inspections increased by a total of 37% and 93% respectively, in U.S. and foreign firms.

To address increasingly aggressive regulatory oversight, forward thinking companies are dramatically improving collaboration with their research and manufacturing partners to alleviate the pressure and reduce risk.

Reference: *http://www.raps.org/Regulatory-Focus/News/2014/10/16/20584/FDA-Announces-Major-Agency-Reorganization-With-Focus-on-Drug-Quality/*

Reference: *http://www.insidemedicaldevices.com/2014/06/04/fda-issues-report-on-2012-qsr-enforcement-activities/*

ROUTINE QSR SURVEILLANCE INSPECTIONS



Section 4

INDIVIDUAL COMPANY RESPONSES

Quality in Corporate Reports

Organizations in life sciences face demands from customers and shareholders to demonstrate that quality in and across the value chain receives the appropriate attention. The strategic objectives that relate to manufacturing and quality management are illustrated by clear statements made in annual reports. Pfizer, for example, outlines the importance of quality, safety and availability of their products, stating that they take a "holistic, multi-faceted approach to quality and compliance programs." The annual report outlines how the company relentlessly challenges itself to enhance systems and processes with numerous ongoing continuous improvement projects. Technology is cited as the key to leverage expertise throughout the supplier network, for the supply of quality products at competitive prices.

MANUFACTURING AND SUPPLY CHAIN

"Pfizer is committed to supplying products to patients that significantly improve their lives. Therefore, our manufacturing and supply division focuses on ensuring that all the Pfizer products are produced to the highest standards of quality, safety and efficiancy and are available when needed."

Pfizer 2013
ANNUAL REPORT

600
major product group

175
markets

130+
market disttribution and logistics center operation

200
contract manufacturers

56
manufacturing sites

Increasing Consolidation

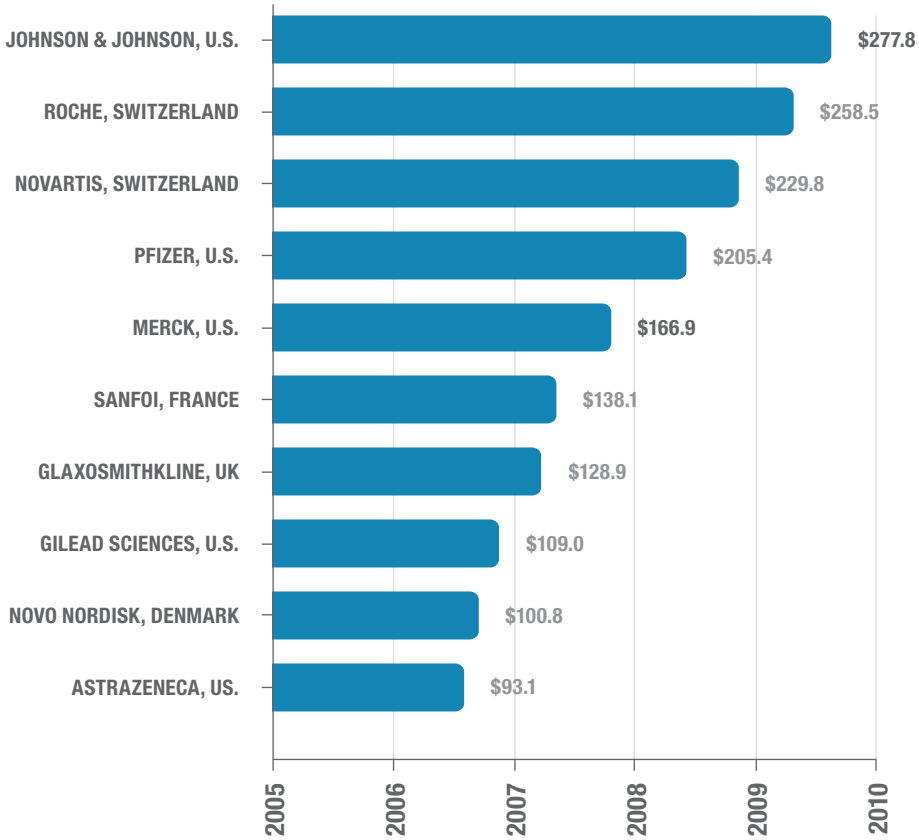
In recent times, 2009 stands out as the year of the merger for life sciences and pharmaceutical companies in particular. Pfizer and Wyeth, Roche and Genentech, and Merck merged with Schering-Plough. On the horizon are others and 2014 has to date been filled with the speculation around the circa $100 billion Pfizer bid for AstraZeneca.

There are many challenges with mergers of all shapes and sizes and commentators have identified some of the financial gains and implications for areas such as R&D spending. However, from a manufacturing and global quality perspective there is enormous effort required to bring together both harmonized processes and best practices, as well as to ensure there are no lapses in compliance. And this all needs to be undertaken while the organization pursues goals for achieving or maintaining operational excellence.

There has to be clarity in objectives and top-level commitment to bring together organizations, and when we consider the re-calibration and harmonizing of the combined might of Merck and Schering-Plough, two organizations of more than 40,000 employees respectively (at the time), this was a significant challenge. Strategy and technology have to align perfectly for a successful outcome.

TOP 10 BIOTECH AND PHARMACEUTICAL COMPANIES WORLDWIDE

BASED ON MARKET VALUE IN 2014 (IN BILLIONS)



MERGERS require enormous effort in harmonizing global manufacturing and quality best practices

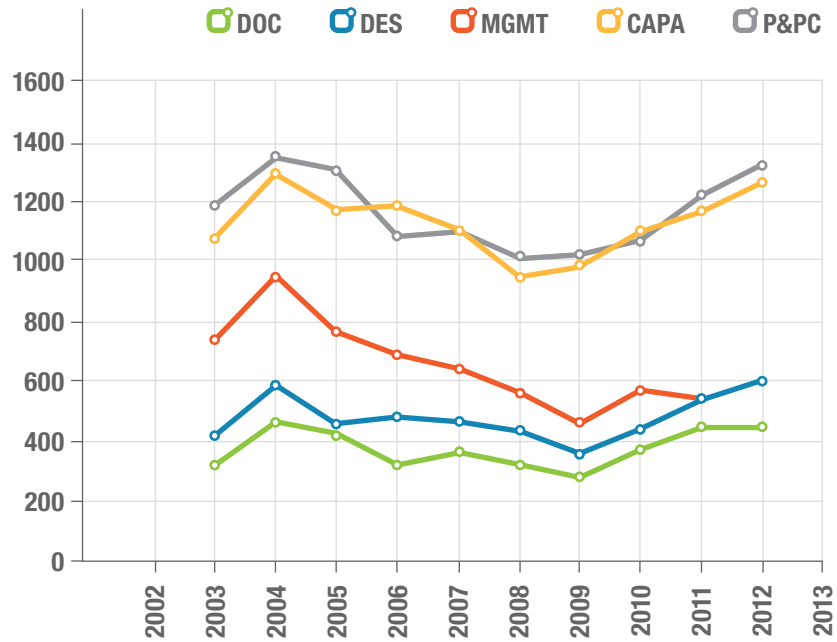
Responding to Regulatory Action

In June 2014 an official statement was posted on Boehringer Ingelheim's website to the effect that a warning letter, or 483 citation, had been lifted. This is an example of one of the top 20 pharmaceutical companies having a plant cited for violations of current good manufacturing practices (cGMP) relative to CFR 21 Parts 210 & 211. The specifics related to an active pharmaceutical ingredient (API) and finished pharmaceutical manufacturing facility in Europe.

The statement included specific reference to the improvements made to remove the warning letter. "The successful lifting of the Warning Letter is a measure of the progress we have made toward improving our quality systems and manufacturing processes." The company continued to say, "We will continue to maintain and further improve our quality systems to provide products of the highest possible standards to patients." This example is used not to single any manufacturer out but rather to highlight how quality management and compliance are a challenge for the larger, well funded enterprise and how a lapse in the quality management system can occur.

Through 2012 FDA data for inspectional observations highlights the two most pervasive lapses in quality subsystems corrective and preventive actions (CAPA) and product and process control (P&PC). As the FDA re-organizes and increases focus proactively on quality both domestically and globally organizations must rise to the challenge.

INSPECTION OBSERVATIONS 2003–2012 BY QUALITY SYSTEM SUBSYSTEM



CERTIFIED MAIL
RETURN RECIPIENT REQUESTED

WL: 320-13-015

May 6, 2013

Senior Vice President

Germany

Dear

During our November 5–12, 2012 inspection of your active pharmaceutical ingredient (API) and finished

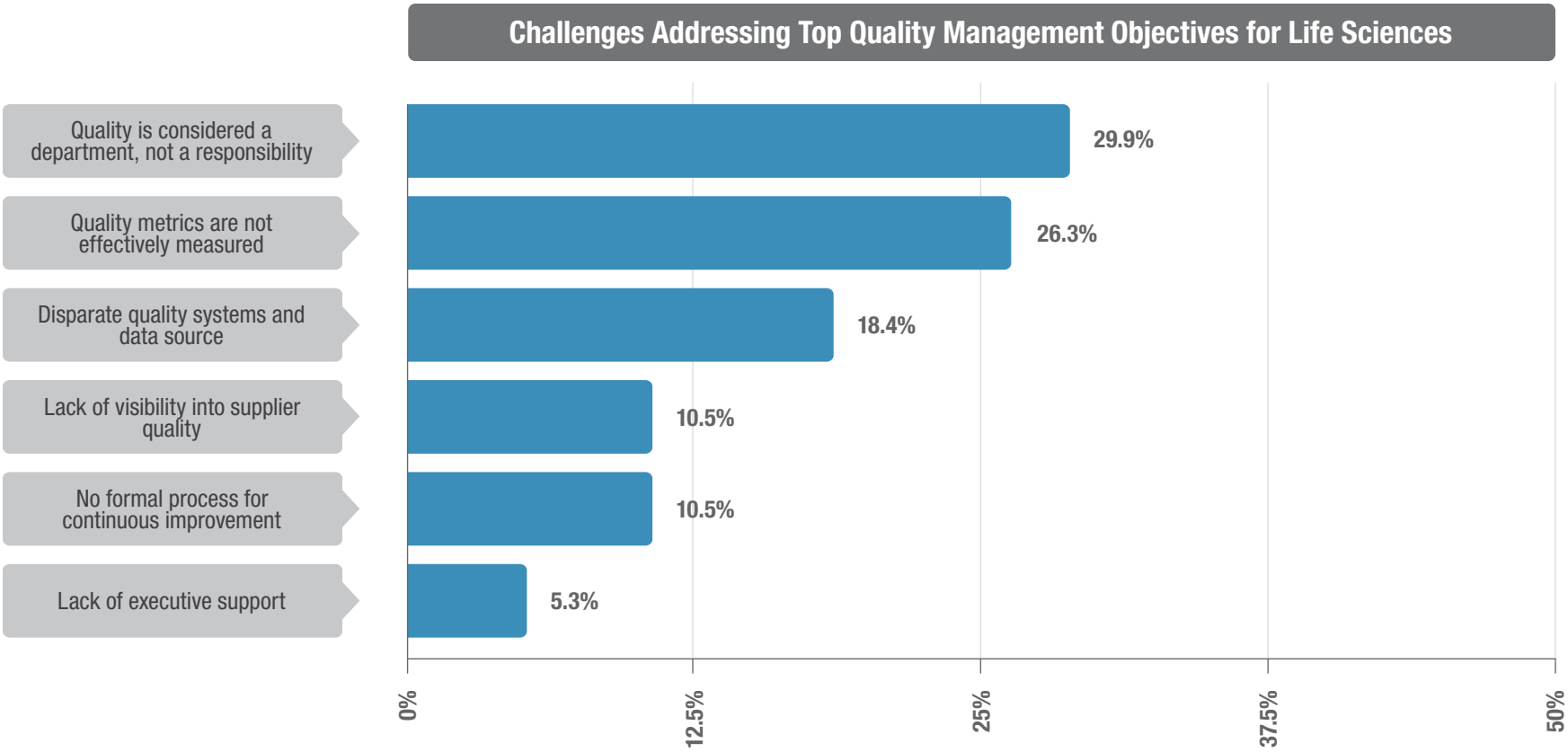
Section 5

INDUSTRY TRENDS AND CHALLENGES

Challenges With Quality Management

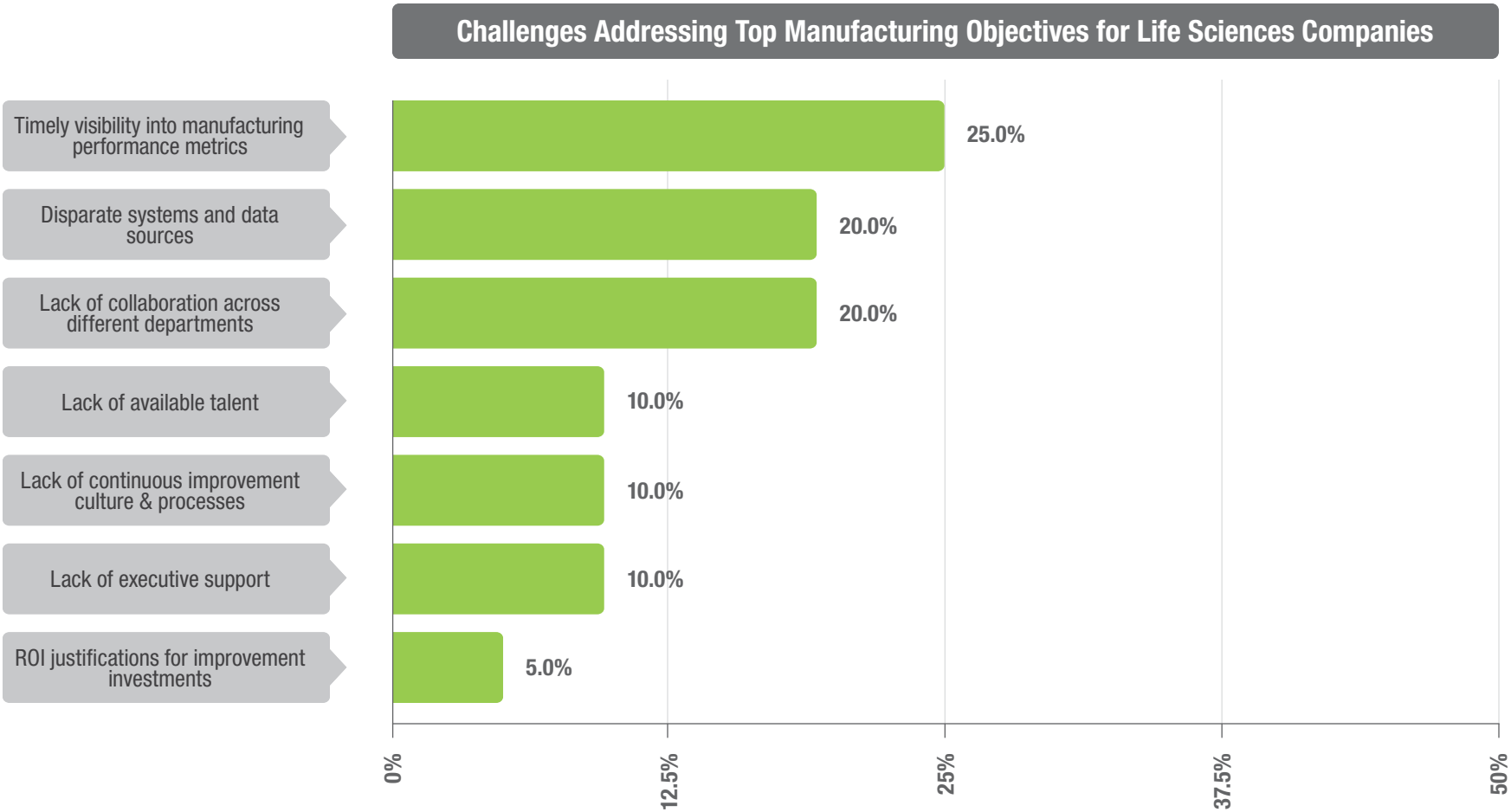
LNS Research's Quality Management survey brings into focus the roadblocks standing between Life Sciences organizations and effective Quality Management. When asked about their top challenges, executives from all Life Sciences industries placed considerable focus on quality culture, effectively measuring quality metrics, and disparate systems and data sources.

Also, deeper analysis of this data shows that pharmaceutical manufacturing companies in particular face challenges with visibility into supplier quality. This is of relevance today as the US FDA and other international regulatory bodies demonstrate more focus on upstream activities.



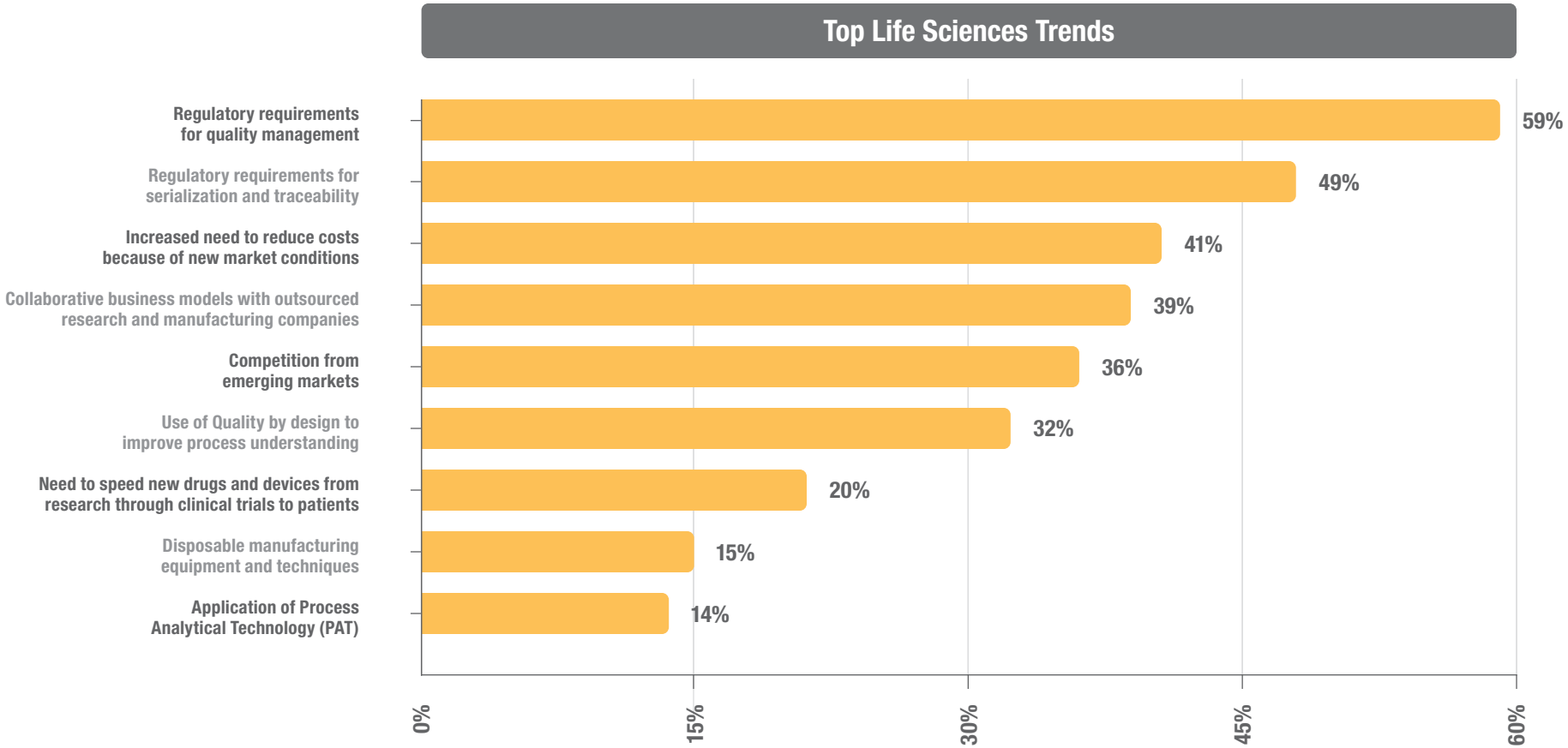
Challenges With Manufacturing Operations Management

In a separate survey—LNS Research's Manufacturing Operations Management survey—executives were asked about their top challenges. The data shows alignment with the quality challenges regarding the effective management of performance as well as operating with disparate systems and data sources. Coupled with collaboration obstacles, this poses significant risk for Life Sciences companies when considering something like ensuring end-to-end traceability in a high-speed, complex global manufacturing environment. Life sciences companies need to be able to quickly react to changes in customer requirements and market demands while also ensuring 100% compliance in operations, which can be incredibly challenging without harmonized IT systems. Furthermore, identifying the root cause of non-conformances, encouraging continuous improvement, and conducting what-if analysis based on real-time performance become increasingly challenging as manufacturing IT becomes more dispersed and disconnected over time.



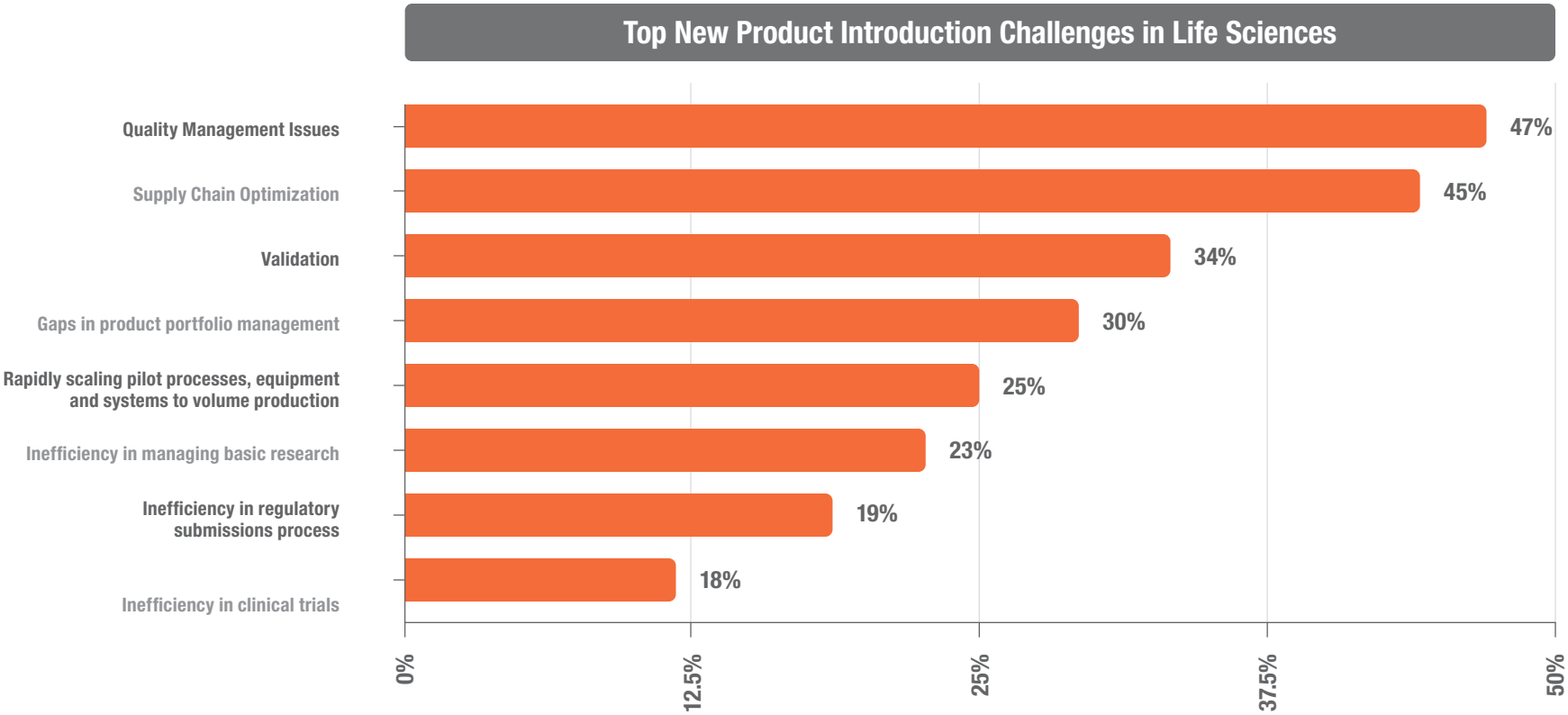
Quality Management and Traceability
Top Trends Impacting Life Sciences

In another question, LNS Research asked Life Sciences executives in particular about the top trends impacting organizations. Not surprisingly, almost two in three noted regulatory requirements for quality management as making the greatest impact. Not far behind were regulatory requirements for serialization and traceability. Given that the top quality management challenges and the top manufacturing challenges were both related to disparate systems and data sources, these quality and manufacturing trends surfacing to the top is not a surprise even though it does create concern. Quality and traceability challenges being at the top greatly highlights the need for next-generation quality, compliance, and manufacturing technology in Life Sciences that provide flexibility while also ensuring compliance.



Challenges With Speeding Products from R&D to Patients

It is no surprise that those organizations able to achieve a seamless New Product Introduction (NPI) process tend to be the ones leading the market. However, doing so is easier said than done. A separate question asked specifically to Life Sciences executives regarding top challenges with speeding products from R&D to patients sheds more light on this topic—47% of executives checked qu ality management issues as the greatest roadblock for successful NPIs, with supply chain optimization coming in second with 45% of respondents. Many may be surprised that these operational issues actually have a greater impact than the actual discovery and approval processes. The following sections in this eBook dive into these "issues," delineating the role of people, processes, and technology in achieving market-leading quality and manufacturing performance.



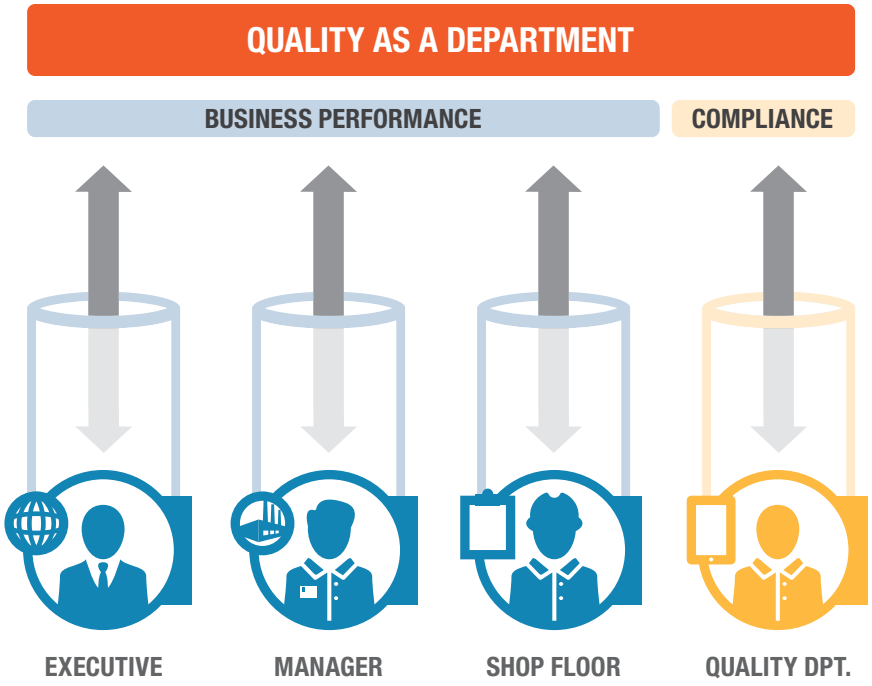
Section 6

MOVING TOWARD A CULTURE OF OPERATIONAL EXCELLENCE

Disconnected Culture

Like all areas of business, leadership and culture experience a similar set of maturity phases that progress over time. When it comes to quality and compliance maturity in Life Sciences, in the early phases, a "culture" of quality is virtually non-existent. There tends to be a disconnect, where quality is considered more of a department than a responsibility. As was revealed in the previous section, LNS Research's survey data shows that almost one in three Life Sciences organizations maintain this mindset. Because of the high quality and compliance requirements in Life Sciences, this can be the source of many challenges.

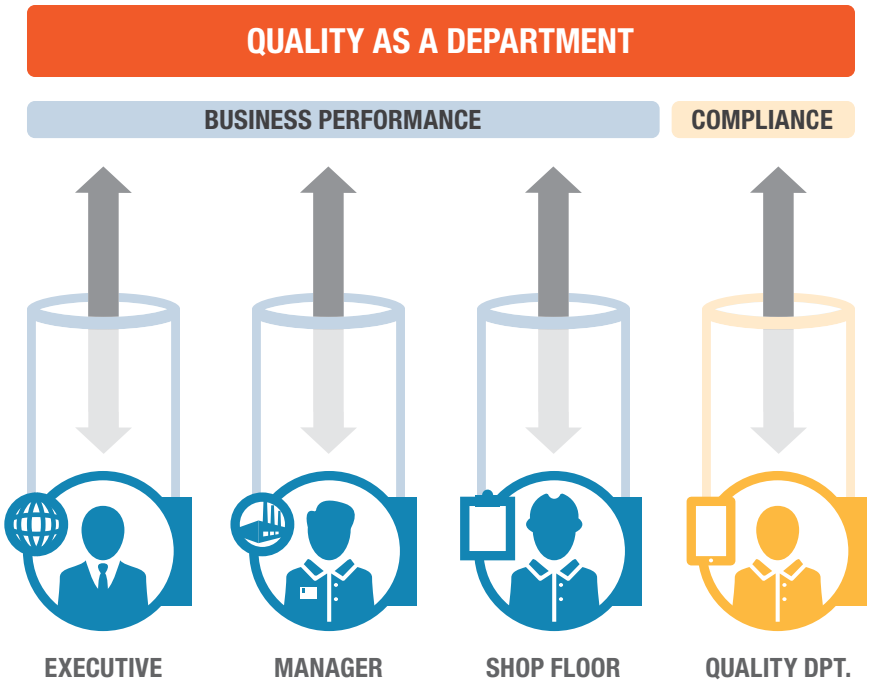
Although many organizations have this "quality as a department" mindset, in many ways it is putting them at a disadvantage. When quality is perceived this way, quality issues are more likely to be dealt with in a reactive manner, employees tend to view quality as a policing function, and quality outside of the manufacturing environment is difficult to manage. Quality is more effectively managed when resources are shifted toward proactive measures, and this rings true regardless of whether discussing people, processes, or technology.

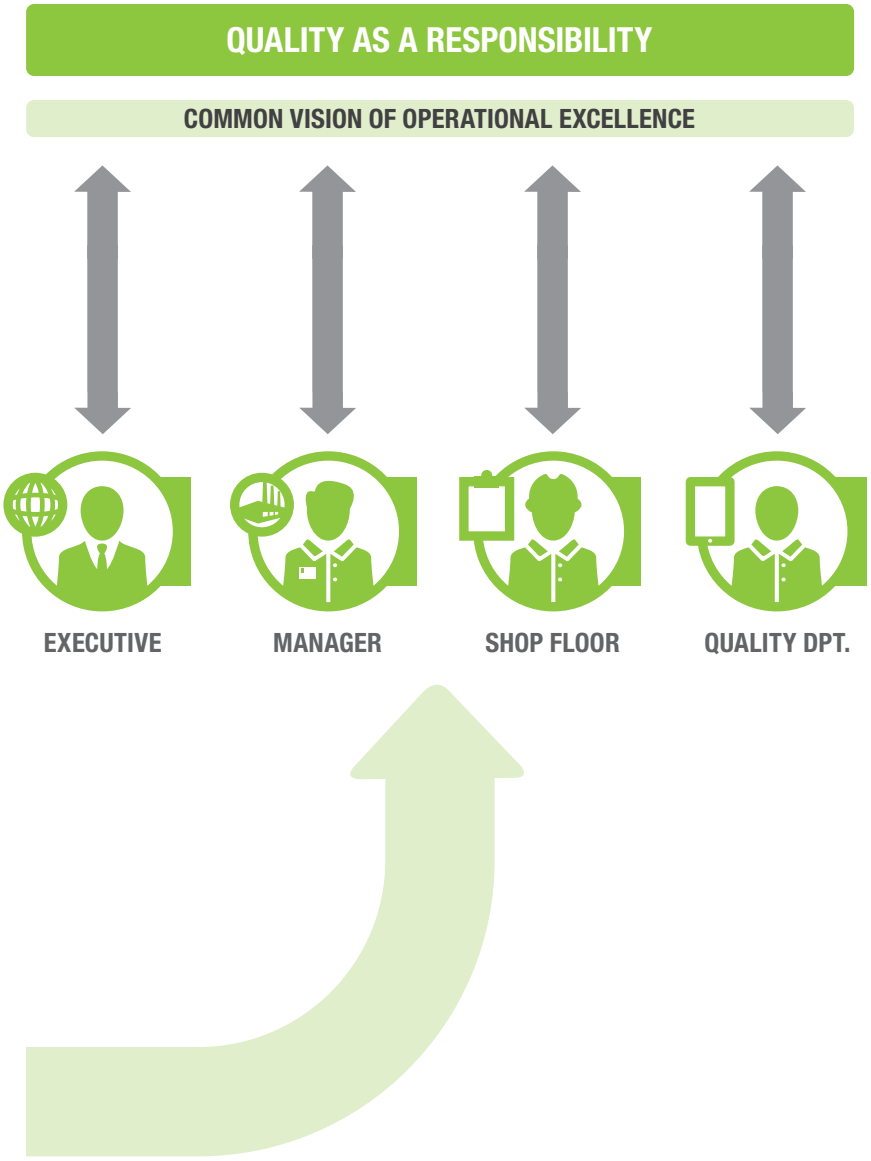


1 in 2 executives stated their organization considered quality more of a department than a responsibility

Bringing Together Operations and Quality

Changes in quality perception are possible, but they need to be initiated at the executive level. Too often, grassroots campaigns fall by the wayside because they are not taken seriously. To gain momentum and drive transformation, LNS Research suggests incorporating quality and compliance into the Operational Excellence strategy. By making quality a pillar within a common vision of Operational Excellence shared by the entire organization, the progression toward quality as a responsibility starts to happen organically, but there are several things executives can do to accelerate that progression.





Accelerating Cultural Transformation

Incorporating quality into a common vision of Operational Excellence requires more than simply making an amendment to a corporate document. It requires investment of time and resources and should be driven from the top down. Successful examples seen in Life Sciences include commitment to and all encompassing business operating system (BOS) that explicitly incorporates global quality, supplier quality, and other management system disciplines.

Executives responsible for quality can help to ensure progress is being made by doing the following:

- Assess and prioritize areas of improvement based on both internal and third party quality audits
- Third party quality audits
- Dedicate a portion of the annual budget to create an internal marketing plan for employees
- Develop a short and long-term plan for internal education, process improvements, and capital investments
- Require managers regularly report on metrics and create plans for improvement
- Set rewards-based performance programs for quality improvements
- Stay current on quality trends, emerging technologies, and regulations
- Develop a resource center with dynamic quality education courses, SOPs, and instructions
- Require quality management metrics such as Cost of be used in operations

Section 7

NEXT-GENERATION MOM SOFTWARE AND TRACEABILITY CAPABILITIES

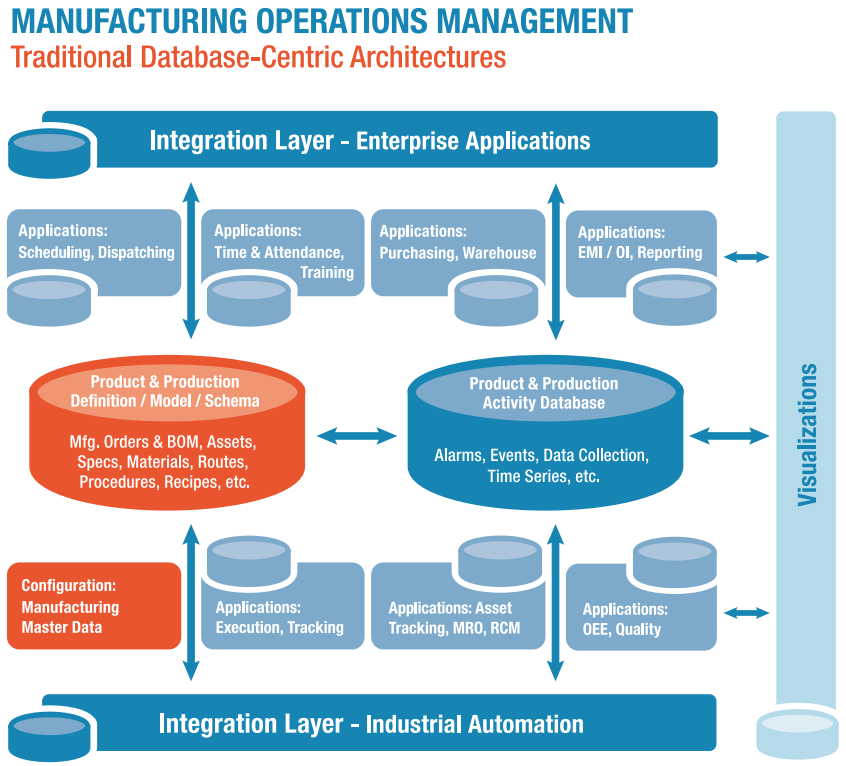
Traditional MOM Software Architectures

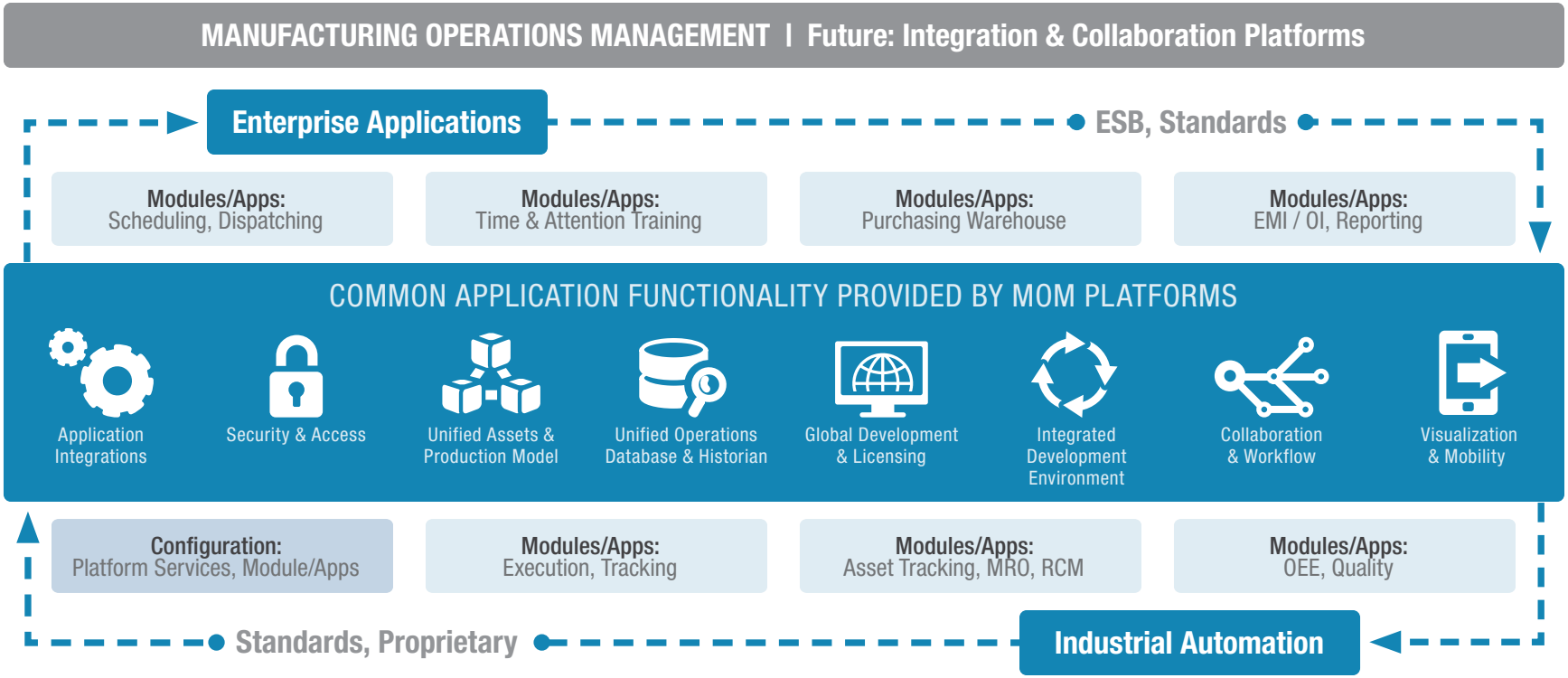
The challenges life sciences companies face today around increased traceability requirements are due in part to the traditional MOM software architectures many companies have in place.

Connecting the automation systems of the shop-floor up to the enterprise reporting software, MOM software traditionally handles a variety of functions, including, production execution, scheduling, planning, risk management, maintenance, quality applications, and others.

With growth—organic and acquisitional—often comes a legacy of homegrown and point solutions for each of these functions mentioned above that typically do not integrate and interoperate easily, and force organizations to deal with costly and time-consuming manual analysis and reporting to obtain the required information. New FDA regulations around electronic batch records (EBR) and electronic medical device records (EMDR) require full end-to-end traceability around the product genealogy of pharmaceuticals and medical devices, rendering this traditional disjointed model obsolete for life science companies.

With the required pace and agility needed of today's operations, particularly with many companies operating large numbers of production facilities spanning the globe, this traditional model of disjointed legacy and point solutions is rapidly becoming obsolete.





The Move Toward Next-Generation MOM Software Architectures

Leading life sciences companies are migrating toward a platform approach to MOM software that simplifies system architecture, eliminates redundant applications and functionality, and facilitates open integration with legacy and enterprise systems as well as supporting the new technologies of Cloud, Big Data, Mobile, and IoT.

With integrated data and information available across the value chain, life sciences companies have the ability to track the entire lifecycle of information, including raw materials/stock feed coming from suppliers, the production process, and delivery and service to customers .

This end-to-end visibility connects batch and device history records up through enterprise reporting and scheduling systems, allowing organizations to pinpoint and isolate product non-compliances and understand their origin, which is crucial for meeting cGMP compliance. A lack of this identification and reporting ability can result in costly and time-consuming shutdowns as well as reputational damage. Additionally, next-generation MOM software applications that heed the FDA's PAT recommendations incorporate quality into the process itself, rather than test after the fact.

Additionally, this type of agility and flexibility is crucial n helping life sciences adjust to customer and marketplace demands and, as personalized medicine moves toward the industry norm, will become an essential capability.

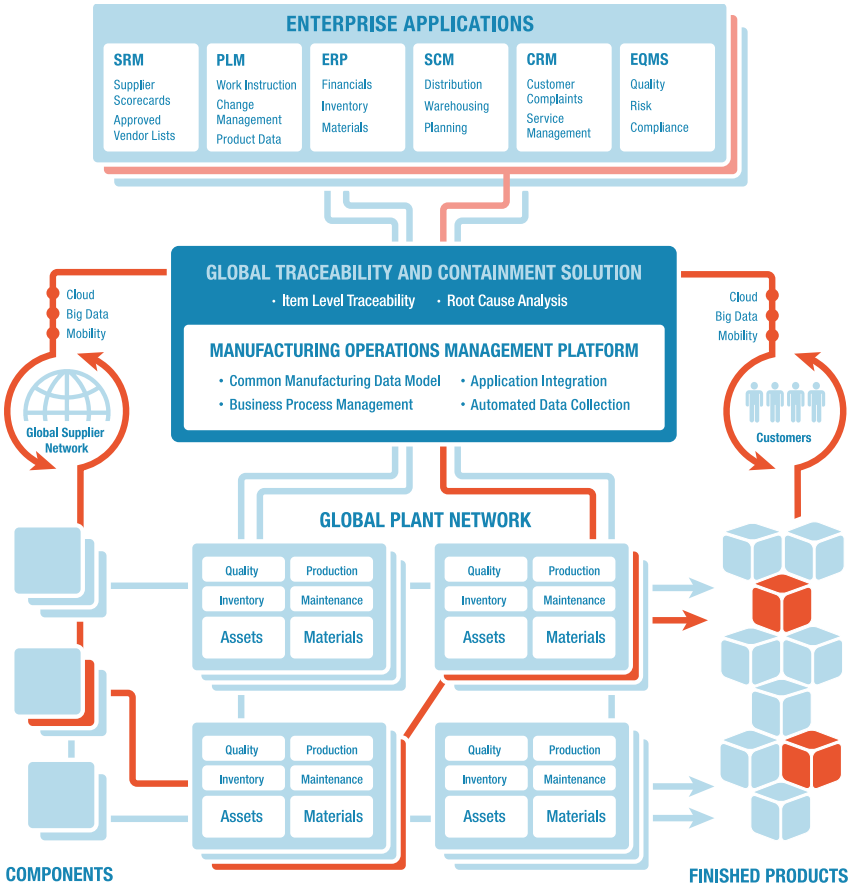
Supporting End-to-End Track and Trace Capabilities

As has already been mentioned numerous times, track and trace with item level serialization is a major challenge in the life sciences industry today and it will only become more important as life sciences companies serve an ever larger global community with ever-more personalized medicine.

The challenges with track and trace are multi-faceted:

- "Systems of record" are often financially based and cannot go to the needed level of detail to due true item level traceability with all the necessary quality, production, maintenance, and inventory data
- MOM software systems are not harmonized across plants and are attempting to integrate with a heterogeneous landscape of the automation and equipment in facilities and multiple enterprise level business systems
- The ROI of investing in track and trace is often difficult to calculate (until there is a major adverse event)

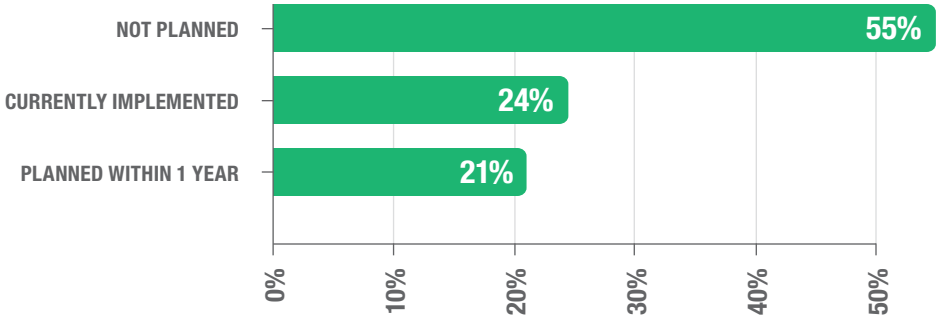
By taking an enterprise level approach to MOM software, life sciences companies can have harmonized processes and systems at the plant level, common interfaces to automation and equipment, and a common manufacturing data model across all facilities. Such an approach can provide track and trace capabilities across the manufacturing network and connections to enterprise systems where needed; allowing for forward and backward traceability through the system when an issue is identified. With a holistic traceability enabled; a quick and minimally invasive identification of contaminated or adulterated products becomes possible across the supply chain, as opposed to when companies attempt traceability with disparate systems only to discover what was believed to be in the system never made it.



Current and Planned Adoption of MOM Software

Though LNS Research MOM survey data shows that current implementations are at 24%, it is noteworthy to see that 21% of respondents are planning to adopt MOM software applications within a year's time. Life sciences companies choosing to adopt new generation MOM software will enjoy real-time, actionable information specific to role, integration with enterprise and automation applications, and visualizations that allow faster, more accurate decision making. These increased capabilities in speed, visibility, and flexibility are instrumental in helping life sciences overcome the aforementioned industry-specific challenges, such as the trend toward personalized medicine, improving collaboration and identifying the root causes of non-conformances. As modern MOM software platforms and applications become more widespread and the industry sees its leaders continue to nudge the bar upward, those organizations that choose to stay with outdated and disparate systems will be in an even further disadvantaged position as they add heightened competition onto their pile of challenges.

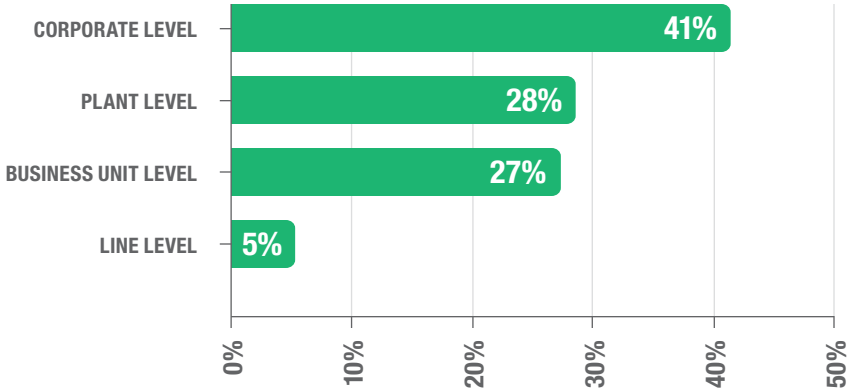
COMPREHENSIVE SUITE OF MOM APPLICATIONS ADOPTED



MOM Software as Enterprise vs. Plant Application

Today, most companies approach MOM above the plant level, as 68% see it as either a business unit or corporate level initiative, whereas the remaining 32% view it as a plant-by-plant initiative. This shows a clear trend toward corporate level standardization of MOM platforms and applications. The holistic performance benefits afforded by taking an enterprise approach to MOM software are a critical step for life sciences companies in standardizing the CAPA processes on which heightened FDA requirements have placed additional pressure.

SCOPE OF MOM SOFTWARE IMPLEMENTATION



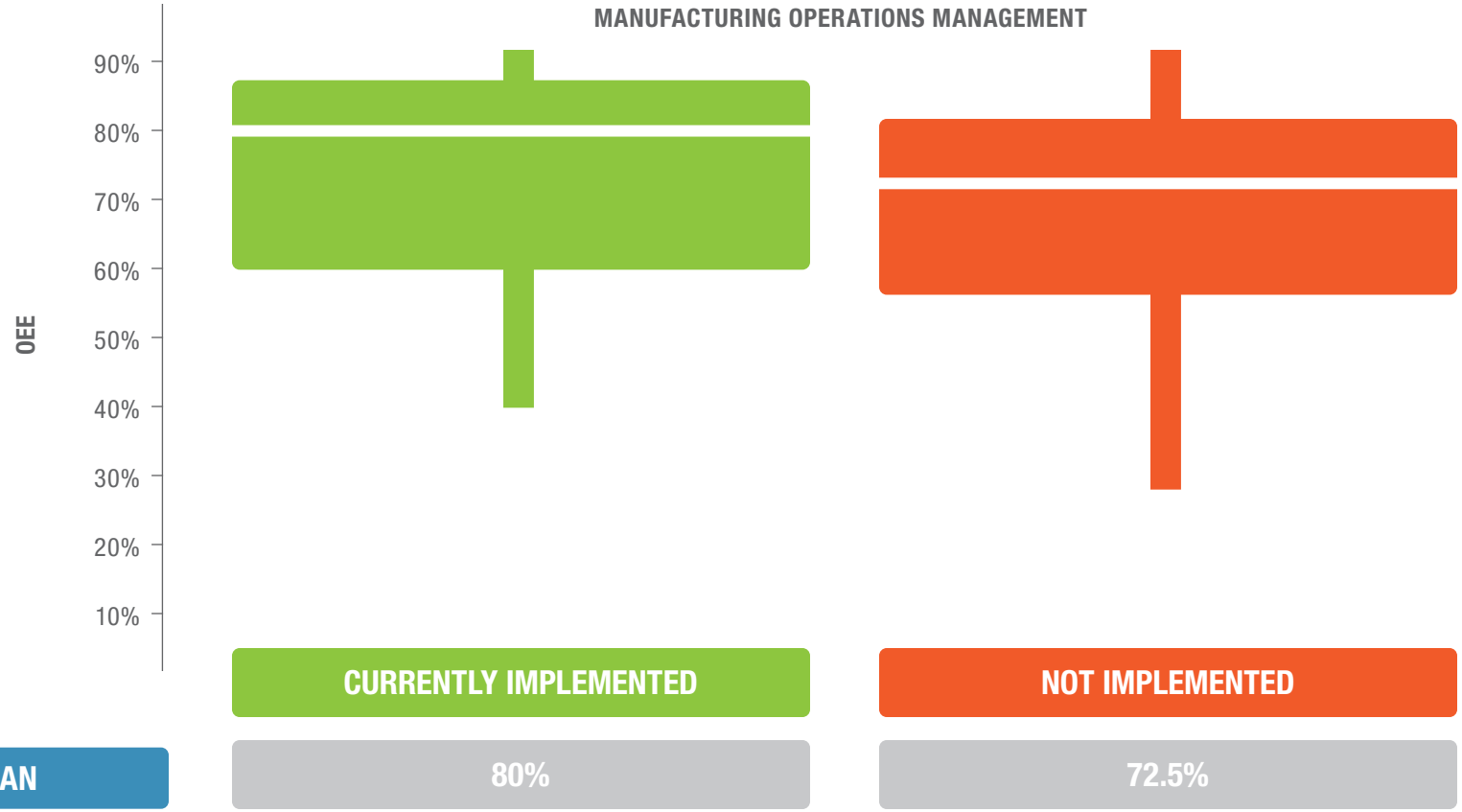
Enterprise Manufacturing Intelligence (EMI)

Perhaps one of the most important MOM software applications in improving collaboration in operations is Enterprise Manufacturing Intelligence (EMI). EMI is critical in helping organizations connect, federate, aggregate, and contextualize data from the shop-floor into actionable intelligence. This may include data on business, energy, production and logistics that flow into different data historians and other databases. Serving as a common data portal and information source for various job roles, EMI is a tool particularly well-suited to fostering collaboration within life sciences and diffusing quality responsibilities throughout, as it breaks down informational silos by integrating disparate systems across the enterprise to form a "single version of the truth."

OEE Performance Benefits of MOM Software

A critical manufacturing metric that comprehensively measures the performance of availability, efficiency, and quality performance of assets is Overall Equipment Effectiveness (OEE). According to the MOM survey, organizations that have implemented a comprehensive MOM software suite report a median OEE of more than 10% over those that have yet to implement MOM software. MOM software allows for improved visibility of manufacturing processes as well as enhanced control of quality, inventory, production, and maintenance.

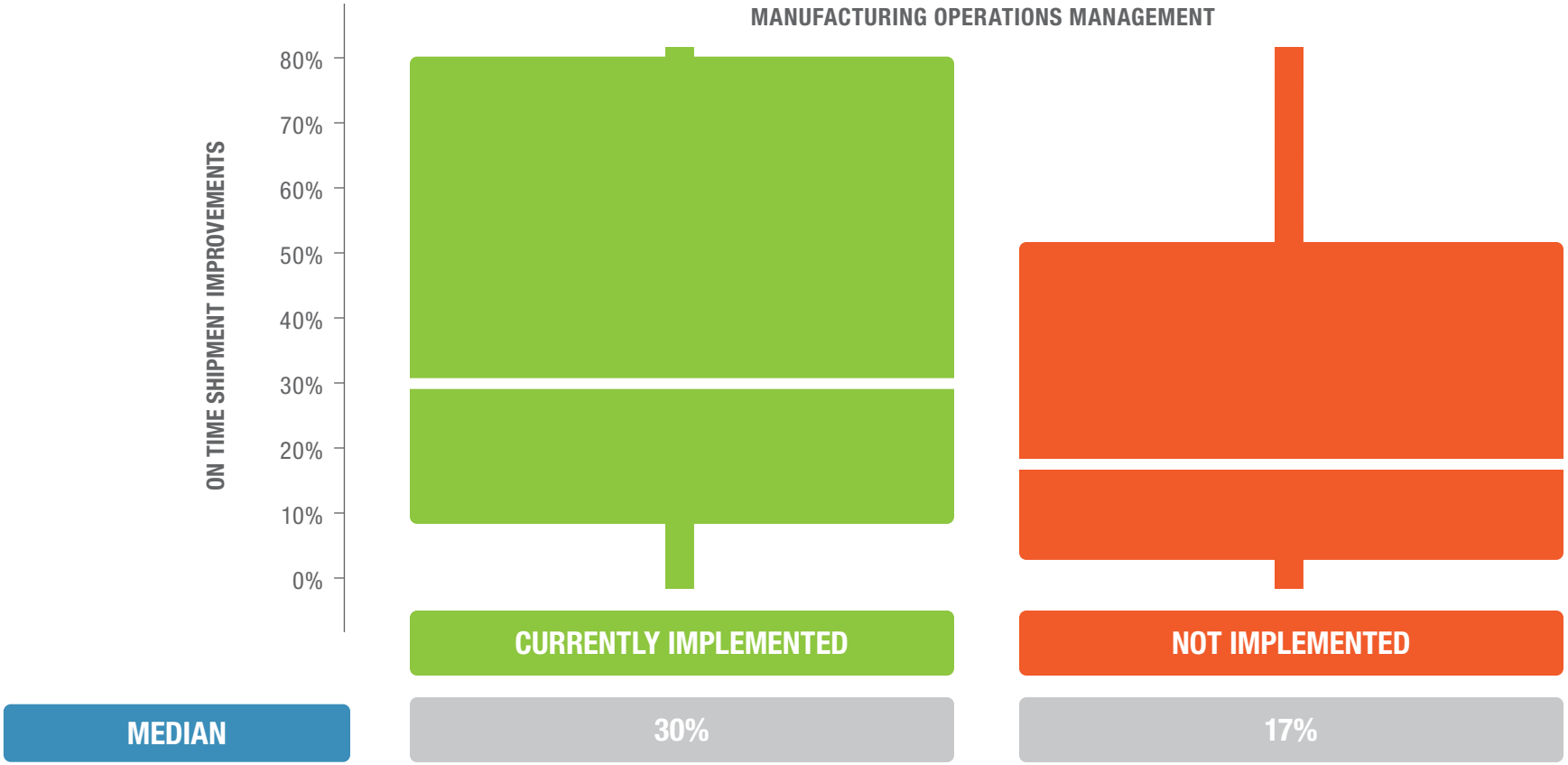
COMPANIES HAVING ADOPTED MANUFACTURING OPERATIONS MANAGEMENT SOFTWARE HAVE A 10% HIGHER MEDIAN OVERALL EQUIPMENT EFFECTIVENESS



On Time Delivery Performance Benefits of MOM Software

One of the most important measures of supply chain performance is on time delivery. According to the MOM survey, users of comprehensive MOM software reported median annual improvements of 30% vs. 17% in On-Time Complete Shipments for the overall respondent average. This demonstrates how taking a broad approach to MOM software can benefit more than a single factory's performance, but instead can improve system wide supply chain performance.

COMPANIES HAVING ADOPTED MOM SOFTWARE HAVE ALMOST TWICE THE IMPROVEMENT IN ON TIME DELIVER YEAR OVER YEAR



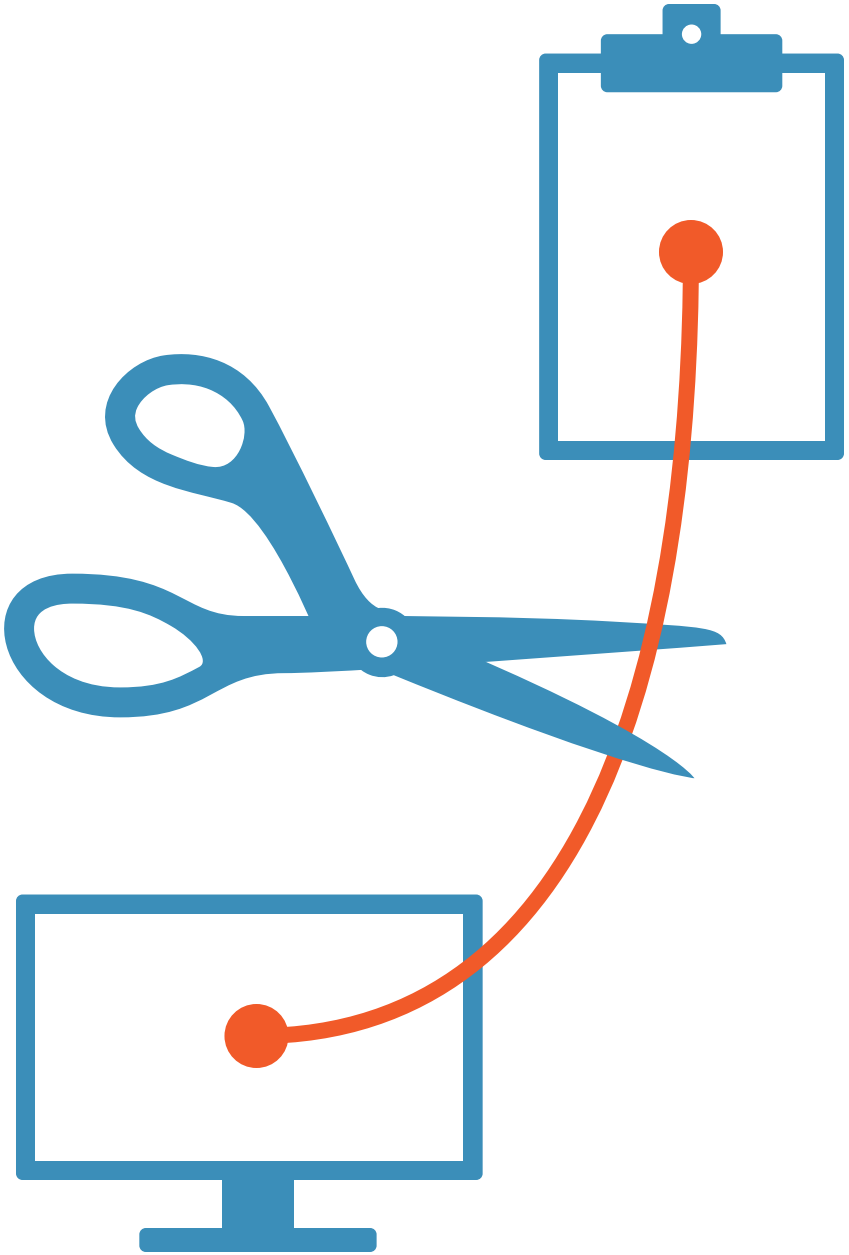
Section 8

THE NEXT GENERATION OF QUALITY AND COMPLIANCE SOFTWARE

Traditional Approaches to Quality

As discussed in the previous section, a culture of quality is crucial for effectively managing and improving quality performance, as well as taking a proactive approach to quality issues. Culture, however, is only part of the equation. Today, many Life Sciences companies are struggling to achieve market leadership due to a disconnected set of IT resources, which greatly reduces the effectiveness of people and leadership. This disconnect can be sourced back to movement throughout the different phases of Quality Management maturity. Technology is generally deployed to supplement and sometimes automate particular business processes. It may also be deployed to enable collaboration internally as well as with upstream partners or contract manufacturers. For Life Sciences, this increasingly includes contract research partners (CRPs). Although IT resources are almost always deployed to solve a problem or set of problems, in the early phases of quality maturity, they tend to be deployed on an as-needed basis rather than with an enterprise vision of quality in mind. Following this strategy year over year has led many of today's organizations to a state of disconnect, where IT resources aren't providing the support needed to keep pace with stringent regulatory burdens. In some cases, this disconnect is delivering more challenges than benefits.

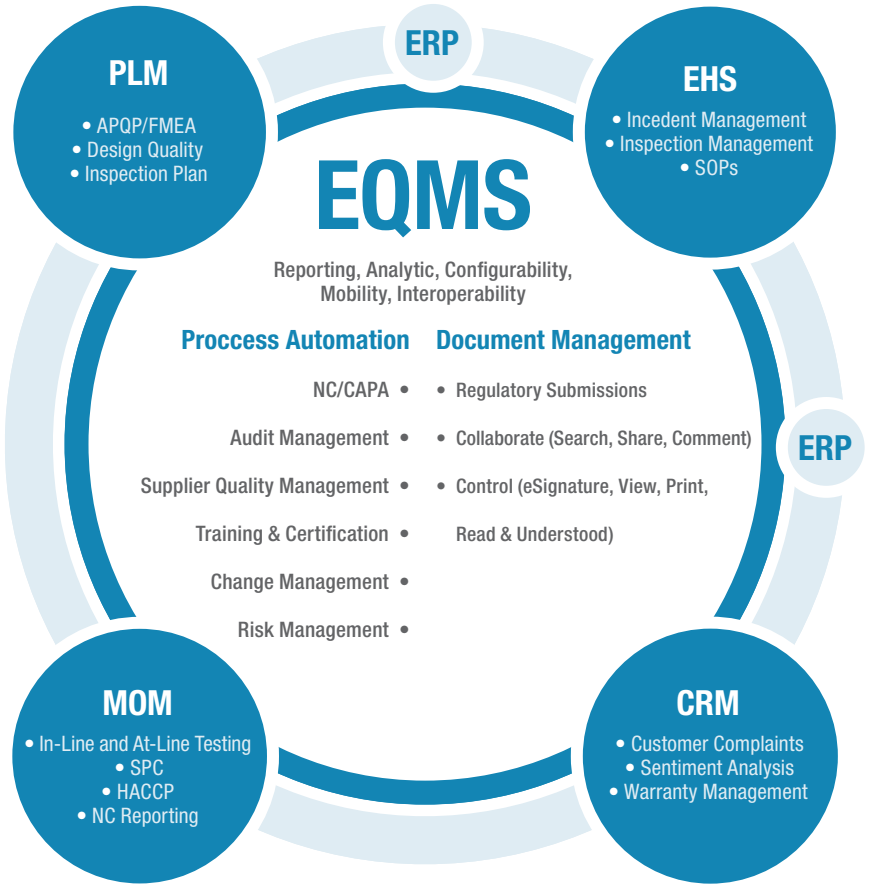
78% of companies report operating in a state of quality management disconnect



Enterprise Quality Management Software

Today's leading organizations are moving beyond managing quality with disparate systems and data sources by investing in next-generation EQMS solutions. With the use of workflows and document control, EQMS enables secure and efficient communication and collaboration on a common platform. It also streamlines, centralizes, and standardizes key quality processes such as CAPA, Audit Management, and Supplier Quality Management. Numerous vendors have solutions tailored specifically to Life Sciences, with FDA eSubmissions or eMDR modules built in.

EQMS is architected to easily integrate with other enterprise systems such as ERP, Product Lifecycle Management (PLM), Environment Health and Safety (EHS), MOM, CRM, and LIMS. This integration is imperative for progressing through the phases of quality management maturity, as it connects quality with operational areas across the value chain. In many ways, EQMS is a hub for quality process content and data. One integration of particular importance for many Life Sciences companies is between EQMS and MOM, which will be discussed in more detail in the next section.



40% of companies are planning an EQMS implementation or already have budget allocated

Quality in the Cloud

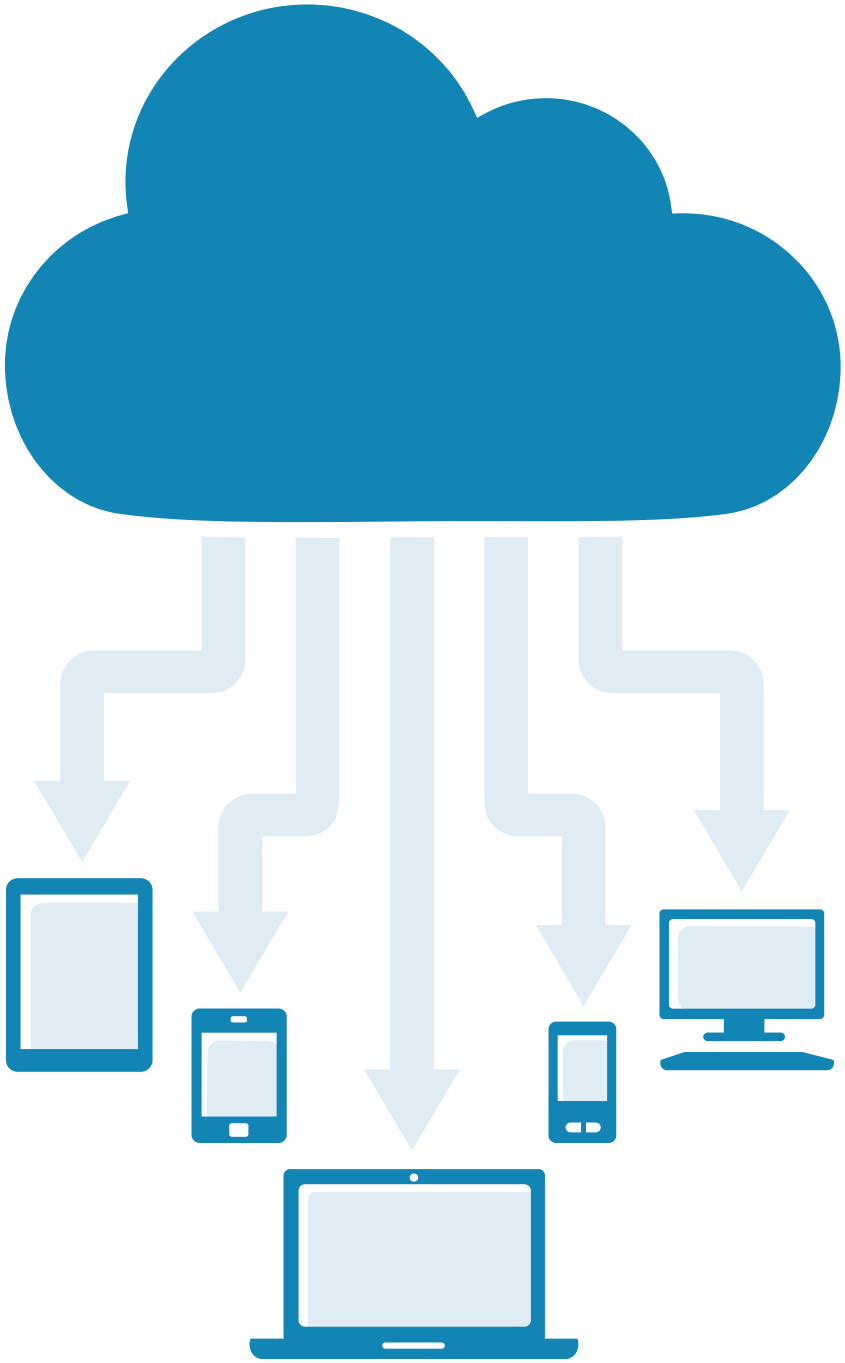
Due to the sensitivity of information in the Life Sciences industry, organizations have been hesitant to adopt cloud-based EQMS solutions. However, from LNS Research's discussions with industry executives and as more use cases emerge, it is clear that these perceptions are slowly changing. Many of today's leading companies are moving to the cloud to more easily collaborate with upstream partners, facilitate quicker FDA approvals, and more efficiently extend quality and compliance functionality to professionals in distributed locations.

CURRENTLY 20%

of companies deploy manufacturing software in the cloud

IN THE NEXT YEAR

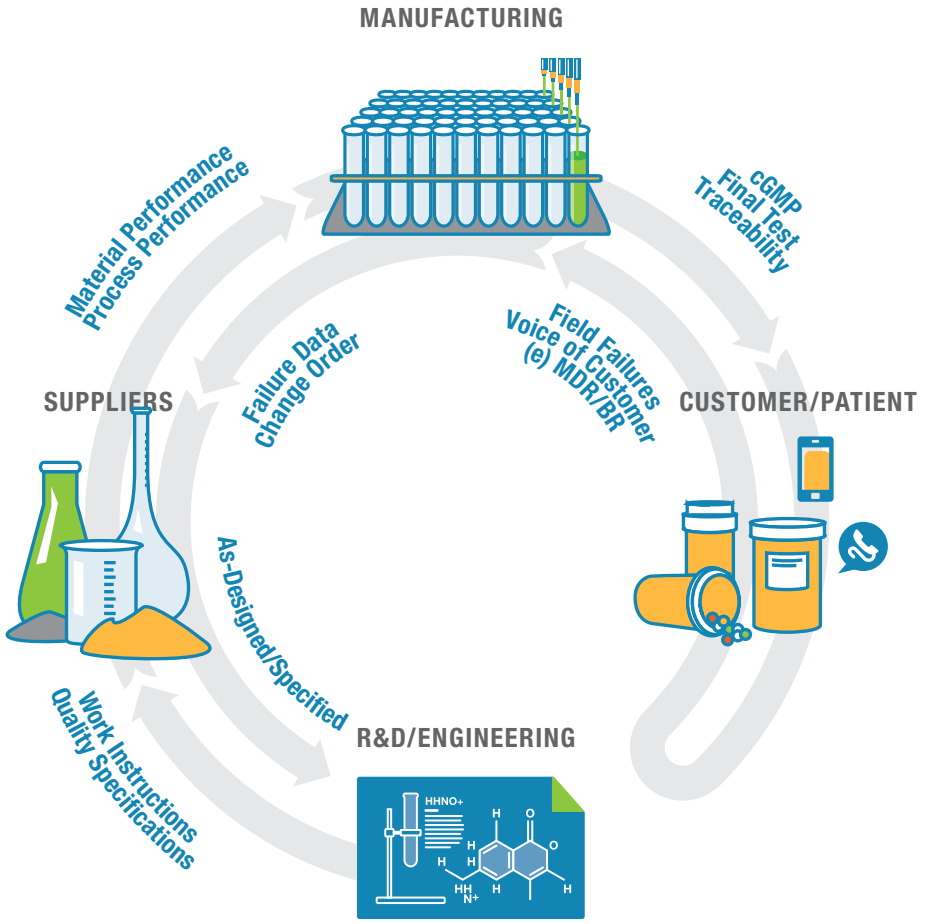
32% plan on deploying manufacturing software in the cloud



Closed-Loop Quality Management

As a drug or device moves from ideation through its actual use by a patient or hospital, quality plays a role in each of those stages. Traditionally, quality in these different stages is managed in silos, which, overall, leads to quality being managed in a reactive manner. Most Life Sciences companies, of course, cannot afford to manage quality reactively. However, as companies continue to build out capabilities, more and more are thinking about quality not just within one functional unit (development, supply chain, production), but how it interacts between functional units. This is the concept of closed-loop quality.

Closed-loop quality enables bi-directional automated streams of information between functional units with the goal of catching quality issues as upstream as possible. With its tight integration with other enterprise systems, EQMS is ideal for creating an environment for effective closed-loop quality management. A medical devices company may, for instance, create a closed-loop quality scenario where as-manufactured data is streamlined back to R&D, so quality non-conformances can be monitored in real-time. As will be shown in the following sections, MOM software applications tie into this vision of closed-loop quality as well.

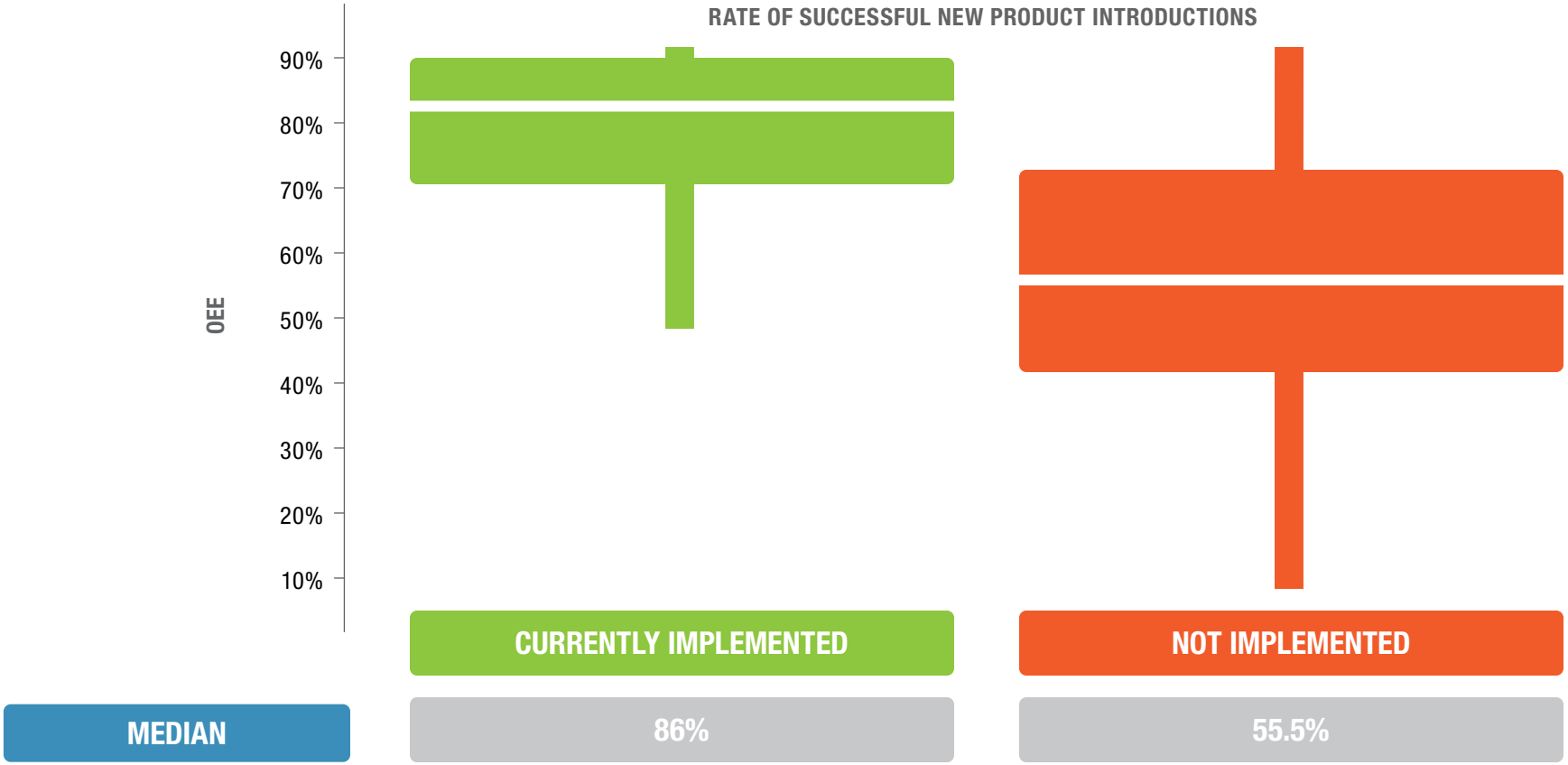


40% of companies are planning to establish closed-loop quality processes within a year

Performance Benefits of EQMS

Analysis from LNS Research's Quality Management survey displays the benefits of taking a platform approach to Quality Management with EQMS. As shown below, companies with EQMS implemented experienced a median successful NPI rate of 86%, while companies without EQMS implemented experienced a median rate of only 56%. Although EQMS has many different functionalities which impact successful NPIs, it is likely a combination of those functionalities coupled with integration with other enterprise systems that are driving these impressive results.

COMPANIES HAVING ADOPTED EQMS HAVE AN 10% HIGHER MEDIAN OEE



Section 9

RECOMMENDED ACTIONS & FINAL TAKEAWAYS

Understand Current and Future Drivers in Life Sciences:

Due to the macro-economic and global population trends in healthcare, the life sciences industry is in the midst of tightening pressures on production, from a multifaceted perspective: product quality, volume, speed, and complexity.

Success Starts With a Top-Down Approach:

Executive management needs to lead the way in instilling a culture of collaboration where quality and compliance initiatives are incorporated into all areas of the value chain, rather than being seen as a "policing function."

End-to-End Traceability and Tighter Quality Management Are Imperative:

In order to make the necessary improvements in quality and traceability to meet FDA regulatory requirements, life sciences organizations need to develop end-to-end product traceability capabilities to produce EBRs and EMDRs upon request as well as tighten quality management.

The Integrated Platform Approach of EQMS and MOM Software Solutions Enable Connecting the Entire Value Chain:

EQMS breaks down informational silos and is critical to establishing closed-loop quality. A platform approach to MOM allows companies to track and trace from supplier to customer, and allows the flexibility in operations needed to keep pace with market demands.

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