PHARMACEUTICAL QUALITY CONTROL

IMPROVING METHODS AND SYSTEMS

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AT A GLANCE

- The definition of quality has evolved with changing business dynamics, particularly in regulated industries such as pharmaceutical, chemical, and food & beverage.
- The Pharmaceutical & Drug industry witnessed a 168% increase in drug approval by the FDA in 2018 compared to 2016, testifying the growing quality adherence among manufacturers.
- Compliance to quality guidelines is only getting more stringent with time. Pharmaceutical & Drug industry also saw high rejection (73) through 2018 including Recalls, Market Withdrawals, & Safety Alerts, highlighting the importance of quality standards set by the industry watchdog.
- While quality is increasingly becoming an integral part of modern-manufacturing practices, our research revealed that some organizations continue to devalue the importance of quality to a mere afterthought.

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INTRODUCTION

Quality plays a pivotal role in the success of a business and is no longer considered an impediment to a successful business.It's often that the release of a product for shipment is delayed due to standards not being met - causing stress on the customer service reps working closely with Customers.Saying yes to sub-standard ‘products to the market’, however, could be catastrophic, with damages that could at times be irreparable. Today, modern day Quality Management is supporting technology initiatives to ensure the right systems are in place to allow the product to pass all quality checks proactively.

This article highlights just a small section of Quality Management related to processes and systems. The intent is to help businesses understand how technology has evolved with the changing business landscape and how manufacturers (in any highly regulated industry) can leverage technology such as the One-Microsoft ecosystem to stay relevant, and ahead of the competition. In this part of the series we will discuss Quality Management holistically, and follow it up with the finer aspects of Quality Management in the subsequent posts..

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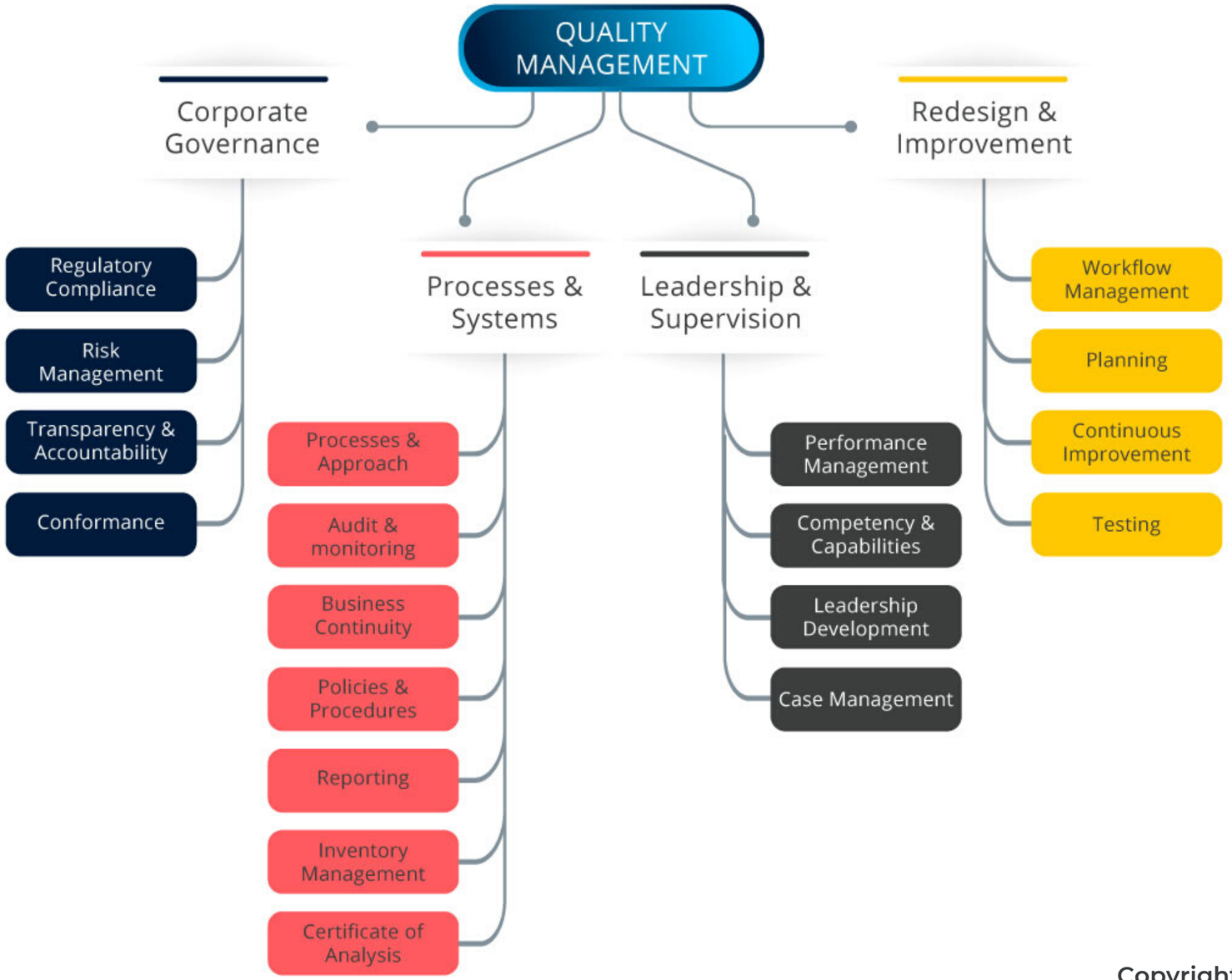
Figure 1: Classification of Quality Management



THE EVOLUTION OF QUALITY MANAGEMENT

Quality management has evolved from being an afterthought to becoming a rigorous self-discipline that most modern-day manufacturing companies have taken onto themselves. What used to be quality control in the 1960s has evolved to become "total quality control" in its present form. The US FDA is tightening its norms to ensure higher quality standards, and companies are responding to such challenges by increasing their quality standards. The below timeline depicts how the definition of quality has evolved over time since the 70s.

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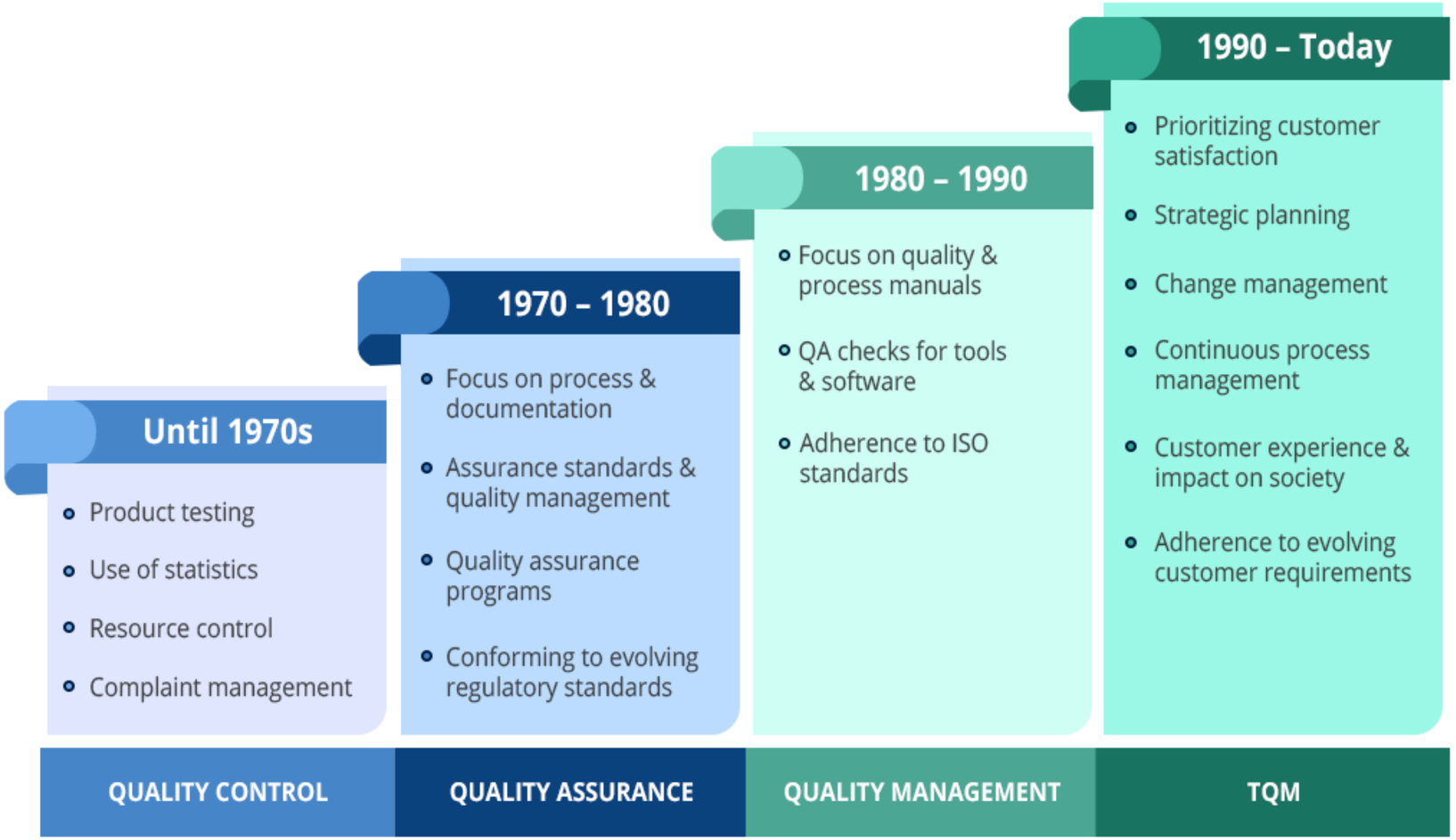
THE EVOLUTION OF QUALITY MANAGEMENT (continued...)

Figure 2: The Evolving Definition of Quality Management



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PROCESS IMPROVEMENTS IN QUALITY CONTROL

Improvements always start by first understanding the issues that reside in a department. Typical activities in the Quality control department of a Pharmaceutical company would be to

- Manage Quality control tests
- Manage Quality control specialists and their workload
- Allocate and calibrate test instruments
- Establish appropriate test methods
  Document test specifications
- Perform tests in the order of priority and
- Accurately record test results

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PROCESS IMPROVEMENTS IN QUALITY CONTROL (continued...)

Trending and analysis, as well as stability studies, would be a follow up of quality data that is captured for understanding the reliability of the batches being produced. This is just a quick and simplified view; in reality, all of the activities listed above have many details involved. Making sure that all processes and procedures are handled with precision ultimately reflects on how well you are able to maintain the quality standards in a Pharmaceutical company.

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PROCESSES IN THE QUALITY DEPARTMENT

A typical day in the life of a Quality control department could start with lab analysis and paper requests to perform quality tests on a sample size of a batch. At times it could be multiple batches for different products that are either produced in-house or received from 3rd party manufacturers. The department prepares the test instruments for each test and accurately records the test results along with any digitally signs-off on the work. If we were to take a quick view of what could be involved in 'getting it right', the understanding towards all essential requirements of an optimal quality process could change.

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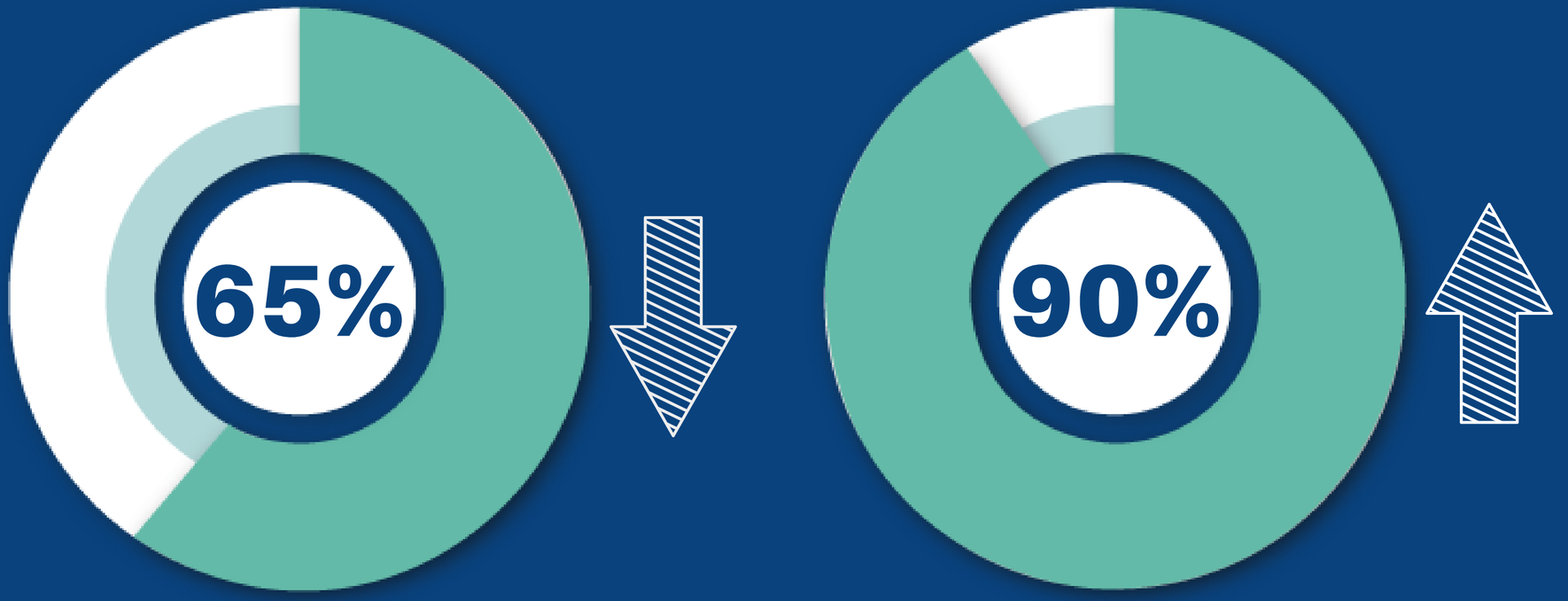
Use cases with DIGITIZATION and AUTOMATION have demonstrated a more than



Reduction in deviations

Faster closure times

-The Future of Quality Control, PharmaManufacturing

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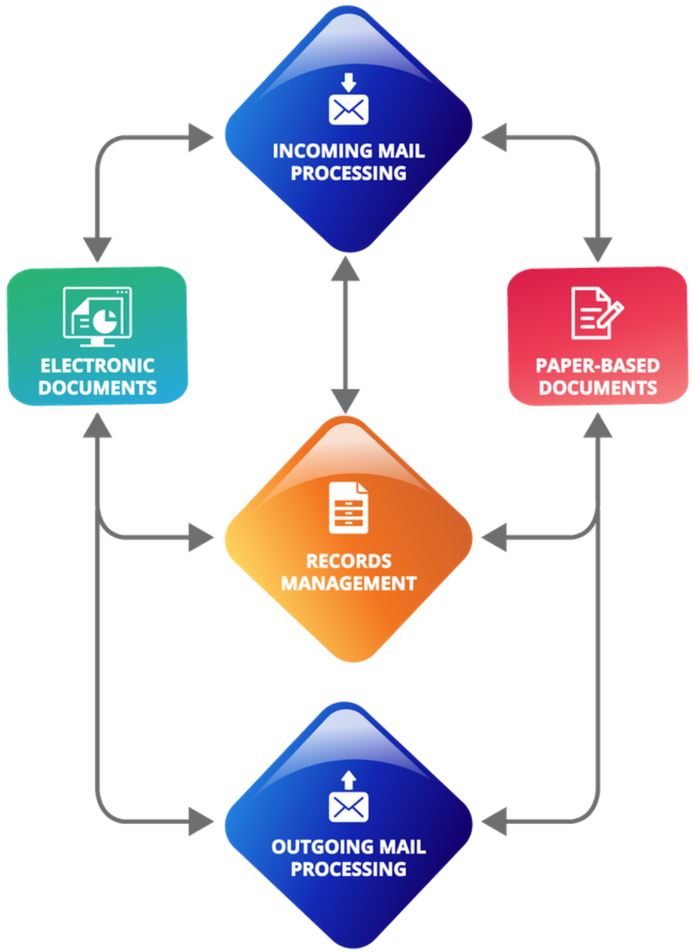
PROCESSES IN THE QUALITY DEPARTMENT (continued...)

It involves having all the SOPs opened up in front of you to perform a test with precision and not allowing any deviation in method unless the 'method to deviate' is clearly spelled out. It could often be challenging to hold the people in your department compliant to the process unless there is a stringent system in place. If the system is paper-based, you are adding laborious tasks with corrections and piled up paperwork. Every time an audit occurs, it would require digging through so many stacks of paper to bring out the right answers.

Figure 4: A Central Filing System to Manage Documents and Information



Electronic documents, paper-basedrecords, and letters

QUALITY CONTROL SYSTEMS

Pharmaceutical companies that are implementing an electronic system need to decide how tightly the system has to be built. The process could add discomfort to users due to various systemic restrictions, or an uneasiness around user errors.People could start feeling anxious about making mistakes, as every change would have a digital stamp tied back to the person modifying the data. It could also get a bit cumbersome to fix errors after the fact in a controlled system that is validated and is 21 CFR part 11 compliant. The idea is not to add discomfort but to build the right kind of habits in users. Ideally business users need to be given enough information about how the overall system works. A well planned training can help the users move from discomfort to being champions promoting the process in the organization.

Anyone with a basic understanding of compliance would prefer an electronic system instead of a paper-based process, for the strength and ability to capture data as is. It then requires a change in the mindset of ' continuously fix errors' to 'proactively do it right in the first place'. At the end of the day you want to foster this efficiency in your whole organization. This can be achieved by evaluating a reliable process that could be leveraged by the Quality Control department.

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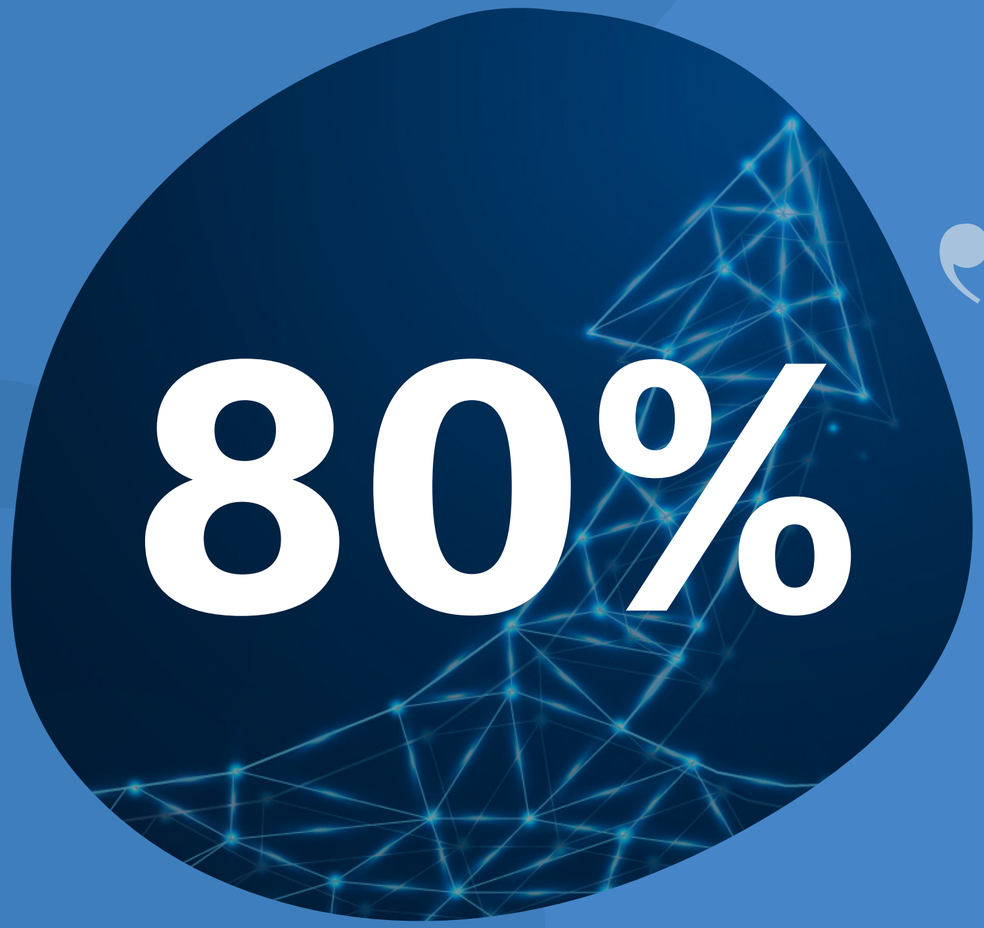

"of manual documentation should be eliminated work to improve productivity

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QUALITY MANAGEMENT CHALLENGES

WHAT DOES A PLANT MANAGER LOOK FOR?

A Plant Manager would have a specific view of the business as their purview is not restricted to one department, but to the overall operations of the plant. Some key concerns that typically need to be addressed be addressed by a Plant Manager or a General Manager of a Pharmaceutical Plant are:

- Quality Management
- Compliance with evolving regulatory standards
  - Take control of your Documentation such as COA
- Safety
  - Corrective and Preventative Actions management (CAPA)
  - Location directives
  - Raise flag when two reactive chemicals are placed in proximity
- User Adaptability and training to conform to the new Quality standards

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THESE CONCERNS ARE TYPICALLY ADDRESSED BY

- Efficient Document Management - allows you to centralize documents into a secure repository that is seamlessly accessible. This ensures quicker decision making and effective change management. It also helps in ensuring visibility of your documents, enhances traceability by tracking amendments, and document safety with revision control features.

- Addressing Non-conformance - can be done through a unified platform to log non-conformance, quality of incoming raw materials, complaints, delay, etc. This helps in addressing compliance at an early stage, paving the way for course correction and registering the same in the system.

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THESE CONCERNS ARE TYPICALLY ADDRESSED BY

- Corrective & Preventive Action - a method with advanced analytical features built in to help you learn and unlearn from records of the past. As discussed, registering a non-conformance incident into the system initiates a workflow for corrective measures. This system learns from past incidents and recommends preventive action to control similar incidents from recurrence.

- Implementing the right kind of tools and technology can help with Process automation and reduce data entry errors along with tracking process efficiency.

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THE PRELIMINARY STEPS INVOLVED

The ideal next steps would be to look at your current state and start making the following tangible decisions:

- Identifying the right system to help you with the needful will be the first essential step to move in the right direction.
- Once that hurdle is crossed, it is important to build a 'to be' mindset instead of worrying about why the system doesn't do what your workforce is used to doing.
- Evaluate how stringent you want your process to be, based on your company's needs and accommodate a well-defined method that is native to the application.
- Implement the change with the right methodology that is risk free and that helps you maintain a stable state during the transition.

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KEY TAKEAWAYS

- Quality management is no longer an afterthought and has evolved to become a discipline in most prosperous manufacturing organizations. Quality management which was once considered as a business function that hindered speed to market and product launch, is now embracing modern technologies to fuel innovation, bring in efficiency, eliminate the scope of incidents within a plant, and offer better predictions for the future.

- Pharmaceutical companies that have evolved to modern, automated quality control systems are able to empower their workforce to rapidly adopt process improvements and optimize all the functions in the department.

- The adoption of better tools in one department typically sets the standard for the entire ecosystem, including functions such as regulatory compliance, procurement, demand management, research & development, inventory and warehouse management, etc.

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ABOUT XCELPROS

Delivering efficiencies that matter

XcelPros delivers transformation through technology. We are a business and technology solutions company with deep industry knowledge in Chemical, Pharma, Life Sciences (including Medical Devices, Bio-Medical & Biotech), Discrete Manufacturing, Insurance, Distribution and Food & Beverage.

Our team is comprised of forward-thinking, experienced technology consultants and Subject Matter Experts (SMEs) with decades of business, industry and regulatory experience.

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XcelPros is a Systems Integrator (SI) and a Direct Cloud Solutions Provider (CSP) offering software licensing, implementation and consulting services for Microsoft Dynamics 365 for Finance & Operations (ERP), Microsoft Dynamics 365 CRM, Microsoft Dynamics AX, AI, Business Intelligence & Analytics (Power BI), SharePoint, Office 365, Azure (Cloud), IoT and Microsoft Flow amongst many others.

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HEAD OF DELIVERY

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