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# THE ROLE OF RELEASE MANAGEMENT IN PHARMACEUTICAL INDUSTRY

G. Chandrasekaran [*1] and C. Annavarapu [2]

Tata Consultancy Services Limited [*1], Chennai, Tamil Nadu India.
School of Management [2], SRM University, Chennai, Tamil Nadu India.

**Correspondence to Author:**
**G. Chandrasekaran**

Project Manager,
Tata Consultancy Services Limited,
Chennai, Tamil Nadu India .

**Email:** cgprasad@gmail.com

**ABSTRACT:** Due to the increasingly tight controls around compliance, pharmaceutical firms continue to seek more efficient ways to track, document and report on code changes in regulated applications such as those developed for managing samples and inventory. Such applications and electronic signatures associated with application development and workflows are subject to stringent regulations such as Sarbanes-Oxley Act (SOX), in addition to related audits. The pharmaceutical industry is in a state of flux, and the increasing regulations are making their job even more challenging! One of the outcomes of the introduction of the Sarbanes-Oxley Act focused organizations toward compliance and controlling changes in their environment. This adherence to compliance helped to stabilize environments to some extent and organizations spent a lot of money and energy into becoming compliant and putting controls into place. Every change introduced to the system has the ability to "break" the system.  The amount of changes and the speed at which change is introduced is directly proportional to disruptions in service and downtime. As the pharmaceutical environment is so integrated that one can follow all of the compliance requirements and pass single objects (change requests) through all testing and pass, yet still have problems once they reach production. Hence, the need to package sets of changes, the need for Release Management. Release Management acts as a coordinator in driving the release train from planning to deployment ensuring high quality on-schedule releases meeting the pharmaceutical business demand. This paper explains in detail about the effectively setting up the enterprise release management function and its benefits for the pharmaceutical industry.

**INTRODUCTION: Release Management:** Release Management is used by the software migration team for platform-independent and automated distribution of software and hardware, including license controls across the entire IT (Information Technology) infrastructure. Proper software and hardware control ensures the availability of licensed, tested, and version-certified software and hardware, which functions as intended when introduced into existing infrastructure.

Quality control during the development and implementation of new hardware and software is also the responsibility of Release Management. This guarantees that all software meets the demands of the business processes [1].

The goals of release management include:

- Planning the rollout of software

- Designing and implementing procedures for the distribution and installation of changes to IT systems

- Effectively communicating and managing expectations of the customer

- Controlling the distribution and installation of changes to IT systems

- Release management focuses on the protection of the live environment and its services through the use of formal procedures and checks. A Release consists of the new or changed software and/or hardware required to implement approved changes.

In common terms Release Management is simply said as "Organizing a set of desired changes into one concise cohesive work package whose components can be developed together, moved to the quality test environment, tested together, and then moved to production as one change (release). Release management helps for efficiently tracking and documenting the outcome and report on code changes in regulated applications such as those developed for managing pharmaceutical samples and inventory" [2].

**IT Alignment with Pharmaceutical firm:**
In general for many organizations, release management is not critical only for development and deployment practice but also for doing business. In those organizations, the delivery of software is a time consuming, stressful and costly process [3]. As soon as an application goes live, issues pop up, forcing the organization into another costly release cycle; usually release is typically a risky, unreliable procedure that costs businesses both time and expense. The **Fig. 1** illustrates the basic Pharmaceutical Business and Information technology alignment and about the functions of development and operation team within IT division.



**FIG.1: PHARMACEUTICAL AND IT ALIGNMENT**

IT Governance has a direct impact on how Information Technology is managed within the organization. The IT Governance Institute has offered the definition "IT Governance is the responsibility of executives, board of directors and consists of the leadership, organizational structures and processes that ensure that the enterprise's IT sustains and extends the organization's strategies and objectives". Successful IT governance is achieved through effective communication among all parties based on constructive relationships, through a common language committing to IT policies and process [4]. High level diagrammatic approach has been shown in **Fig. 1** about the Business and IT delivery alignment.

The intension of this approach is to make things crystal clear i.e. inception of the requirement from the pharmaceutical research team (business) till the delivery of the product satisfying the business need. Both Business and Information Technology are part of the organization and in real world - IT is the service provider for the business. IT encompasses different technical groups such as Business Analyst, Architects, Development, Quality analyst, Release Management and Project management. The requirement's from the Business are received and analyzed by the business analyst in conjunction with the technical architects. The criticality of the need is added to the Road map through the program delivery team and the essence of the technical requirements were placed with development team and later with the Quality team for testing.

After couple of deployments in test environment - system and integration testing's were performed. Business team is also involved to do the User Acceptance testing (UAT) and do sign-off, which is the sign of acceptance of the product to hit the production. Release team manages the overall release life cycle adhering the organizational release process and policy. The identified major or minor release hit the production environment on time with the agreed quality metrics and handed over the delivered product to the business. Business does a quick validation and it may yield a positive or negative results. If concerns are raised; they were handled by the IT release management through a warranty support mechanism as depicted in the **Fig. 1**. The successful release closure from
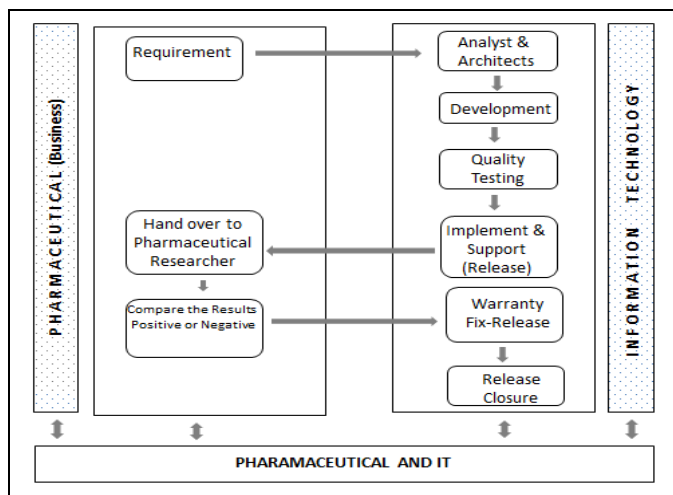
the IT side is the symbolic hand-shake representation for the Business and IT alignment.

**Role of Release Management:**
In **Fig. 2**, the various touch points are depicted like players, tools, workflow as well as the complexity of modern day application release to production. This is a fragile process that needs to be repeatable, error free and agile. The release manager and the release management function straddle development, QA, and production functions and environments. This critical diagram explains the variety of modules available across the management and engineering disciplines to ensure a complete and efficient software delivery process. It further segments by the functions of development, operations and the commonality under the DevOps [5]. It is easy to get carried away into thinking that Development and Operations (DevOps) begins and ends with Application lifecycle Management (ALM) module in conjunction with Automation - Continuous Delivery module, while these different modules serve an important purpose and have been readily embraced by development teams, they still leave huge gaps in the application delivery workflow. Project and portfolio management becomes very important in enterprises and especially Release management provides the glue between development and operations.

Organizations with few developers and few applications may take a linear approach to portfolio management. The unicorns tend to have a homogenous environment, a single application, and a development driven release approach. The moment we move away from this model, things change radically. A portfolio with multiple products and releases in tandem makes this a very complex workflow!

In most enterprise IT departments, development and operations need to work together to deploy applications across complex environment. The applications themselves exhibit a large variety in languages used, in complexity of how they are architected and Service Level Agreement expectations from consumers within and outside the organization. Lastly in most organizations, development and operations teams are highly

distributed and applications themselves are in various stages of their lifecycle – legacy apps, bug fixes, new functionality to new applications, etc [6]. Changes to applications and environments can have far reaching affects, in some cases catastrophic depending on its use and dependencies placed on its behaviour.
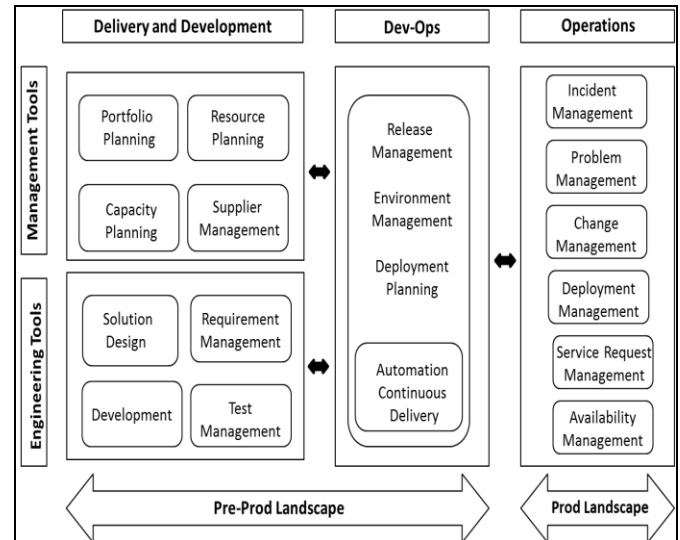


FIG. 2: INFORMATION TECHNOLOGY DELIVERY WORKFLOW

**Effective way to set up Release Management:**
Release Management (RM) is primarily concerned with the flow of change through various preproduction environments culminating in successfully deploying into the production IT environment in the least disruptive manner. Release activities should include planning, designing, configuration, roll-out planning, testing, communication and deployment. Release management should make the change management process more proactive and predictable and is crucial to managing the volume of independent change within any IT organization [7]. Pre-production environments like development, system testing, integration testing, performance testing and user acceptance testing, all fall outside the formal change management controls of IT Operations.

Given the velocity at which these environments change during build and test, an appropriate balance needs to be found between agility, flexibility and control. Release management and the release manager truly ensure that the functions of development and operations i.e. the disciplines of agile programming and IT service management

come together. While it is common to think of release management as the final promotion of a component into a production environment, we take a far broader view of release management ranging from

- The strategy of establishing quarterly, monthly or fortnightly release windows.

- Prioritizing the contents of each release.

- Understanding the complex dependencies, and tracking delivery as they meet the integrated delivery targets.

- And lastly, aligning the necessary non-production or test environments to support the coordinated release strategy [8].

Enterprise release management success depends on the following best practice approaches and they are explained as below

### a. Review Existing RM Process:
The first place to start is with a review of the existing Release Management function. This entails a review of the current personnel, processes and tools within the function.  A successful release management function is characterized as having capable people, a clearly defined regular process and a tool that supports all participants in the process.

### b. Establish an Enterprise Release Strategy:
It is equally important to establish an enterprise release strategy that clearly articulates regular release cycles.  As enterprise release management is concerned with ensuring all release components such as projects and work packages arrive at the same time within a defined window for integrated testing - it is essential to establish a release strategy that enables the new feature to be deployed to customers at regular intervals. Release management mission and goals are well articulated by using de-facto policies, or by taking a more formal approach. Goals may be metrics that are centered on a number of successful releases, decrease in release based downtime and outages, or more strategically, measuring and growing the top line by an agreed upon percentage.  Next is the need to define Rules

of Engagement - it essentially defines entry, journey through and exit out of the release management pipeline. Examples of these rules can be:

- Empowering release management to accept or reject a new release based on specific acceptance criteria

- Release manager will sit on all change advisory board (CAB) meetings and will be empowered to assist in analyzing and approving changes

- More tactical rules that help with organizing changes into units and groups before releasing into production

- Both pre-release and post-release into production quality are tested and will be approved with sign-off from release management

- Depending on release and production environment criticality, a back-out strategy to be developed [9]

Lastly, it is important to define critical success factors that will define the success or failure of a release.  These range from measuring number of incidents caused by releases, number of failed releases, number of releases implemented but not tested, number of releases without operational assurance, etc. Other examples of metrics may be number of releases implemented late, volume of major and minor releases, % of releases where back-out plan was used, etc.  The most successful enterprise release management functions are those that are exercised regularly and tweak their processes slightly after each release based on the lessons learnt.  These organizations strive to hold steadfast when it comes to their broader release management strategy, well defined rules of engagement and the feedback loop that takes the critical success factors into account.

The next step in an effective release management function is to define an optimal release management process. This has the following ingredients:

## c. Identify the Release Management Process Inputs:

The release management process should consider the following as inputs to the process – portfolio and program management systems, service management systems, quality management systems, configuration management systems and deployment solutions.

## d. Identify Key Activities for Release Management:

Key activities that need to be considered for an effective release management process workflow include – release planning, coordination, design, building and configuring of releases, coordinating release acceptance, conducting rollout planning, coordinating release communications, training activities, coordinating distribution and deployment of releases into production, measuring and providing management with overview of release management processes and key performance indicators (KPI)

## e. Identify the Release Management Process Outputs:

This will closely mimic to the Release Management Process Inputs. Except in this case for example when looking at Incident management, the connection needs to be made as to which release fixed a specific incident and so on. As the service management is linked, the modules like Incident Management, Problem Management, Change Management, Configuration Management, Service Level Management, and Service Monitoring are to be focused and aligned with the overall release delivery approach.

## f. People Investment:

It is critical to invest in the right people to be custodians of the enterprise release function. The team with the best players wins and it is no different in release management. Program Managers and Project Managers will manage a broad set of work stream and activities to deliver to key milestones. Development managers will manage developers and product work packages for deployment. The key roles that participate in a successful release function include the Release Manager, Environment Manager, Test Manager and Implementation Manager. The skills required

across these roles include – Leadership, Organization and Planning, Technical, Project Management, Communication and Teaming. The Release Manager with executive support is responsible for all releases. He or she should coordinate the various functions and work activities at all levels, provide the authority or ability to promote releases, as required and manage the process end-to-end so as to ensure optimal overall performance and quality. The Environment Manager should ensure proper capacity utilization, configuration and uptime of all environments. Test, Staging and Production Support environments are critical as they each have their own needs, differing degrees of flexibility, and also multiple stakeholders with vested interest in using them.

The task of the environment manager is to coordinate a limited supply of environments across various release stages and stakeholders. The Test Manager should ensure proper testing protocol is adhered throughout the release process. He or she should ensure testing at each stage (unit testing, integrated testing, user acceptance testing etc.) is adhered to and relevant testing gates are maintained. The test manager should coordinate and communicate with the release manager, the environment manager, and development manager.

## g. Tools for Effective Release Management:

As seen earlier, a variety of tools across development, test, operations, are already being used. In addition, a robust release management tool is essential to ensure success of the release management process. Such a tool should help with stakeholder management, communications, release calendar, workflow capabilities, data extraction and reporting, collaboration and auditing the process capabilities, dashboard for various stakeholders and ability to integrate with existing tooling, as well as a robust API for use by other tools in the environment.

## h. Test Environment Usage and Optimization:

All phases within the release process require IT environments to be in place for test execution and validation well prior to the completion of any code. The release infrastructure covers the hardware, storage, network connections, bandwidth, software licenses, user profiles and access permissions. In

complex integrated and secure environment, this is no trivial matter and requires thorough planning, understanding of interdependencies, alignment of specialist skillsets and resolving contention with competing initiatives. Critical environment bottlenecks must be eliminated early before they hold up delivery.

### i.   Staging Releases and controlling Activities:
Releases encompass many moving parts; transparency and control of each phase within the Release is critical as Releases move through their key phases like integrated gates and milestones, the work packages are being promoted through various environments for various forms of testing and validation. It is recommended to have a transparent baseline of the environments as well as a clear understanding of the composition of work packages being promoted prevents significant rework.

### j.   Transparency and Stakeholder Engagement:
A sign of an efficient and working release management function and a worthwhile goal for any IT organization is to be able to publish the target release plan for the next 12 months. While the composition of releases may not be known with certainty, the intent is to lock in the release windows so that all teams work towards not only the final release date but also the intermediate targets such as completion of integrated testing, completion of user acceptance testing and so on.

In an environment where targets are continually shifting, being able to set and communicate release windows 12 months into the future essentially shifts the discussion to release composition rather than release date.

Once the release dates are defined and approved, stakeholders should be engaged to prioritize outstanding feature requests and allocate them to future releases. There should be certainty around the immediate next release and less definition about the composition of releases scheduled further into the future. Regular structured releases give customers confidence that they can order something and it will be delivered.

### k.   Continuous Communication:
Regular communication with stakeholders, delivery teams and suppliers is essential to ensure all parties have a consistent view of the expected outcomes and the manner in which they are achieved. All the information's relating to the progress of the release should be always available in a frictionless manner and all parties should have a systematic way of accessing the information they need in real time.

### l.   Sponsorship & Metrics:
In addition to the above in terms of what we are advocating as Effective Release Management, practitioners should consider having an active senior sponsor, who bode well for any release management function. Additionally, having visible metrics to monitor end-to-end release health is very critical. Taking the time to define these release health metrics and ensuring they are consistently measured and published is essential to establish credibility. Understanding the business impact is critical to the release management function being taken seriously sponsored and prioritized [10]. Finally, understanding the business value is a key to the success of the release management process.

Organizations will definitely benefit by implementing the release management functions focusing on the key areas as explained.

### Survey Findings:
Had an in-depth survey with 418 senior professionals related to the need and contribution of release management in the journey of IT delivery aligning to the business needs? The key questions and survey results are shown in Figure 3. The questions were framed covering all the relevant areas such as product delivery, quality analysis and control, customer interface, stakeholder's management, process capability, internal and external integrations and key metrics. It is understood from survey that, organizations that rely solely on project centric delivery will encounter various obstacles that will inhibit their ability to implement their deliverables successfully without incurring additional costs and missing key deliverable dates. The major obstacles in common are:
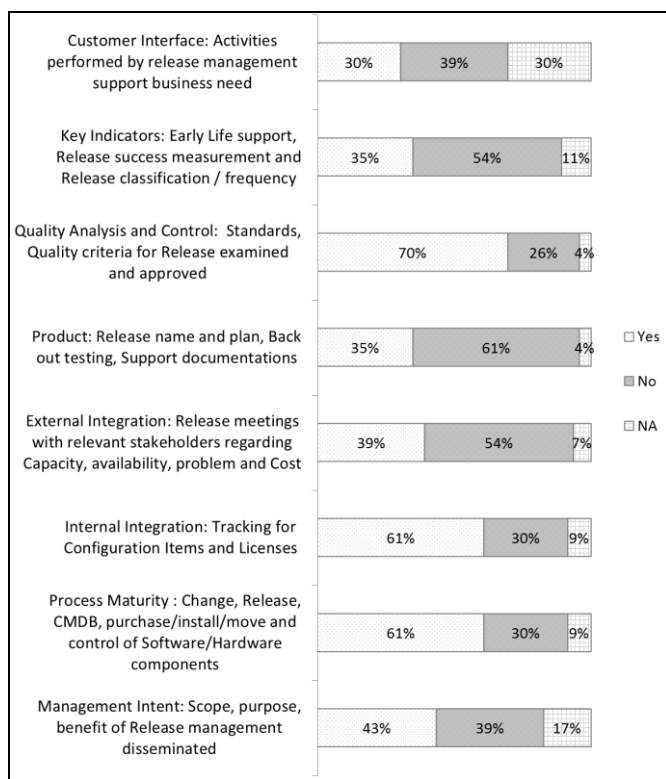
**FIG. 3: EXPERTS OPINION ABOUT RELEASE MANAGEMENT**

### 1. Technology:
A lack of a thorough understanding of the end to end architecture of organizational technologies increases the risk of failure in the delivery and deployments into production environments.

### 2. Complexities:
Organizations that incorporate significant customizations across their technical landscape increase the complexities in building, testing and deploying new items. An inadequate understanding of the interdependencies on the underlying technologies will undermine project implementation success.

### 3. Accountability:
Not having a role for the accountability for oversight related to multiple changes within the same delivery stream will deter from a successful project ending. A project manager is driven by his schedule budget and scope to ensure his deliverables are implemented into production. Having one or more projects heading along the same timeline into the production environment without oversight of the technical integrations will result in deployment collisions creating havoc on the Project Manager's schedule.

### 4. Planning:
Priorities as well as project schedules are key drivers in creating a production delivery plan. An integrated plan for multiple projects is essential to a successful deployment and without input from cross project technical stakeholders - chances of success are greatly diminished [11].

Survey results also help to interpret that, the inception of release management for some organizations is more driven from a need than a want and still there are room that, many organizations are yet to invest in this area. Mostly, the need for release management was derived from the lesson's learned outcomes, which were used to examine the challenges experienced by projects along the road to production implementation. Though not formally recognized within the pharmaceutical organizations, the practice of release management was being performed by a variety of teams but not in a coherent manner. The result of the survey lead to the fact that the release management benefits were mostly hidden and to name a few are, release management process provides accelerated time to value, enhances agility and flexibility by responding to new, emerging needs or competitive threats as they arise. Effective release management increases the productivity through the creation and enforcement of standards and best practices across the release journey as well as by ensuring more efficient allocation of test environments to support releases.

**CONCLUSION:** In summary, the implementation of release management function in any pharmaceutical industry will need to address the increasingly tight controls around compliance, and it will help the pharmaceutical firm which continues to seek more efficient ways to track, document and report on code changes in regulated applications such as those developed for managing samples and inventory. Release Management also helps to mitigate the release failure by providing real-time visibility into enterprise wide release status and results, which enable the researcher to pinpoint the root cause and mitigate quickly. In future, it is expected to realize more values by automating the release deployments and the research may extend to remodel the test environments for better utilization and involving

the required stakeholders in various phase gates of major releases which will help further to identify and compare the results with the expected and actual values in real time. The other benefits of release management are lower costs per change, fewer production errors, more comprehensive testing and better prioritization of work.

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