How to Achieve Good Governance

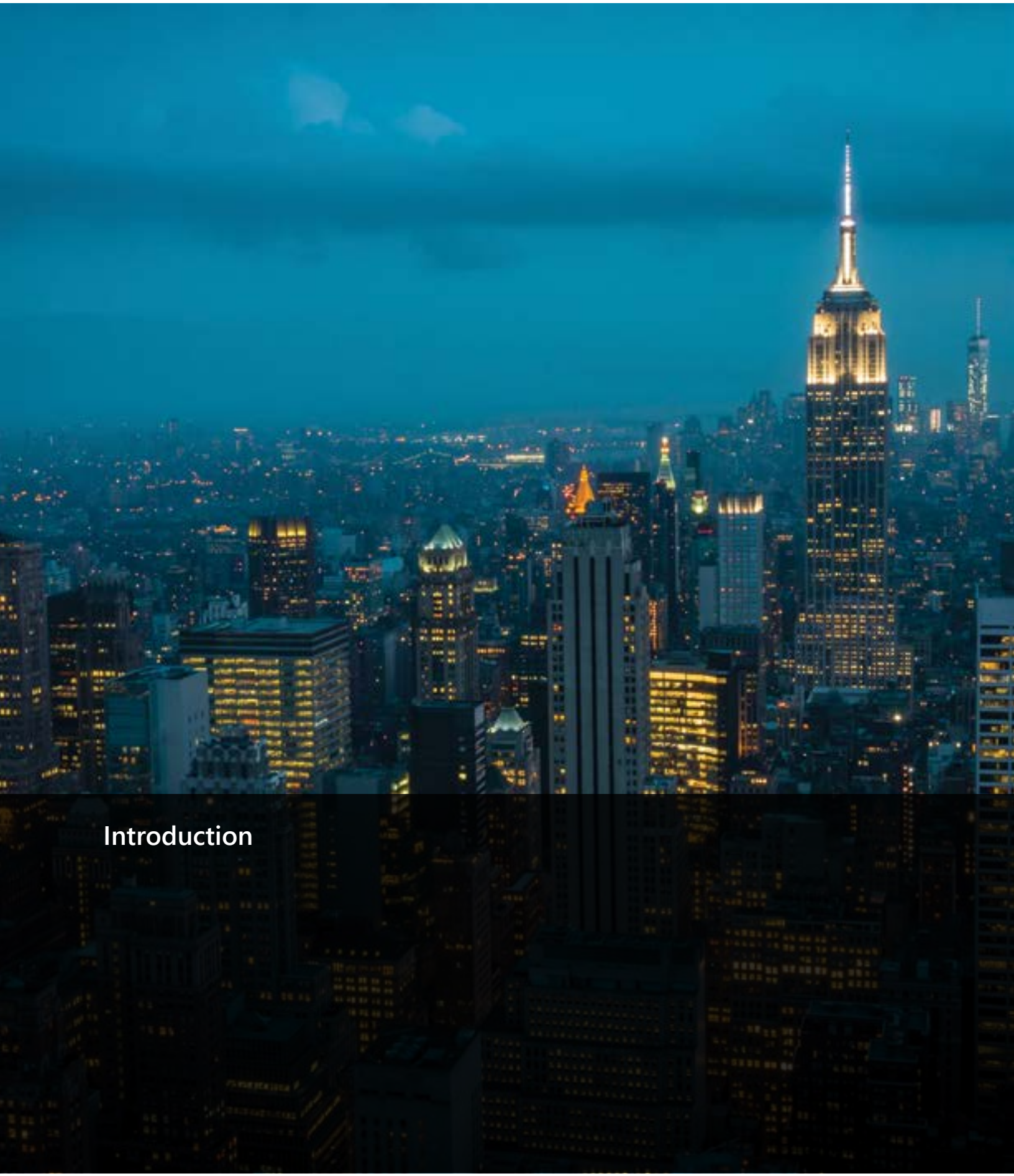
in Pharmaceutical Projects

Cora Systems White Paper

cora

Abstract

In 2016, the FDA approved less than 50% of the drugs from the previous year. This white paper explores why this happened and explains the latest cost models involved in bringing a drug from discovery to the patient. We chronicle the overall challenges that pharmaceutical companies face today before describing some specific project management challenges. We highlight the function of an EPMO (Enterprise Project Management Office) and how it enables organizations to respond quickly to changes by establishing techniques and processes that provide visibility standardization, measurement and process improvement. PPM (portfolio project management) software allows project managers and senior management to more efficiently bring new pharmaceutical products to market, from discovery to R&D to marketing, providing insight, control and competitive edge.



Introduction

We all remember the final scene from the 1985 movie, Back to the Future, when Marty McFly and Doc Brown accelerate the plutonium-powered DeLorean "time machine" back to the 21st century - October 2015. Marty declares that there is not enough road to accelerate to 88 mph, with which Doc replies, "Roads? Where we're going, we don't need roads." Great Scott.

Two "movie" years since Doc went back to the future, and we still have roads. Doc Brown could never have predicted the rapid pace of scientific advancements in our understanding of diseases at the molecular level. However, the scientific, technical and regulatory challenges related to drug development have created complexity. The science is difficult and the risks are higher than ever. The overall likelihood that a drug entering clinical testing will eventually be approved is estimated to be less than 12%.[1]

The U.S. Food and Drug Administration approved only 22 medicines in 2016, a 50% drop from 45 approvals in 2015.[2] Similarly, the European Medicines Agency (EMA) approved fewer prescription products in 2016, from their 19-year high approval rate of 2014. Moreover, according to a recent Deloitte study, the return on investment from research and development fell dramatically in 2016 to 3.7% from the high of 10.1% in 2010.[3] The message is clear; getting new drugs through the approval process has become more challenging, the consumer market is changing year-on-year and the associated costs of taking a drug from the discovery stage to pharmacy shelves is staggering.

In 2014, the Tufts Center for the Study of Drug Development examined 10 pharmaceutical companies and 106 randomly selected drugs that were first tested in human clinical trials, estimating that the true cost to bring a drug to market was $2.56 billion (in 2013 dollars).[4] Considering the 20 year patent exclusivity period commences once the clinical trials are approved by the FDA, the window for investors to get a return on their investment is small - which explains the ever escalating price increase of pharmaceutical drugs and medical devices. Furthermore, the Pharmaceuticals are also facing major resistance from healthcare insurers

[1] Small Steps with Giant Impact in Pre-Clinical Research White Paper Publisher: Elsevier

[2] New drug approvals fall to six-year low in 2016. Publisher: Reuters. (Jan, 2017)

[3] 2016 FDA Drug Approval Trends. Publisher: Ogilvy Common Health Worldwide. (2016)

[4] Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Publisher: Tufts Center for the Study of Drug Development (March, 2016)

and governments about the rising cost of medical treatment. It is a tough, competitive business.

The latest annual report from the FDA's Office of New Drugs provides some insights for the drop in approvals with one of the primary reasons being violations of manufacturing standards at the facilities where the drug was being produced. Or in simple parlance - failures in the manufacturing supply chain. The reality is the FDA cares that the production processes meet standards and in general regulatory policy and compliance in developing a new drug are becoming more stringent.

There is some good news for the pharma industry. In December 2016, Congress passed the biggest health care reform act since Obamacare. The 21st Century Cures Act authorized $6.3 billion in funding, mostly for precision medicine and biomedical research run by the National Institutes of Health (NIH).[5] It aims to speed up the drug and medical device approval process, especially for diseases with unmet medical needs. Understanding the costs of bringing a drug to market, this sizable budget is actually less than the total cost of bringing 3 new drugs to US customers. However, this new funding is a harbinger for many new R&D projects over the coming years, complex projects where the rewards are high and the challenges great.

[5] Biomedical Research Bill Approved in House. Publisher: The Scientist Author: Ben Andrew Henry. December 1, 2016

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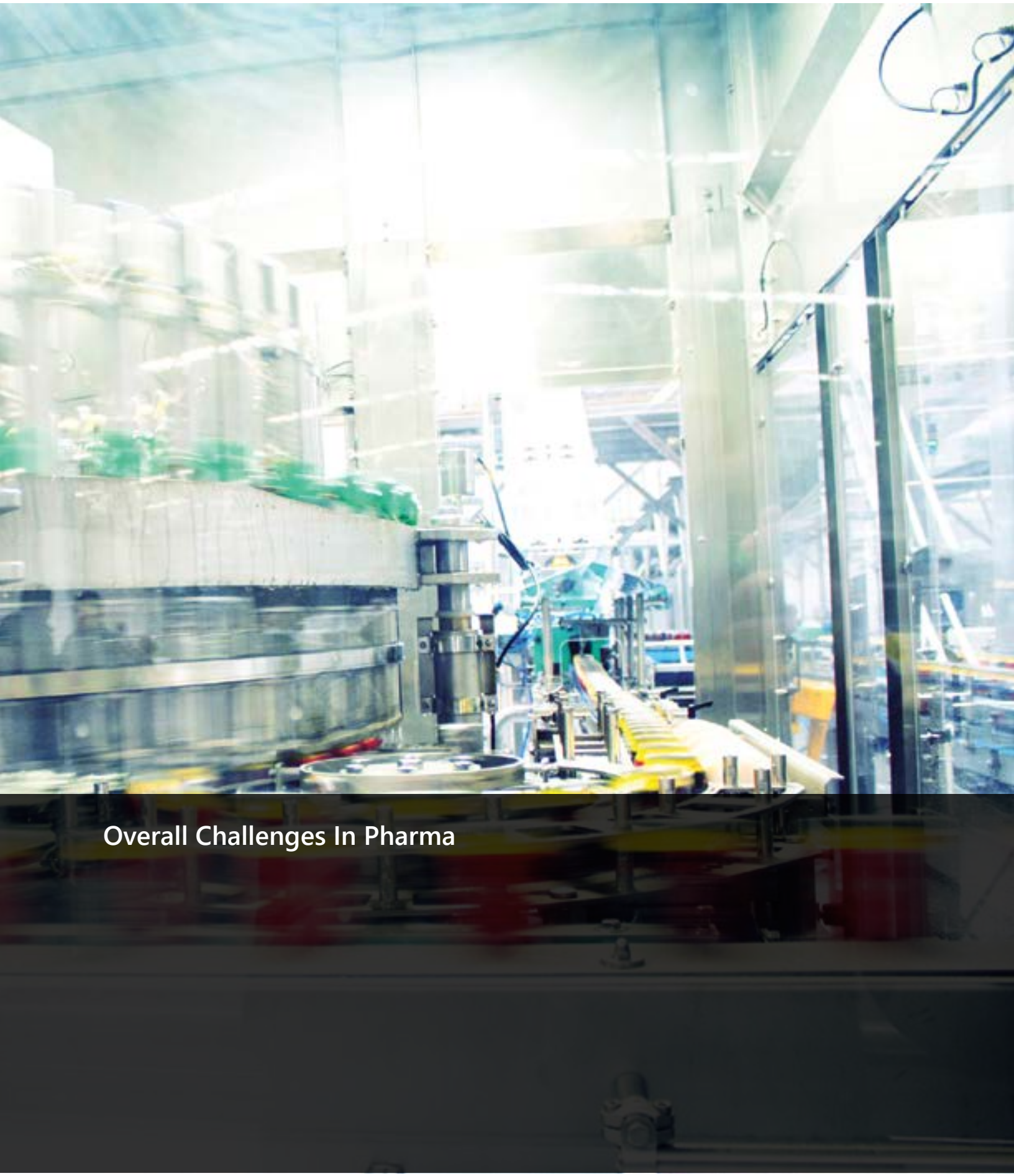


Overall Challenges In Pharma

The commercial environment is getting harsher, as healthcare payers impose new cost constraints on healthcare providers by carefully scrutinizing the value of medicines. New online pharmacies selling generic drugs have become the competition. Insurers and governments alike want new therapies that are clinically and economically better than the existing alternatives.

Even though technology has changed the Pharmaceutical landscape forever, the scientific processes and methodologies are still understandably thoughtful, deliberate and oftentimes slow. Speeding up research projects has dangerous consequences. Making scientists accountable for success driven projects is also fraught with danger.

On average, it takes at least ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years on average. How do we, or should we increase scientific productivity? Pharma's output level has remained more or less at a stable level for the past decade. And there is little reason to believe that this productivity will suddenly increase any time soon. Precision or personalized medicine, to get the right patient the right treatment at the right dose, first time can potentially be addressed by technological advancements.

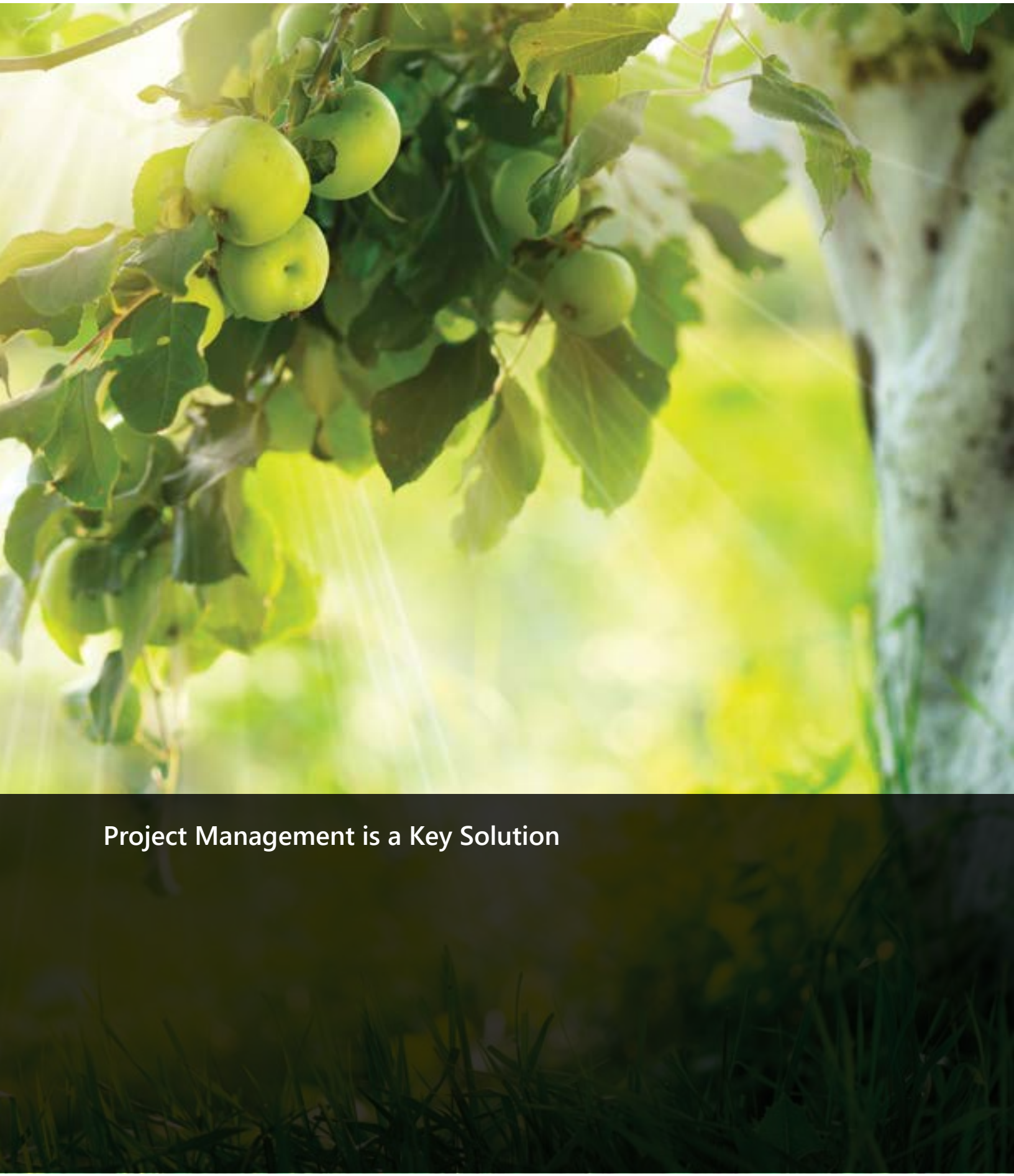
The harsh reality is that through increased consumer demand, shorter research and development lifecycles and cut-throat competition, the pharmaceutical industry is moving faster than ever. Some would argue that pharmaceutical companies suffer from a legacy of "the old guard" style of management where the cultural environment can feel similar to public sector. Massive organizations need to change and change fast if they are too survive.

Large pharma companies are buying earnings through mergers and acquisitions, developing internal generic pipelines, looking at emerging global markets, collaborating with other large pharma companies, diversifying product or biosimilar categories and looking for new techniques to speed up the time to market. It's becoming an ever more complex industry which explains the overwhelming interest in better and faster project management practices.

Project Management Challenges

Project management for drug development is highly specialized and is still a relatively new practice. Taking on a role as Project Manager is no easy task requiring skills and qualities around communication, decision-making, delegation and risk taking. You are expected to deal with the day-to-day challenges that arise from managing projects including the following:

- Projects require massive coordination between R&D, regulatory, legal, finance, supply chain, sales and marketing
- Projects are highly regulated with complex compliance processes
- Organizations lack an appreciation of the importance of project management especially the executive board
- Projects lack sponsorship or visibility from top decision makers
- Research projects are often geographically distributed and disconnected
- IT and back-office functions including large Contract Research Organization (CRO) projects are often outsourced
- Resource pools are often distributed, with poor overarching resource management function
- Lack of a single project management process framework
- Reporting progress and financial burn down to boards and investors is very difficult
- Lack of specialized pharmaceutical project management skills



Project Management is a Key Solution

Project management is the key practice in bringing all aspects of pharmaceutical projects together.[6] Project managers are becoming an increasingly integral part of the entire process. The question of "what is pharmaceutical project management?" may appear to be a fairly rudimentary question, but it is an important one. The PMI define a project as "a temporary endeavor undertaken to create a unique product, service, or result." Projects are "temporary" and therefore distinct from operations, whose primary goal is sustaining the core business. Effective pharmaceutical project management organizes and manages resources in a way that achieves project completion within the defined scope, quality, time and budget.

In general, project managers need to have very strong people and analytical skills, negotiating skills, and the ability to resolve conflict and communicate progress effectively. These are skills that are not normally associated with scientists or academics alike. In order to overcome these skills shortages there has been an observable increase in the number of management consultancy firms offering specialized pharmaceutical project management services. Contract development and manufacturing organization (CDMO) have become an important part of the success of the drug industry. The pharma company must place their trust in a reliable CDMO. For their part, CDMOs can help build trust, and ensure on-time and on-budget delivery with effective communication facilitated through providing talented project managers.

[6] A program consists of a series of related and possibly interdependent projects that meet an overarching objective.

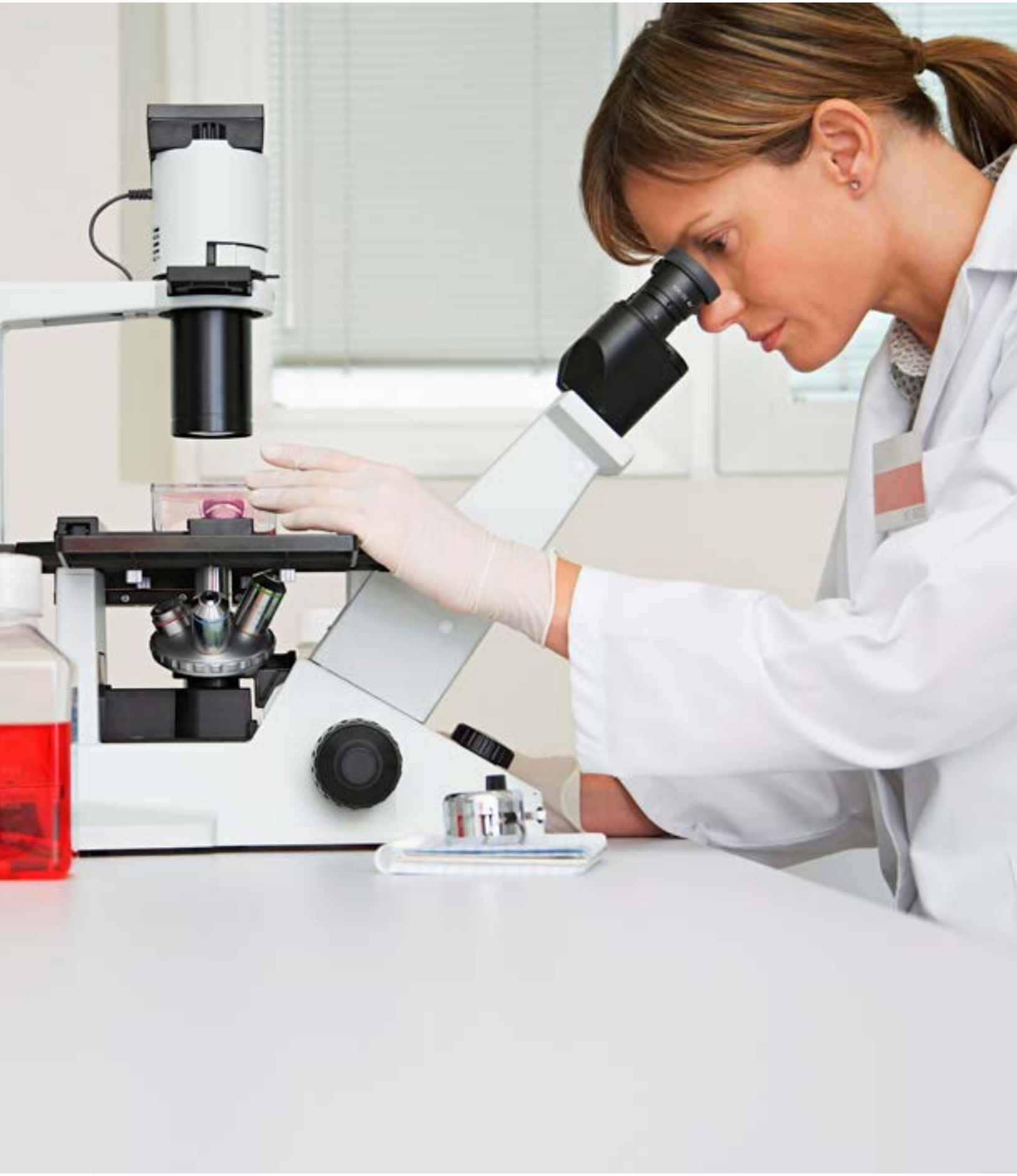
1. Apply Good Project Management Practices

In the pharma industry, with all the added uncertainties from the process of scientific research, project management encompasses the following activities:

- Scope management of individual projects and overall programs
- Project planning, execution, and monitoring
- Putting strategic plans into practice
- Establishing measures of success of each project
- Standardizing routine tasks especially around regulatory or compliance
- Budget and timeline management
- Change management
- Value chain management
- Incorporating quality best practices
- Optimization of resources
- Stakeholder management
- Providing senior management insight into project progress
- Management of regulatory and compliance strategies
- Environmental safety
- Risk management

Common elements of governance relevant to the pharmaceutical sector:

- Transparency
- Accountability
- Participation
- Consensus
- Ethics
- Efficiency
- Information
- Rule of law
- Regulation
- Leadership
- Equity
- Efficacy
- Policy formulation & planning



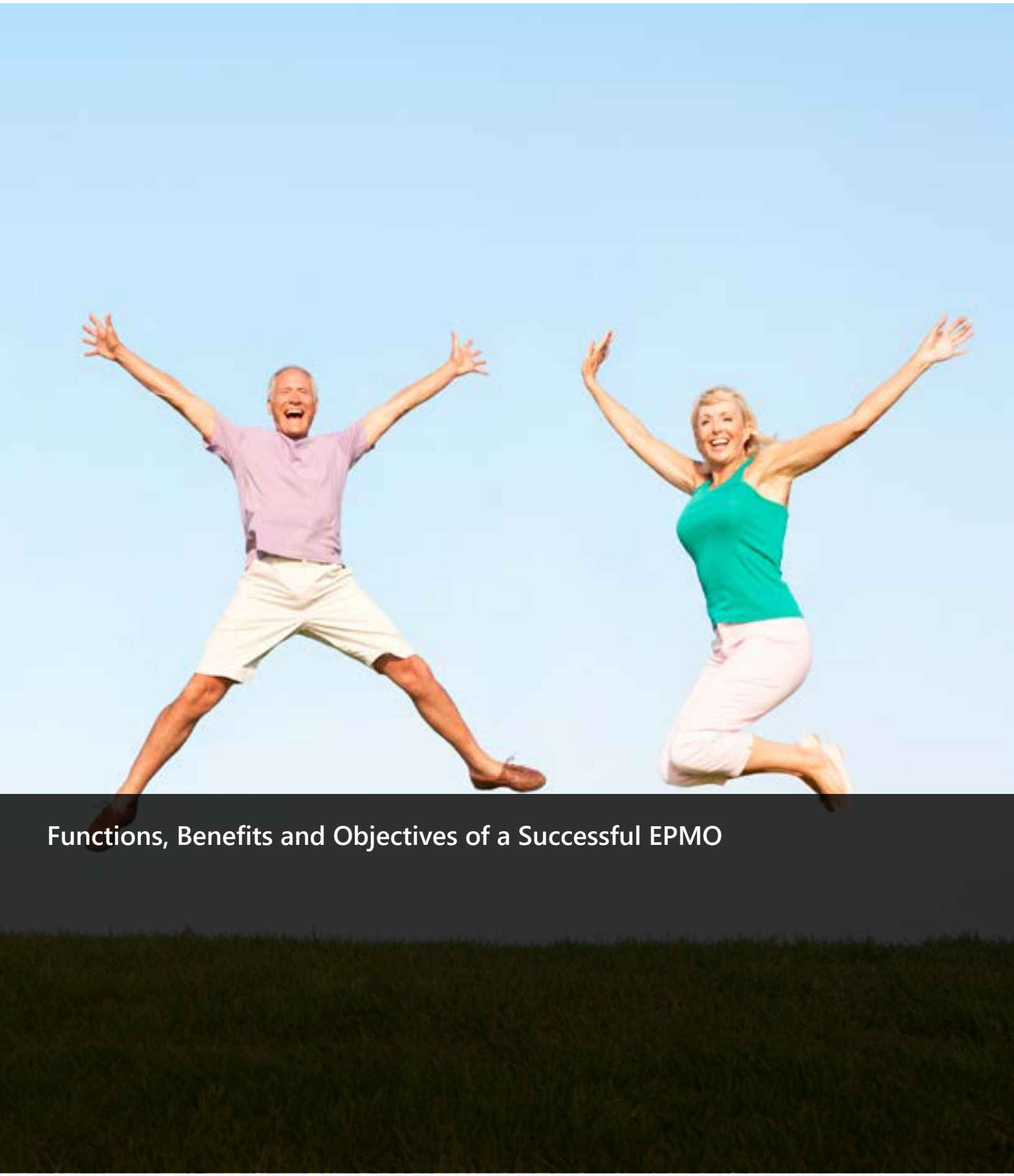
Founding an EPMO[7]

PM Solutions have been carrying out PMO yearly surveys since 2000, providing insightful empirical data for 17 years. In 2014 they concentrated the survey on the foundation of PMO's with a massive 90% (up from 47% in 2000) of large companies having a PMO, and 30% of those without a PMO plan to implement one within the next year. Mid-size (88%) and large (90%) companies are far more likely to have a PMO than small companies (61%). The average PMO is 4 years old, with 47% of them 5 years old and older (up from 34% in 2012).[8] In the United States, the PMO budget is 4.4% of the total average project budget. Most PMOs report to a VP or higher; 43% directly to the C-level. Undoubtedly strong executive management commitment and support is one of the key criteria for success.

The reality is that if a Pharmaceutical company does not have an enterprise wide PMO to govern the overall portfolio of related projects then they should. The aim to this approach is the central coordination of all aspects of the projects in an organization. It becomes the single point of success or failure and the single source of truth. The biggest challenges PMOs face are that they're seen as overhead and their organizations continue to be resistant to change. The PMO covers the three areas critical to any pharmaceutical project's success: scientific operations, client services and resource management.

[7] Readers of this paper should note that the author uses the term Project Management Office but could have also used Program Management Office. A program is simply a logical grouping of projects.

[8] State of the PMO 2014. Publisher: PM Solutions (2014)



Functions, Benefits and Objectives of a Successful EPMO

In this section we take a brief look at the functions, benefits and objectives of a successful PMO. Some of the key functions are as follows:

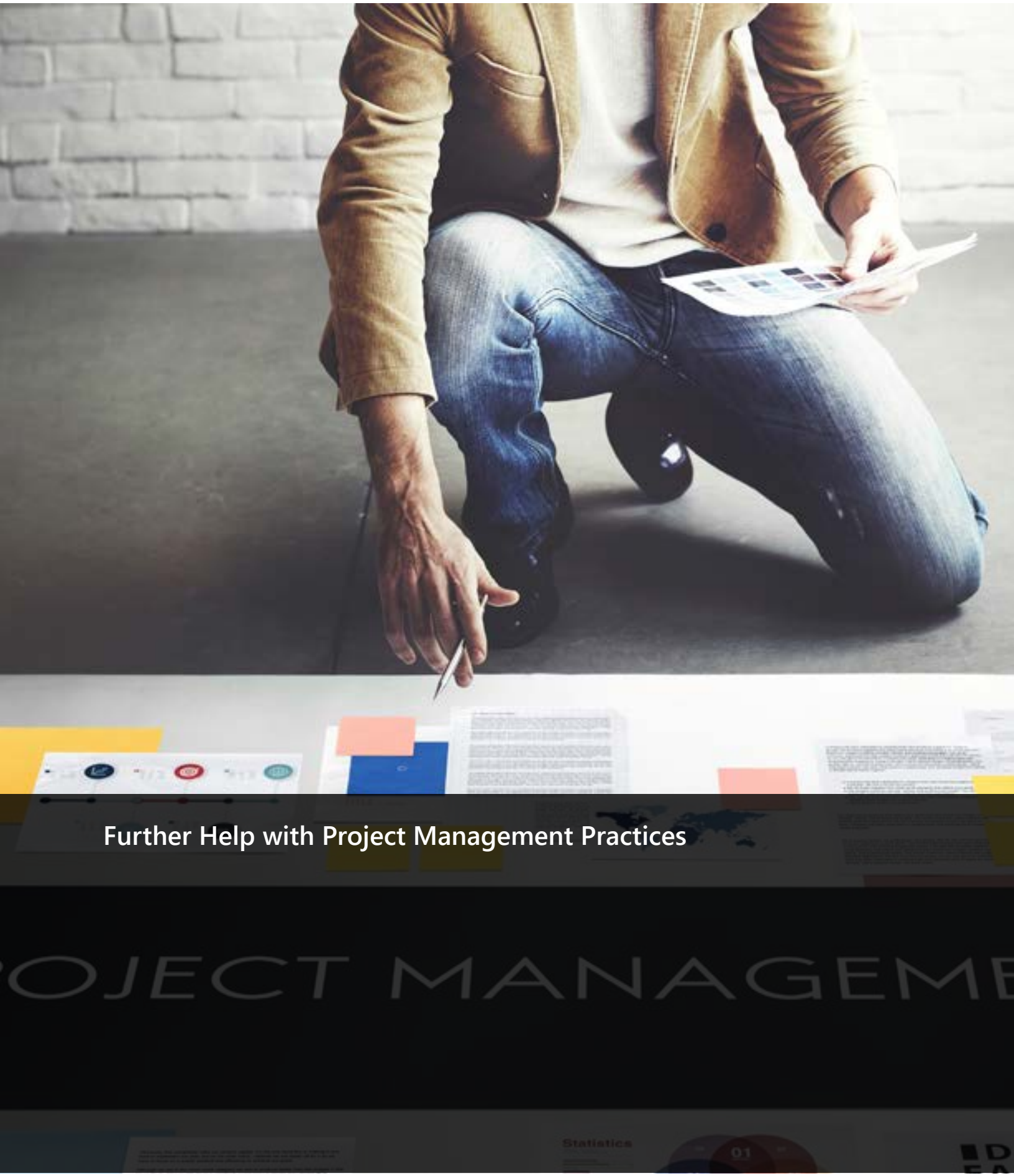
1. Sponsor the project tools for planning and controlling
2. Provide direction and oversight of project management policies, procedures and templates
3. Accountable for the creation of auditable and traceable documentation through research and development project phases
4. Co-ordinate project initiation, planning and closing phases of projects
5. Owner of the program roadmap
6. Responsible for the alignment of projects against the strategic objectives
7. Tracking portfolio and performance
8. Centralized archive of lessons learned
9. Project administration support including the facilitation of project web site, special meetings and war rooms
10. Managing the CDMO (Contract development and manufacturing organization) relationship, Providing of PM training, coaching or mentoring programs

There are a number of key objectives that a PMO should be responsible for:

- Alignment to Strategic Objectives: How aligned are projects and the portfolio to a firm's strategic objectives?
- Process Alignment: How useful, consistent and comprehensive are the company's project management processes across the entire enterprise?
- Program/Project Roadmap: A Project or Program Roadmap is a simple presentation of the project objectives and project goals alongside a timeline
- Performance Management: How well do the projects add value to the overall organization and how well does it reward teams and individuals for contribution to successful projects
- Organization architecture/modeling: Defining the organizations roles and responsibilities and agreeing an unambiguous organization chart
- Staff Culture: How well understood is the objectives and role of the PMO and how does the organization encourage, recognize and develop good behaviors
- Information architecture: Ensuring that the organization have ready access to and make good use of project information for their decision-making

There are a number of key benefits of establishing a centralized PMO:

- It fosters an environment where collaborative decision-making is easier
- It minimizes the risks to individual projects in terms of business impact
- Controlled and efficient resource management
- Having a full transparency into all aspects of the projects
- Having better control over projects
- Being better equipped to make the optimal decisions related to projects
- Minimizing uncertainty and associated risks
- Increasing support and buy in from all stakeholders


Further Help with Project Management Practices

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit international society providing scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. The ISPE is an international society for professionals involved in the engineering and manufacture of pharmaceuticals and related products. ISPE, provide baseline guides to help interpret and implement difficult processes and for the design, construction and operation of pharmaceutical facilities.

This could help pharmaceuticals that may have recently failed an FDA audit or non-approval of drug.

IPSE has an excellent guide entitled: Project Management for the Pharmaceutical Industry.[9] It's a good reference for any project manager and it describes the tools and techniques supporting pharmaceutical project delivery, the life cycles in a typical project and how to navigate complex compliance and regulatory projects.

[9] Publisher: IPSE URL: www.ispe.org/publications-guidance-documents/project-management-pharmaceutical-industry

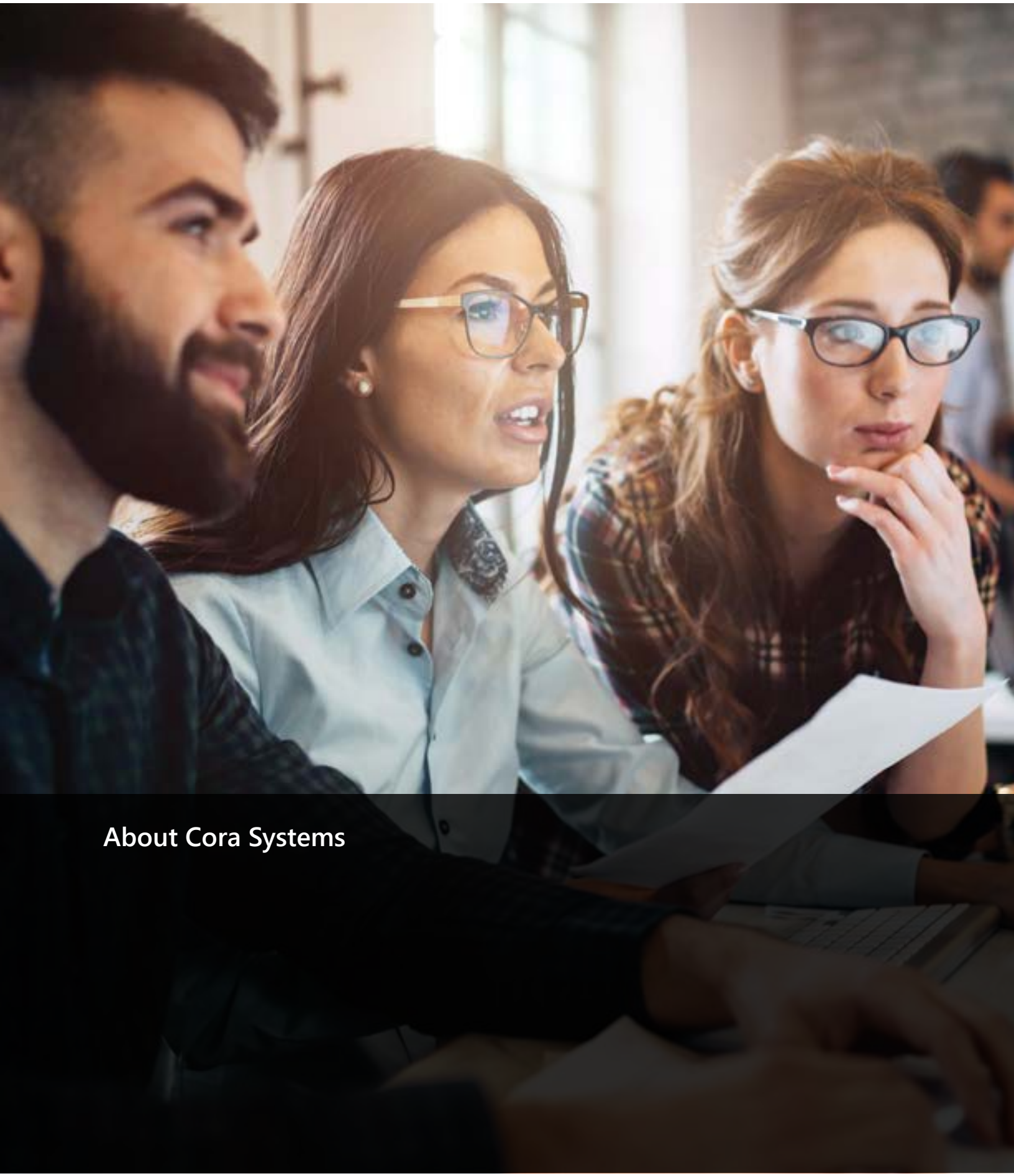
Conclusion

A lot has changed to the pharmaceutical industry in the past 20 years, and yet in so many ways the fundamentals have stayed the same. A new drug cannot be released without going through strict regulatory processes. Generics are challenging the industry as a whole. Discovering new exciting compounds are rare. Pharmaceutical companies, like every other industry, is intensely competitive and under more scrutiny than ever before for better value. New emerging markets are being explored while scientific research has become more result oriented.

There is now growing awareness that these big budget, complex projects need highly skilled project managers and proven practices to make them work- collaboration, co-ordination, tools, process, negotiation, reporting and clear and consistent processes are what pharma companies need to succeed. Every pharma project of any significance requires a spectrum of new project management skills. If you don't have these skills in-house, then go and invest in them now. In this paper, the most important overall message is that Pharmaceutical companies need to embrace the founding of an Enterprise Project Management Office.

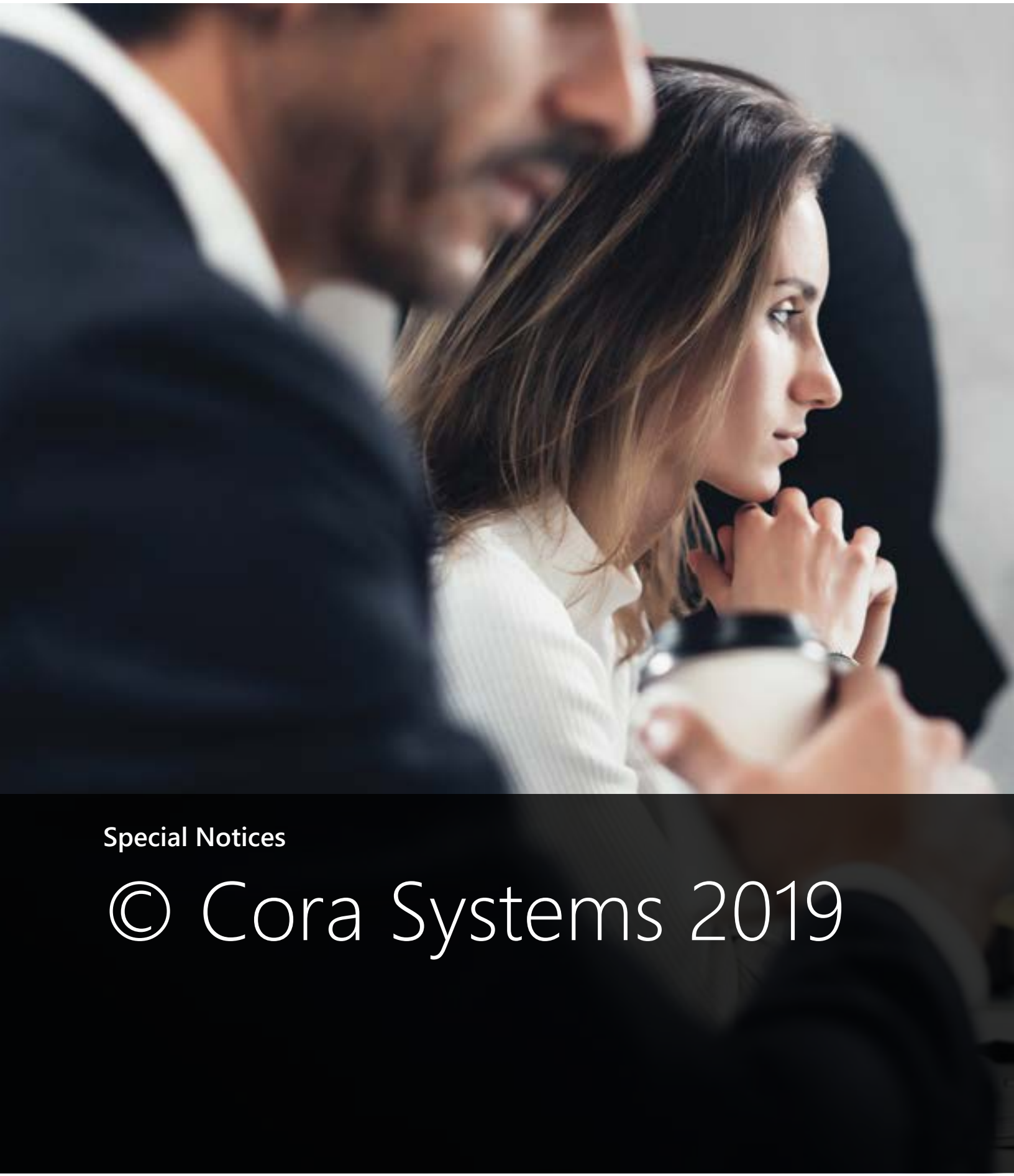
Doc Brown did say: "If my calculations are correct, when this baby hits 88 miles per hour, you gonna see some serious shit." The pharmaceutical industry just hit 88 miles per hour. It's time to make project management a key focus over the coming years.

> If my calculations are correct, when this baby hits 88 miles per hour, you gonna see some serious shit.
>
> **Doc Brown**



About Cora Systems

Cora Systems is a worldwide leader in providing enterprise PPM solutions to global organizations and government agencies, such as Honeywell, Allergan, PwC, City of London and the UK's National Health Service. Cora is a proven foundation for the delivery of projects, digital transformation and strategic objectives. Fully digitizing program and project lifecycles, providing total transparency, empowering decision-making, and streamlining governance and reporting. Every day, across more than 50 countries, over $20 billion worth of projects are managed on the Cora platform. Headquartered in Ireland and with regional offices in Dublin, Bedford and Boston, Cora's client base includes Allergan Pharmaceuticals, Boston Scientific, City of London, Honeywell Building Solutions and the UK's National Health Service. For more information, visit: **www.corasystems.com.**



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