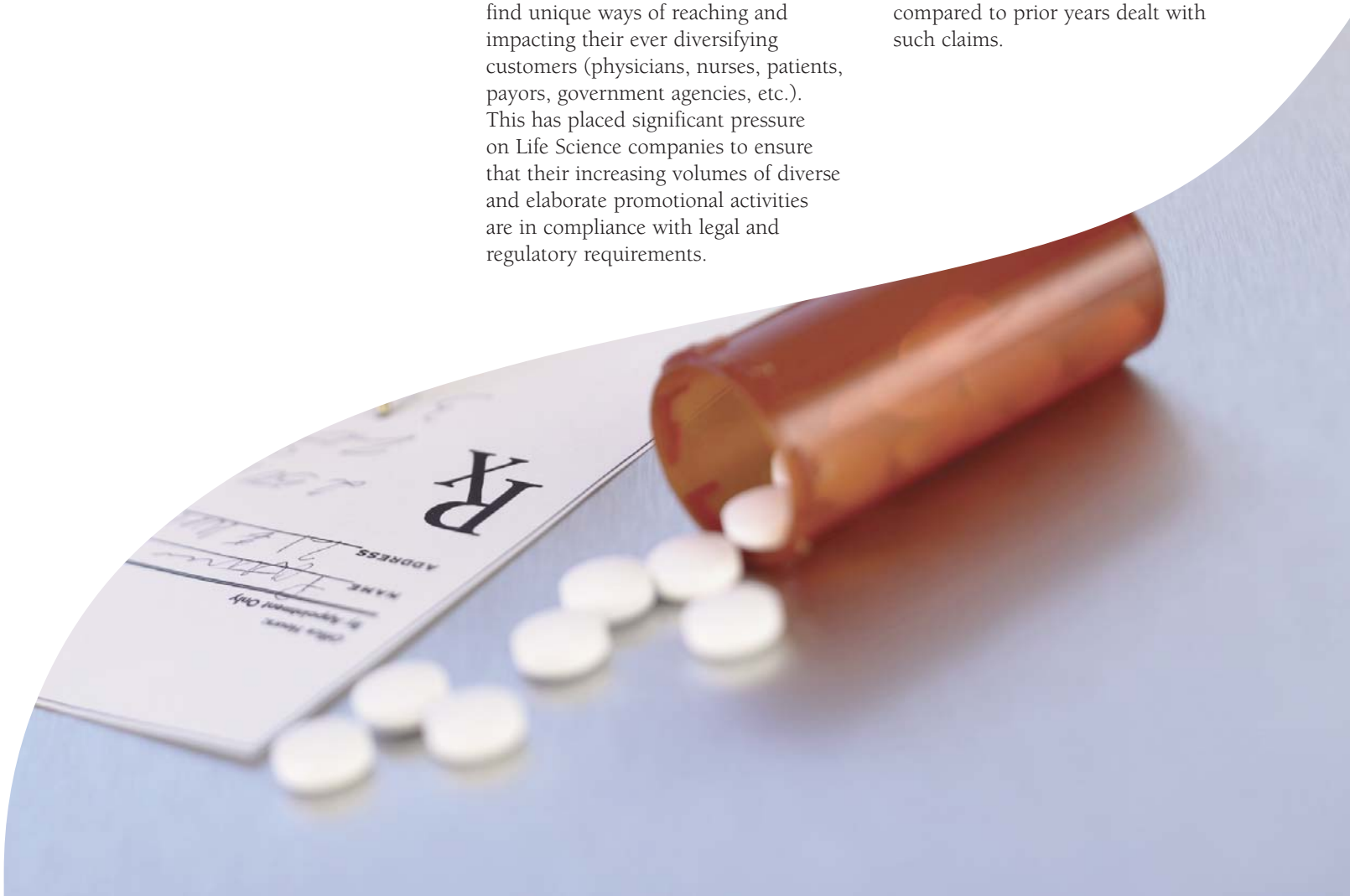
# Copy Review Process

## Necessary Burden or a Means to Enhancing Commercial Impact?

### The Balancing Act

Today's Life Science companies are constantly involved in a variety of traditional and non-traditional promotional activities such as emarketing, e-detailing, closed loop marketing, etc. These activities help in launching new products, warding off competitive challenges, or increasing market penetration. Several avenues of communication and forms of media have helped the Life Science industry find unique ways of reaching and impacting their ever diversifying customers (physicians, nurses, patients, payors, government agencies, etc.). This has placed significant pressure on Life Science companies to ensure that their increasing volumes of diverse and elaborate promotional activities are in compliance with legal and regulatory requirements.

However, these companies are not the only ones feeling the pressure. Lately, the FDA has received criticism regarding their handling of Life Science companies' direct to consumer (DTC) advertising and other promotional campaigns. Recently, they have focused on marketing and sales, particularly in dealing with unsubstantiated, comparative or superiority claims. In fact, a larger percentage of FDA-issued warning letters in 2007 compared to prior years dealt with such claims.



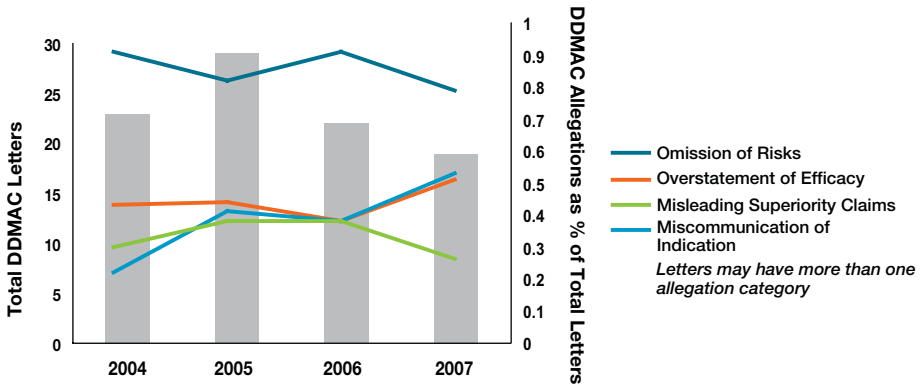
With the increasing volume of promotional activities and the added scrutiny by the FDA, significant time passes between the identification of a misleading advertisement by the Division of Drug Marketing, Advertising, and Communications (DDMAC) and the FDA's request to remove it from dissemination. This not only causes negative publicity to the company, the product and the campaign, but may also have financial impacts.

Life Science companies must be flexible and able to deal with a dynamic regulatory environment while remaining commercially aggressive. Creating a process to help deal with these dynamics goes a long way in ensuring the organization's legal and regulatory compliance in regards to promotional activities. Acknowledging that the Copy Review Process is at the heart of the balancing act, many companies are re-examining and reengineering their processes to deal with this challenge.

**The Copy Review Process is designed to balance legal and regulatory compliance with the need to be commercially differentiating.**

**An ill-defined copy review process becomes a bottleneck in a demanding and resource-intensive marketing environment.**

**Figure 1: Total DDMAC Letters and Allegations**




Source: Covington and Burling LLP, January 18, 2008

## The Bottleneck Challenge

Traditionally, brand teams have developed promotional materials with external agencies in isolation and then reviewed them in collaboration with legal, regulatory and medical teams prior to dissemination. However, today's Life Science organizations have myriad teams including brand marketing, managed markets, sales, medical, and organizational communications working on promotional materials. There is a necessity for these teams to collaborate with each other to ensure that they are in alignment with the corporate strategy, brand messaging and consistent customer communications. The legal, regulatory and medical reviewers are also starting to play a significant role in the early stages of promotional materials development.

In addition to the increased resource involvement and collaboration, the frequency and volume of review activity is dictated by product demand and life cycle. Activities such as reiterations of material, revisions, and reopening of settled issues also play a large part in creating bottlenecks and draining resources.

Without a detailed outline of process ownership and a clear definition of roles and responsibilities, organizations are quickly exposed to the risks associated with lack of compliance. This is further complicated by new trends in marketing, such as closed loop marketing, which require rapid response times in engaging with a variety of stakeholders.

In order to overcome the bottlenecks, a Copy Review Process typically consists of five major sequential sub-processes including:

- Development of the promotional material,
- Review of the material,
- Internal material approval,
- FDA submission, and
- Lifecycle management of the material.

## Three Step Approach to Designing and Implementing Efficient Copy Review Processes and Supporting Systems

In order to meet the real-life challenges of the Life Science industry, Capgemini employs a pragmatic approach that leverages lessons learned from our experience across the industry. Based on this expertise, we've developed a proven three step approach to deploying a successful Copy Review Process characterized by increased efficiency, reduced cycle time, and industrialized processes.

### *Diagnosis and Future State*

In order to deal with the complexity of a demanding and resource-draining review process, different teams in the organizations tend to develop "home grown" standards and processes. This can be further complicated by copromote situations where separate companies impose their own processes on material review and approval.

Additionally, lack of IT infrastructure to support and standardize the workflow and management of documents, only adds to the ever growing inefficiencies. It is therefore essential to get a firm understanding of the current Copy Review Process(es), the issues whether process or behavior-related, and associated root causes. Stakeholder focus interviews, review of existing processes, metrics and systems can be leveraged to formalize the current process. Review of best practice, identification of optimization levers, formulation of potential concepts, and prioritization and quick wins are also used to define the future state Copy Review Process.

These critical activities conclude with the creation of a transformation map that outlines the activities required to achieve the desired future state process.

### *Detailed Design*

This step demands constant engagement of the extended stakeholder team, executive sponsor support, and the creation of a roadmap to draft the new and efficient Copy Review Process. The key activities that need to be carried out include:

- **Process Improvement:** Quick win and high impact opportunities are further evaluated, refined and incorporated to reap the expected benefits.
- **Control Document Creation:** Standardized forms, policies and process charters ensure that there is a well articulated, understood and standardized process.
- **Governance Structuring:** A properly defined governance structure helps ensure that the process, roles and responsibilities, policies, and metrics are efficiently managed and aligned. Pre-defined governance models for various operating structures are often used to help customize the governance structure.
- **Metrics Creation and Management:** Performance metrics need to be clearly aligned within the organization, easy to understand and communicate, possible to measure and influence, and have a dedicated owner. Additionally, behavioral-based metrics are often leveraged to enable user compliance and can be used to provide a platform for user feedback.
- **Infrastructure Evaluation:** Sufficient time should be allocated to evaluate IT systems that can be leveraged to support the Copy Review Process from a work flow and document management perspective. This evaluation will enable the organization to make informed decisions during infrastructure selection and implementation to enhance the robustness of the process.

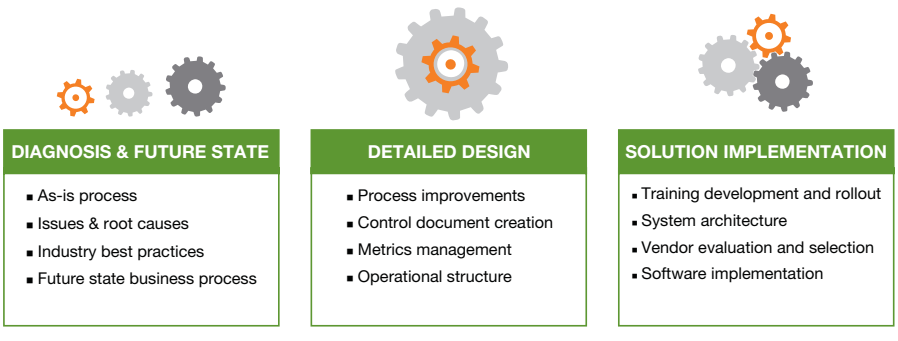
### *Solution Implementation*

A core team within the extended stakeholder team is often engaged during the solution implementation step. It is imperative to build a strong project management team to oversee all aspects of process training and IT infrastructure evaluation and rollout. The project management team will also encourage buy-in from all stakeholders, manage the process dynamics and facilitate the right levels of top-management interactions.

The implementation of the new efficient Copy Review Process can be classified into three major activities:

- **Policy, Process and Behaviors Adoption:** Users will be expected to unlearn the "business as usual" approach and adopt the new, efficient Copy Review Process. Training is one

**Figure 2: Three-Step Copy Review Process**

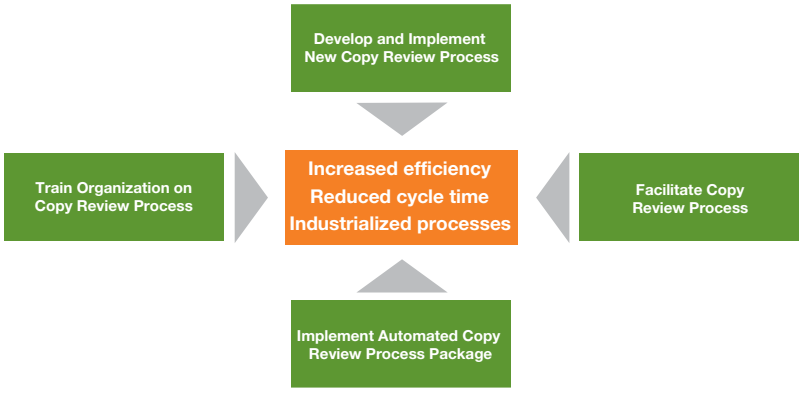



Source: Capgemini 2008

means to allow people to fully and quickly understand the benefits of new ways of working and is a powerful means of promotion and motivation. For this reason, training is a vital element in meeting the outlined challenges. Very often the stakeholders involved in the design and development of the process are leveraged in designing and delivering the training as well.

- **Roll-Out and Monitoring:** It is imperative to obtain buy-in from all stakeholders, executive sponsorship, and cross-departmental collaboration on an on-going basis throughout the implementation process. Relevant performance metrics to benchmark successes, continuous improvement efforts and quality assurance are key drivers for running an efficient Copy Review Process.
- **Infrastructure Support:** Successful roll-outs should be followed by appropriate IT systems implementations that support the process and its operating model. Within each step of the business process, requirements must be developed in key areas of Document Management System functionality (document repository, team collaboration, workflow, security, integration and publishing). This effort includes evaluating, designing, building, and validating the information system and data exchange to be used. Last, but not least, it is also essential that the appropriate IT infrastructure is efficiently managed to ensure increased process efficiency, reduced cycle time, and an industrialized process.

**Figure 3: Copy Review Value Proposition**




Source: Capgemini 2008

## Unique Capabilities to Assist Life Science Companies

As one of the world's leading providers of consulting, business transformation, IT and business process outsourcing services, Capgemini has years of experience and expertise to share with Life Science companies. With a dedicated team of experts and practitioners with unique industry references, Capgemini utilizes a collaborative, hands-on approach to help Life Science organizations address Copy Review challenges.

Through collaboration with Capgemini, your company can gain both strategic insights and operational assistance in developing and implementing an efficient Copy Review Process, training the organization, facilitating the Copy Review meetings or implementing an automated IT-enabled Copy Review system.

## About Capgemini and the Collaborative Business Experience

Capgemini, one of the world's foremost providers of consulting, technology and outsourcing services, enables its clients to transform and perform through technologies. Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working—the Collaborative Business Experience—and through a global delivery model called Rightshore®, which aims to offer the right resources in the right location at competitive cost. Present in 36 countries, Capgemini reported 2007 global revenues of EUR 8.7 billion (approximately U.S. $12 billion) and employs over 83,000 people worldwide.

More information is available at **www.us.capgemini.com.**

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