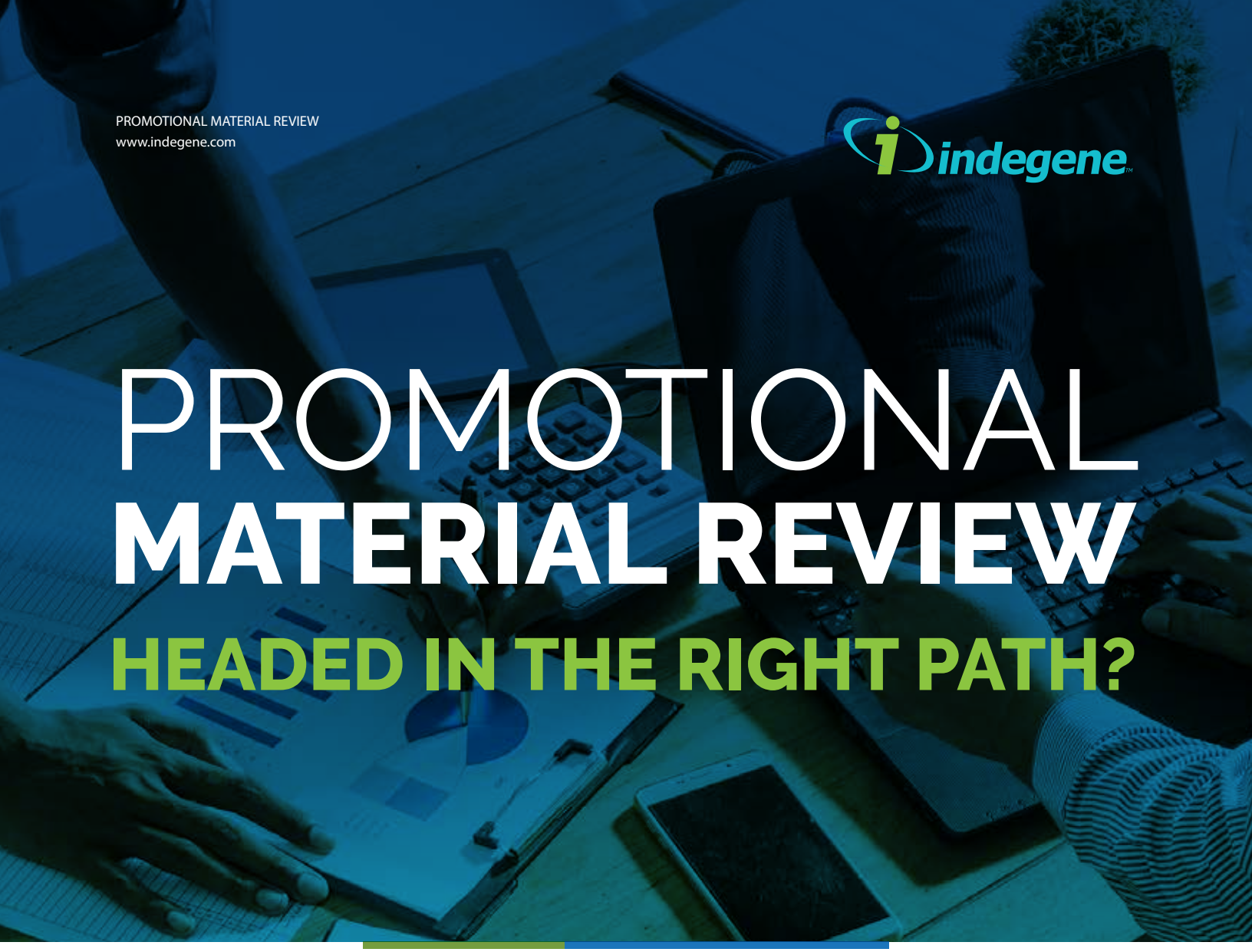


PROMOTIONAL MATERIAL REVIEW

HEADED IN THE RIGHT PATH?

INTRODUCTION AND OBJECTIVES

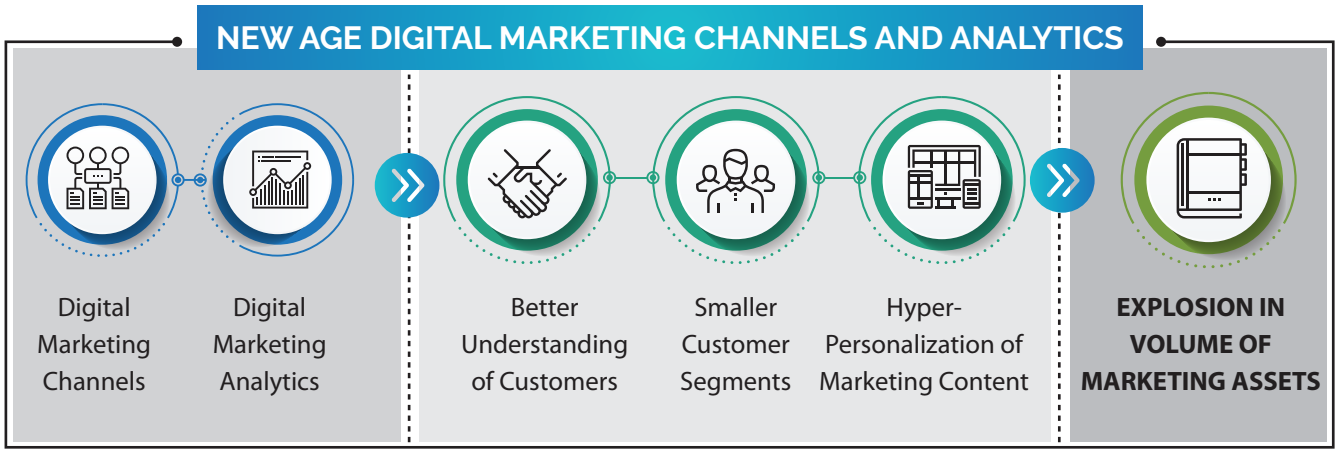
Material review is a critical function of the Medical Affairs team in pharmaceutical companies. This function is responsible for ensuring that all material—commercial or scientific exchange—contains accurate information that can be reasonably substantiated by evidence, is fair-balanced, and adheres to the regulatory guidelines of various markets.

Material review process is becoming increasingly complex today as it has to not only balance the objectives of the marketers but also the regulators. Marketers, in the face of increasing competition, are striving to ensure that assets reach the market as quickly as possible, while regulators are becoming increasingly stringent in protecting patient rights and ensuring that HCPs and patients are provided with complete, accurate, and fair-balanced information. In this paper, we take a look at the key strategic challenges that the Medical Affairs teams face today.

Understanding these challenges is a crucial step in ensuring that this function transforms to meet the needs of the foreseeable future.

STRATEGIC CHALLENGES FOR THE MEDICAL AFFAIRS TEAM

1 DIGITALIZATION OF THE MARKETING FUNCTION



The commercial teams within pharmaceutical companies are increasingly using digital marketing channels, augmented with digital marketing analytics and insights, to communicate with customers, HCPs, payers, key opinion leaders, and other stakeholders in the health care ecosystem.

Digital marketing channels such as e-mails, iDetails, pay-per-click advertising, web sites, SEO, social media, and display advertising have enabled pharmaceutical companies to reach wider audience, faster and at a fraction of the cost of traditional channels. Contemporary analytical techniques such as web analytics, app analytics, social media analytics, advertising analytics, audience analytics, and big-data analytics have enabled pharmaceutical companies to understand customer preferences and behavior better. Proliferation of these technologies, along with the reach and insights they provide, has allowed marketers to better segment the market and identify smaller customer segments.

Companies are increasingly using modern technologies such as robotic process automation (RPA), artificial intelligence/machine learning (AI/ML), and natural language processing (NLP) to personalize messaging for each of the customer segments. Marketers do not need to wait for months to analyze the performance of a campaign, as this information is usually available on a dashboard within a fraction of the time that was taken previously.

The net outcome is that there has been an exponential increase in the volume and velocity of marketing assets, putting immense pressure on internal systems and processes to turn around assets faster, without compromising quality and compliance. This exponential growth will only continue.

2 OPERATIONAL CHALLENGES

Data on the material review process at various pharmaceutical companies demonstrate the following:

KEY DATA FROM OUR EXPERIENCE ACROSS MULTIPLE PHARMACEUTICAL COMPANIES

50-60
DAYS

Average MLR review cycle per job for mid- and large-sized pharmaceutical companies

250-350
HOURS

Spent every month in MLR meetings, across stakeholders, across all BUs

50%-80%

Preventable errors in agency submissions

30%-40%

Agency files submitted for review do not follow submission guidelines

50%

Reiterations due to changes post MLR review

25%

Post-production files have errors introduced

5%-10% **FDA LATE SUBMISSIONS PER YEAR**

These operational challenges result in an increase in time to market, inaccuracies in content, inefficiencies in the medical affairs function, and possibly an increase in the probability of facing inquiries from regulatory authorities. The material review process has traditionally been the rate-limiting step in the life cycle of materials. If this reality is juxtaposed with the expected increase in the volume of marketing material, it seems unlikely that pharmaceutical companies may achieve their marketing objectives unless they significantly transform their material review process.

3 EFFICIENT USE OF MEDICAL AFFAIRS PERSONNEL

Surveys and interviews with key Medical Affairs/Commercial functions regarding the material review process reveal that

Most teams prefer a more strategic role that facilitates access and responsible use of products through stakeholder engagement by dissemination of credible scientific information.

Considerable review time is spent in correcting routine errors in grammar, style, and referencing. There is also the challenge to deal with the wide disparity in submission quality among multiple vendors.

The review process is not as efficient as it ought to be. Assets are often "gold plated," even when it may be unnecessary.

TIME TO STRATEGICALLY TRANSFORM THE MATERIAL REVIEW PROCESS

Pharmaceutical companies should consider a robust strategic material review process to meet their marketing and compliance objectives. Consider the following to potentially transform the material review process:

Augment the review process with modern technologies such as RPA, AI/ML, and NLP to improve accuracy, productivity, and efficiency. Modern technologies have evolved to a point where they could be effectively used to sensibly automate significant pieces of review work.

Improve operational efficiency by performing detailed studies of processes to identify bottlenecks in the system. Use of innovative resource allocation models, adoption of efficient SOPs, investments in continuous training, and a strong focus on continuous improvement are some of the critical activities that companies could undertake to achieve operational excellence.

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ABOUT THE AUTHOR

Sameer Lal heads the business unit responsible for medical affairs and review solutions at Indegene. He drives its overall P&L through sales and marketing efforts, capability building, innovation, and delivery. His expertise lies in building long-term strategic client relationships, developing programs to address specific business problems, and effectively delivering the desired business outcomes.

Sameer has over 21 years of pharmaceutical experience, both in the industry and on the services side. Before joining Indegene, Sameer served in a variety of leadership roles in pharma companies such as GlaxoSmithKline as well as in the healthcare advertising agency – Sudler & Hennessey.

ABOUT INDEGENE'S PROMOTIONAL MATERIAL REVIEW SOLUTIONS

Indegene is a full-thickness provider for simplified and faster material review and approval solutions. It offers a modular set of solutions that include medical review (technical and nominated signatory), editorial services (proofreading and fact-checking), and operations support (coordination, reference tagging/uploading, and asset management). Indegene's hybrid operating model is simple, scalable, flexible, and cost-effective and provides shorter time-to-market, improved accuracy, decreased compliance risk, and increased operational efficiency.

ABOUT INDEGENE

Indegene enables global healthcare organizations to address complex challenges by seamlessly integrating analytics, technology, operations and medical expertise and drive better health and business outcomes. Indegene's IP-based solutions help clients drive revenues and productivity by making transformational leaps in digitalization of customer engagement, health reform, healthcare cost reduction, and health outcomes improvement. Indegene partners with global pharmaceutical and life sciences companies to modernize their medical and commercial functions. We seamlessly combine clinical know-how with contemporary machineintelligence and process reengineering to transform traditional pharma processes.