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Good Promotion Practices Alliance

Prolifiq and Reprints Desk Team Up to Offer Compliance Solutions

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Pharmaceutical marketing fraud and abuse has been a hot topic for Congressional oversight and has helped the US Department of Justice (DOJ) earn $17 for every dollar spent on enforcement from FY2007-FY2009. That's a return on investment any marketer would be proud of.

There is plenty of attention being paid to these cases in blogs such as Pharma Marketing Blog and in the general media. Most of this attention, however, has been critical of the industry and has served to expose the problems. But there hasn't been much attention paid to good compliance solutions or best practices. That's the mission of the Good Promotion Practices Alliance (GPP), which is co-sponsored by Reprints Desk and Prolifiq Software.

About Reprints Desk and Prolifiq

Reprints Desk helps pharmaceutical companies implement FDA's Good Reprint Practices (see box) by ensuring that every reprint distributed by sales reps has been cleared by the company's legal/regulatory people (see "ePrints NRx for Physician Detailing"; PMN Reprint #95-02; http://bit.ly/PMN9502; use code '95RDE' to download it free).

Prolifiq for Life Sciences is used to organize, send and track approved digital content to healthcare practitioners. Mobile sales representatives can rapidly disseminate approved sales materials to prospective customers from their mobile devices. An embedded rules engine monitors the communication and helps users engage in Good Promotional Practices. This real-time auditing and monitoring helps regulatory people discover promotional practices that may not be compliant and correct the problem before receiving a discovery order from the DOJ.

Maureen Shaffer

Recently, *Pharma Marketing News* interviewed Maureen Shaffer, Vice President of Life Sciences for Prolifiq and the Founder, Publisher and Executive Editor of the Good Promotional Practice's blog at www.goodpromotionalpractices.com.

The Compliance How-to Gap

Shaffer contends that there's a gap between the ever-evolving rules and regulations that legal/medical executives say that pharmaceutical sales and marketers must obey and the how-to of customer-facing implementation.

"I know I'm supposed to be doing this," said Shaffer, imitating a pharma marketing professional, "I know there are huge penalties for not doing it correctly, but how do I implement it? What keeps me and my company safe?" If you are a marketer or sales person, how do you make compliance part of your daily habits?

Another missing piece is a customer-facing focus on how to comply with regulations.

The GPP Mission Statement

These are the gaps that GPP aims to close. The Alliance's "about" statement says: "Good Promotional Practices (GPP) ensure that Life Sciences companies successfully promote their products and solutions to the health care community and comply with applicable laws, codes of ethics, and accepted industry standards. The GPP Alliance (GPP) is a forum for learning about the practices and technologies that lead to a balanced approach to sales, marketing and compliance. GPP is sponsored and managed by Prolifiq Software and Reprints Desk. Join in the discussion. We are committed to an Alliance where education, collaboration, and idea sharing is priority one."

Good promotional practices refer to the composite set of policies and standard operating procedures that ensure life science companies comply with

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FDA's Good Reprint Practices

FDA guidance on the distribution to physicians of medical journal articles (reprints) on "unapproved new uses of approved drugs" by Rx drug marketers (see http://bit.ly/fHCUrk).

FDA has detailed many conditions under which this distribution of "off-label" information would be "allowed" by the FDA.

For example, reprints must "not be marked, highlighted, summarized, or characterized by the manufacturer in any way," "be accompanied by the approved labeling for the drug," "be distributed separately from information that is promotional in nature," and "be accompanied by a prominently displayed and permanently affixed statement disclosing any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer," among others.

applicable laws, ethics codes, and accepted industry standards. By adhering to GPP, life science companies can ensure that they maintain good standing as respected, ethical providers of valued information to the healthcare practitioner community.

GPP Blog
The GPP Blog is written by several industry insiders, each of whom has more than 20 years experience in their field, which includes marketing, sales, and legal/regulatory.

"Dee Mahoney, for example, worked at Pfizer as Senior Vice President, General Manager of Pfizer's Specialty Products Business Unit," said Shaffer. Mahoney partners with clients to maximize the commercial value of their product portfolios with a focus on providing solutions to help them develop a culture of compliance. "She understands how to help sales become and stay compliant," said Shaffer.

"The scrutiny on the pharmaceutical and medical device industries does not show any signs of letting up," warns Mahoney on the GPP Blog site (see "Under Investigation: 180 Qui Tams for Pharma or Device Fraud"; http://bit.ly/e17niM). "Biopharmaceutical and device manufactures must ensure that they not only have policies and procedures in place that govern lawful promotion, but must also conduct effective training that will bridge the gap between written policies and procedures and compliant field conduct."

Social Media Compliance is an Issue
While presenting at a recent RAPS (Regulatory Affairs Professionals Society) webinar ("Promotional, Scientific, and Educational Content Review Strategies for Today's Dynamic Regulatory Environment; http://bit.ly/GPPRAPS; access to this webinar is available through March 31st, 2011), Shaffer learned that only 50% of the companies attending the webinar had a cross-functional review committee who met consistently and 0% had incorporated social media in the promotional review procedures. See "*5 Short and Sweet Tips for Content Review*" for more on this (pg 4).

Resources for Good Promotional Practices
Visit the Good Promotional Practices Alliance Web site/Blog at www.goodpromotionalpractices.com for the latest posts by industry experts. There is also a Good Promotional Practices Forum (http://bit.ly/dkE10C) on Pharma Marketing Network where you can get daily updates from the GPP blog as well as the @GPPnews Twitter account.

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Good Promotional Practices Alliance (GPPa) Forum
GPP is a forum for learning about the practices and technologies that lead to a balanced approach to sales, marketing and compliance. GPP is sponsored and managed by **Prolifiq Software** and **Reprints Desk**.

5 Short and Sweet Tips for Content Review

By **Stacey Homan**
(Originally published on GPP Blog, February 4, 2011; http://bit.ly/guaJ87)

Here are five short and sweet practical basics I learned while going through the creation and management of a cross-functional promotional review committee (PRC):

1. Put the correct people in the room. You don't need every senior executive in your company to have final approval; keep it to a minimum to ensure a thorough review with a quick sign-off. However, make sure you have the final decision makers–the ones with the power to make the right judgment calls on risk and appropriateness. Marketing, Regulatory/Clinical affairs and Corporate Compliance should have a seat at the table, plus legal if you have in-house counsel. The more people that need to be present, the more time documents take to get obtain approval from everyone in the room.

2. Dedicate a weekly meeting time. Have your committee set aside a dedicated weekly appointment for the review, editing and approval of documents (the amount of time will depend on the amount of materials needing approved). The committee should meet in person to discuss all documents. This ensures that if someone has a concern regarding a specific document, it can be discussed and resolved while everyone is together, saving valuable time and avoiding potential miscommunication.

3. Paper approval works better than electronic. I'm a Millennial, so it pains me (PAINS ME!) to say that the paper signature process works better than an electronic system. Collateral and its accompanying final approval by paper signature during the weekly meeting can be uploaded into an electronic system, e.g. MasterControl, for record keeping. I once tried an entirely electronic approval system, where individuals could log in to review documents, request corrections and approve, but it was difficult for senior executives to remember to log in to approve documents.

Source: Promotional, Scientific, and Educational Content Review Strategies for Today's Dynamic Regulatory Environment (Webinar). RAPS 09/29/10.

4. Training, Training, Training. Individuals who have approval privileges should be highly trained in the laws, interpretations and enforcement trends surrounding promotional activities across geographies with an emphasis on their functional expertise in the meetings. The meeting is not a place to be reading FDA guidance documents for the first time. By the time a document enters the PRC approval process, it should have ALREADY been reviewed by Marketing to ensure proper branding, copyright permissions, grammar and spelling.

5. Be Inclusive/Communicate Broadly. All company employees should be well versed in your internal procedures, and internal guidelines should be set up for the possibility of rogue employees breaking out on their own. What happens if a random employee answers questions on Facebook or another message board? If a sales rep distributes content without a physician's request? If an engineer bypasses the system to give a presentation to a customer? These concerns should be addresses through your PRC and possibly HR.

I'm interested to hear the challenges our readers have encountered in creating a PRC for their organizations, as well as success stories or tips from which others can learn.