

WOMEN IN HEALTHCARE

Call to Action for Companies in the Life Sciences Industry



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DIA | HBA Leadership Project

Accelerating leadership talent & impact among women
in regulatory, medical, legal and compliance



NEW BUSINESS MODEL REQUIRES RECOGNITION OF REGULATORY, LEGAL, COMPLIANCE AND MEDICAL FUNCTIONS AS HIGH-VALUE BUSINESS PARTNERS

The DIA-HBA Leadership Project has announced a call to action for members of the C-Suite and Commercial Operations to proactively reach out and embrace professionals in the regulatory, legal, compliance and medical roles as high value business partners. These four functions enhance innovation, reputation and marketing excellence, which in turn drive company growth and valuation in order to meet the medical needs of the patients they serve.

BACKGROUND

In June 2012, the Healthcare Businesswomen's Association (HBA) and the Drug Information Association (DIA) launched a collaborative effort to advance the careers of women in the regulatory, legal, compliance and medical roles, and to assist companies with leveraging their functional value.

The initiative, which is known as the DIA-HBA Leadership Project, is guided by a Steering Committee of executive women representing drug and device companies from around the world.

The DIA-HBA collaboration makes strategic sense given the complementary natures of the two organizations: HBA is the premier catalyst for the leadership development of women



Participants enjoying the special DIA 2013 49th Annual Meeting workshop, DIA-HBA Skill-Building Series: A Custom-Fit Leadership Approach for Women in the Regulatory, Medical, Legal and Compliance Functions, presented by DIA and the Healthcare Businesswomen's Association (HBA) on Sunday June 23.

ISSUE 5

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VOL 5

in healthcare worldwide. DIA is the leading global scientific membership association for professionals involved in the discovery, development, and life cycle management of medical products. Its members include many representatives from regulatory, legal, compliance and medical functions.

BENCHMARK RESEARCH IDENTIFIES DISCONCERTING META ISSUE

According to Susan Cantrell, DIA Director of North America, benchmark research conducted by the project's leaders identified a disconcerting Meta issue: Regulatory, Legal, Compliance and Medical are too often perceived as support functions and necessary cost centers rather than high-value partners that generate revenue and help drive business forward.

"Professionals in regulatory, legal, compliance and medical roles

have far-reaching impact that goes beyond merely protecting companies from costly liability," Cantrell underscores.

"In addition to saving money, these functions make money, which benefits employees, customers, suppliers, channel and alliance partners, shareholders, investors and society at large."

Ilyssa Levins, DIA-HBA Co-Chair concurs: "Professionals working in these four roles around the world are business drivers at every phase of a product's life-cycle, from research and development, to registration and product promotion. They create and protect intellectual capital and are vital catalysts for cross-functional collaboration and ideation. These professionals also create efficiencies that enable companies to achieve their business objectives and maximize profitability." Levins is the president of the Center for Communication Compliance

(CCC) and an HBA Corporate Board member.

Specifically, regulatory, legal, compliance and medical functions help their companies:

- Exceed business objectives and financial targets with clinical studies that differentiate products, replenish pipelines and establish higher bars of entry for competitors
- Enjoy a competitive edge by paving the approval pathway for new indications in the shortest amount of time through new evidence generation strategies that deliver required data for payer reimbursement
- Expedite entry into key emerging markets through an intimate understanding of global registration guidelines, approval processes and more cost-effective ways to register products and protect patents

- Optimize competitive claims that are compliant with government regulations to make marketing campaigns more effective and durable. As a result, objective and compelling promotional messages about medical solutions inform healthcare professionals, patients and the general public
- Engender trust among key opinion leaders and global regulators through proactive and transparent communication about product effectiveness and safety. This enhances corporate reputation which impacts purchase intent and brand loyalty.

CHANGES OCCUR WHEN INDUSTRY BUSTS MYTHS

Industry is beginning to recognize that regulatory, legal, compliance and medical professionals are collaborative, strategic business partners and that their image as watchdogs or as technical versus strategic thinkers has become outdated. This evolution in perception is key: findings from benchmark research conducted by the industry publication *Rx Compliance Report* suggest that to sustain a competitive advantage in a compliant culture, commercial and compliance must collaborate closely and be in alignment.

Life sciences companies are already supporting the DIA-HBA initiatives by partnering with the project's leadership to host events that establish industry models and best practices. For example, an executive women's breakfast

series entitled "Myth Busters for Compliance and Commercial Alignment," convenes regulatory, legal, medical and compliance executives with their commercial marketing colleagues to identify and bust the key myths that hamper maximum collaboration.

The pharmaceutical industry is facing new challenges that require bold thinking at this time of change. When these four functions are viewed as strategic partners, the overall business can more effectively navigate today's evolving climate. "Leadership in Regulatory, Legal, Medical and Compliance play critical roles at a time when both compliance and commercial excellence need to be prioritized," says Levins. "These functions create healthy tension within an organization, providing checks and balances to reduce risk while helping drive the business through operational efficiencies, supporting strategic





decision-making and focusing on continued innovation.”

“The DIA-HBA Leadership Project’s call to action is a catalyst for continued and ongoing communications to support an ever-growing community of like-minded professionals that embrace this new business model of collaboration,” say Cantrell. She concludes: “By recognizing that regulatory, legal, compliance and medical functions are high-value business partners, and by placing more members of these functions in executive leadership positions, companies will continue to grow their businesses while mitigating risk -- an ideal combination to maximize patient care around the world.”

**CASES IN POINT:
REGULATORY, LEGAL,
COMPLIANCE AND MEDICAL
ARE MORE THAN JUST
“COST SAVERS”**

Business problem: An outdated sampling system raised red flags upon internal audit. Upon further analysis, the system was found to be inefficient.

Business solution: Compliance helped the company deliver more samples more efficiently by driving a new automated process. Since this function routinely executes industry benchmarks, it was able to recommend an approach that minimized risk and also reduced headcount in the sampling area. In turn, resources were deployed to other parts of the business.

Business problem: Physicians didn’t have access to state-of-the-art therapy with key product characteristics necessary to enhance patient adherence and persistence.

Business solution: Medical Information channeled physician dissatisfaction into a recommendation for a new product extension based on an advanced formulation. FDA approval enhanced patient outcomes with minimal investment in R&D, resulting in an increased revenue stream (estimated at \$2MM annually).

Business problem: Unnecessary rewrites of noncompliant promotional materials submitted by agency vendors were draining already limited marketing budgets. It was estimated that 25% of promotional review committee members’ time was wasted on rewrites, and that marketing budgets were further diluted to pay for agency fees to correct the materials they originally produced. (Please see article on page 74 of your December 2012 *Global Forum* [Volume 4, Issue 6] with published data.)

Business solution: Regulatory, Compliance, Legal and Medical partnered with Marketing to mandate a multi-faceted regulatory compliance education program for agencies-of-record to enhance promotional efficiencies and effectiveness. These agencies agreed to pay for compliance education as part of their ongoing investment in the client relationship. (\$1MM+ in projected agency fees to be reallocated; plus an equivalent of \$1MM+ in time saved by promotional review teams; or a total annually of \$2MM for 10 marketed brands.)

Business problem: A limited indication for a currently marketed product hampered the company’s competitive advantage.

Business solution: Medical and Regulatory designed an innovative clinical study to prove the product’s safety/efficacy in medical cases where competitors had no indication. The company gained FDA approval, driving market leadership and rapid global penetration.

Business problem: Government requirements under consideration would require costly product changes for the company’s entire franchise.

Business solution: Legal, Regulatory and Medical developed alternative solutions that addressed the requirement and further enhanced patient care. As result, the company was able to reinvest money earmarked for these requirements into continued innovation (estimated at \$50MM+). ●