



By Carolyn Gretton

▶ DIA and HBA Collaborate on Women's Leadership Project

TREND: The associations' career-building initiative focuses on regulatory, medical, legal, and compliance functions within the life-sciences industry.

The DIA/HBA Leadership Project is a multiyear initiative launched by DIA and the Healthcare Businesswomen's Association (HBA) to advance the careers of women involved in the regulatory, medical, legal, and compliance functions of healthcare.

The project is led by a steering committee of senior-level women representing pharmaceutical, biotech, and medical device companies, co-chaired by Ilyssa Levins, president of the Center for Communication Compliance (CCC), and Minnie Baylor-Henry, DIA president-elect and VP of worldwide regulatory affairs at Johnson & Johnson Medical Devices and Diagnostics. The committee is developing a plan for building a community of like-minded professionals who share insights into how to nurture and inspire leadership; creating and implementing a skill-building road map for success; and shaping the direction of women's initiatives currently under way and in development to support the regulatory, medical, legal, and compliance functions.

"Women involved in the regulatory, medical, legal, and compliance functions of healthcare can positively enhance an organization's reputation, value, and diversity while stimulating innovation and maximizing the effectiveness of their commercial operations," Ms. Levins observes. "We must accelerate the growth of their leadership skills and increase their impact on the changing business and regulatory environments."

Ms. Baylor-Henry adds that the initiative is aimed at building portable and visible skills that go beyond mere technical expertise.

"The partnership will also establish women in regulatory, medical, legal, and compliance as strategic business partners within an organization," she says. "Both are practical goals designed to benefit current and future leaders."

▼ For more information, visit hbanet.org.



Ilyssa Levins



Minnie Baylor-Henry

tensive launch planning process by combining Quintiles' consulting, clinical, and commercial expertise with state-of-the-art software. The service can be customized to each company and product to help identify key market challenges, fast-track launch rollout, and improve efficiency in resource management.

According to Dean Summerfield, VP, consulting, for Quintiles, biopharma companies are looking for new ways to optimize product value, expedite market access, and mitigate commercialization risk, yet retain asset value while reaching patients across diverse geographic regions.

"To maximize value, they need to start planning product launch early in the drug development process, especially when preparing to enter new geographic markets," Mr. Summerfield says.

"Allume coordinates decision-making around the late phases of development as well as the launch of an asset," adds Michael Ackermann, Ph.D., senior VP, global commercial solutions, at Quintiles. "It is a well-structured and interactive way of accessing the expertise customers need without surrendering strategic control of their asset."

▼ For more information, visit quintiles.com.



Dean Summerfield



Dr. Michael Ackermann

VIDEO THE DIA/HBA LEADERSHIP PROJECT



Leaders from the DIA and HBA discuss this unique partnership.

bit.ly/DIAHBA-leadership

Allume Helps Biopharma Navigate Market Entry

Quintiles has launched **ALLUME**, a comprehen-

sive go-to-market service to help biopharmaceutical companies efficiently launch new products and shorten timelines to peak sales while retaining strategic and corporate control of their assets.

Allume organizes the complex and resource-in-

In other news...

Parexel has created a dedicated unit focused on the needs of small and mid-sized biopharmaceutical companies to help them achieve their development goals.

The Parexel BioPharm Unit seeks to support this critical pipeline by providing the precise expertise, global infrastructure, operational excellence, and turnkey technologies needed to help small biopharmaceutical companies advance their drugs through the development cycle.

The unit is designed to provide each company

with a senior management leader and dedicated team offering ongoing, frequent communication and proactive solutions that provide the opportunity to accelerate patient recruitment, increase the speed of clinical trial study start-ups, shorten the time to database lock, and improve the overall efficiency for meeting critical development milestones.

"The creation of the Parexel BioPharm Unit is especially important for small pharma and biotech sponsors that have needs that are meaningfully different from large pharma sponsors," says Ubavka DeNoble, VP of biopharm services for Parexel.

▼ For more information, visit parexel.com.

Advanced BioHealing, acquired by Shire Plc. in 2011, has changed its name to **SHIRE REGENERATIVE MEDICINE**

as part of plans to build a regenerative medicine campus in San Diego to expand Shire's operational footprint and presence in the area.

"Becoming Shire Regenerative Medicine is an exciting milestone that more closely aligns us with our parent company and demonstrates our commitment to providing regenerative medicine solutions that enable people with life-altering conditions to lead better lives," says Kevin Rakin, president of Shire Regenerative Medicine.

▼ For more information, visit shire.com.



Renee Selman

Catalina Health and other healthcare partners are disseminating newly designed **PATIENT MEDICATION INFORMATION (PMI)** to patients filling prescriptions at participating pharmacies as part of a quality improvement (QI) initiative with the goal of providing patients clearer medication information.

Through voluntary telephone and online responses, Catalina Health is surveying patients to confirm they received the newly formatted PMI, assess whether they found the information useful, and determine how they would like to receive PMI in the future.

All survey data collected by Catalina and other healthcare partners will be kept in accordance with all federal and state privacy laws.

"Patients frequently receive safety information about their prescriptions that is difficult for them to understand and too often not followed correctly," says Catalina Health President Renee Selman.

▼ For more information, visit catalinamarketing.com/health.



Dr. David Segarnick

MedEvoke is a new division at **MEDISYS HEALTH COMMUNICATIONS** dedicated solely to Medisys' proprietary ISIS (Integrated Scientific Information Sharing) methodology designed to

align global teams from Phase II/III through launch.

The MedEvoke division is headed by Chief Medical Officer David Segarnick, Ph.D., and offers global alignment and scientific platform development, services distinctly different from traditional medical communications business.

MedEvoke's core offering, ISIS, translates complex scientific and medical data into narratives that articulate a product's key attributes and clinical benefits across the useful life of the brand.

"Products in development today are designed to address treatment-resistant diseases — advanced cancers, cardiovascular, and neuropsychiatric diseases — with novel targeted mechanisms of action," Dr. Segarnick says. "At the same time, pharmaceutical and biotechnology companies are increasingly dispersed geographically and functionally with fewer resources to do more complex work. ISIS creates scientific platforms that enable organizations to speak effectively with one voice around the world to all constituents on the most intricate and subtle of scientific medical and marketing issues."

"ISIS fulfills a different need than traditional medical communications," adds Medisys Founder and CEO Anna Walz.

▼ For more information, visit medisyshealth.com. PV



Anna Walz

AROUND THE GLOBE ►►

Gilead Sciences is collaborating with global specialty and generic company Mylan Laboratories and India-based firms Ranbaxy Laboratories and Strides Arcolab to promote access to high-quality, low-cost generic versions of **GILEAD'S HIV** medicine emtricitabine in developing countries. Gilead is to provide a technology transfer for the manufacture of emtricitabine, together with funding to assist with investment in process improvements to reduce overall manufacturing costs.

▼ For more information, visit gilead.com.

Global biopharmaceutical services provider Parexel International has been selected by the Korea Drug Development Fund (KDDF) to help Korean companies develop and commercialize healthcare products for the global market. The KDDF is working with Parexel to establish various

collaborative channels providing essential resources to Korean academic and research institutions and biopharmaceutical companies.

▼ For more information, visit parexel.com.

Prexton Therapeutics is a Geneva-based spinoff company built around **MERCK SERONO'S R&D** portfolio in the field of Parkinson's disease. Prexton is focused on programs that target the metabotropic glutamate receptors mGluR3 and mGluR4.

▼ For more information, visit merckserono.com.

Quintiles has opened its Global Commercial Solutions business in Brazil, offering customized salesforces, market penetration strategies, and product solutions to help biopharma companies looking to expand into the growing Brazilian market. Leading the business is General Manager Vera Valente, based in Quintiles' offices in São

Paulo. Most recently, Ms. Valente was a director at Interfarma (the Brazilian Pharmaceutical Research Companies Association).

▼ For more information, visit quintiles.com.

United Drug Plc. has agreed to acquire Pharmexx from Celesio AG to expand its growing international contract sales capability. The addition strengthens United Drug's U.S., U.K., and Irish businesses. Pharmexx joins the Ashfield Group of companies that sit within the sales, marketing, and medical services division of United Drug.

▼ For more information, visit united-drug.com.

Verum, a full-service, German-based CRO, has opened a new office in Carlsbad, Calif. The company opened the office to make its clinical trial services more readily available to U.S. clients.

▼ For more information, visit verum.de.