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Gender gap

The life sciences industry suffers from a lack of gender diversity at all levels and at all stages of developing new technologies, writes Susan Windham-Bannister, president and CEO, Biomedical Growth Strategies LLC, in Life Science Leader. Research by the Association for Women in Science found that in the last two years only 2.2 percent of total venture capital dollars and less than 15 percent of angel funds went to companies started or led by women, she says. In addition, from 2011 to 2013, only 3 percent of all venture capital dollars in the U.S. went to companies with a woman CEO, and only 15 percent of the companies receiving venture capital investment had a woman on the executive team.

Breakthrough devices and the FDA

The Food and Drug Administration issued final guidance for the agency's new Breakthrough Devices Program. The program was established by the 21st Cures Act to provide developers with a more agile process to get feedback from the FDA during the premarket clearance process. Sponsors of devices obtaining breakthrough status will receive "interactive and timely communication" with assigned FDA staff, as well as clear communication of the agency's expectations. Breakthrough devices, which includes those granted designation under the FDA's Expedited Access Pathway, will be placed at the top of the review queue; however, review times for these devices might still be longer than for other devices because of the "novel scientific issues these devices may raise," the FDA wrote. Click here to view a statement from FDA Commissioner Scott Gottlieb, M.D., and Jeff Shuren, M.D., director of the FDA's Center for Devices and Radiological Health.

Intellectual property: What can be patented these days?

The move toward connected medical devices has a major effect on one of the most important considerations for a medical device company -- intellectual property, says Roman Fayerberg, a Greenberg Traurig patent attorney, in a recent issue of Medical Design and Outsourcing. Patent attorneys have been working to protect IP for products such as catheters and stents for a long time, he says. The situation, however, is changing now that there are more supplemental technologies such as connected functions, software, augmented reality and artificial intelligence. Expect more guidance from the U.S. Patent and Trademark Office about what a medical device company is able to patent or not patent in terms of such supplemental technologies, according to Fayerberg. "It's very important to have that strategy: How do you protect your core product, and how do you build a fence around it?"

Needed: Physician innovators

We are on the cusp of a new generation of tech companies that can improve health and healthcare, write two researchers in Stat News. But a lack of physician innovators can hinder startups that lack an understanding of clinical needs at the patient-physician level. One reason for the shortage is that many physicians lack the desire to make the jump to startups. Doctors are, after all, trained to be cautious, not disruptive; to follow strict, evidence-based patterns of reason, not take shortcuts; and to be guided by the consensus of well-tested research, not necessarily a new and perhaps yet-to-be tested innovation, report the researchers. Even so, there are increasing signs that physicians are intrigued by the prospect of interacting with innovators and startup founders. For example, the American Medical Association's Physician Innovation Network is a growing online community of physicians seeking to collaborate with entrepreneurs. In Silicon Valley, the AMA-founded Health2047 connects a network of entrepreneurs, corporate partners, and physicians from across medicine to identify critical health issues and develop solutions. Two companies have already been spun off, and more are in the pipeline. And medical schools such as the Dell Medical School at University of Texas, Austin, or Sidney Kimmel Medical College at Jefferson University in Philadelphia are now embedding a focus on innovation and entrepreneurship into their curricula.

Value analysis training

Do you or your manufacturer partners – or both – need training in value analysis? Dee Donatelli Consulting, LLC, in conjunction with the Association of Healthcare Value Analysis Professionals (AHVAP), will sponsor the inaugural Value Analysis Apex (VAApex™) event, to be held March 7-8, 2019, in Dallas, Texas. The VAApex forum will assemble a faculty of leading value analysis experts, who will guide supplier sales and marketing executives through a 1 ½ day curriculum "designed to build a profound understanding of the hospital value analysis process, in turn providing healthcare suppliers with and effective ways to introduce products to hospital value analysis committees," according to organizers. For more information, go to www.VAApex.com