

## **An Affygility Solutions White Paper: Ten EHS Trends in the Biotechnology, Pharmaceutical, and Medical Device Industry for 2012**

by Dean M. Calhoun, CIH, President and CEO of [Affygility Solutions](#)

Well another year has gone by, and it's time for the Affygility Solutions' annual trends in environmental, health and safety (EHS) in the biotechnology, pharmaceutical, and medical device industry. While some people hate trends and forecasts, I believe they are absolutely necessary for both short-term and long-term strategic planning. So here we go.

1. **Global harmonization system (GHS) in the U.S. will become reality.** No big surprise here, the environmental, health and safety community has been waiting on this one for quite sometime, but it will happen in early 2012. So if your responsibilities include the [authoring of safety data sheets \(SDSs\)](#), training of employees in hazard communication, or the like, you need to be ready. Safety data sheets will need to be revised to incorporate the new information, written programs will need to be updated, training in the meaning of the GHS pictograms will need to be performed, etc. One area will cause confusion, and one that will require careful training, will be that under GHS, Category 1 is the most toxic, and under most [potent compound safety](#) schemes, Category 1 is the least potent.
2. **Criminal enforcement of occupational health and safety regulations on the rise.** Potential criminal actions against UCLA<sup>1</sup>, Imperial Sugar<sup>2</sup>, and British Petroleum<sup>3</sup> have shown that regulators are out to prove a point – violate the rules and you will pay. In order to prevent aggressive legal action, companies need to make sure that they have effective compliance management systems in place to ensure ongoing regulatory compliance, and [corrective actions](#) when deficiencies are discovered. With the vast number of EHS regulations and other requirements that a typical life science company must comply with, [EHS software](#) systems are a must.
3. **ISPE will issue its revised [Good Practice Guide on Assessing the Particle Containment Performance of Pharmaceutical Equipment](#).** However, I don't

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1 Los Angeles Times. December 28<sup>th</sup>, 2011. Felony charges filed against UC and a UCLA chemistry professor after fatal laboratory fire. Online at:

<http://www.latimes.com/news/local/la-me-1228-ucla-death-20111228,0,7543387.story>

2 Savannah Morning News. February 7<sup>th</sup>, 2011. Feds still might be seeking criminal charges against Imperial Sugar. Online at: <http://savannahnow.com/news/2011-02-07/feds-still-might-seeking-criminal-charges-againgt-imperial-sugar#.Tv9tXSP1KDI>

3 Fox News. December 28<sup>th</sup>, 2011. First Criminal Charges Prepared in BP Oil Spill. Online at: <http://www.foxnews.com/us/2011/12/28/first-criminal-charges-are-prepared-in-bp-oil-spill/>

expect to see significant changes in how containment validation and surrogate monitoring is performed. If you want more information on [containment validation and surrogate monitoring](#), I would suggest that you listen to the [Biopharma EHS podcast episode no. 17](#).

4. **Skilled environmental, health and safety people will be increasingly difficult to find.** I have brought up this point for the last several years – there are very few young people entering into the environmental, health and safety field. According to the National Institute for Occupational Safety and Health (NIOSH)<sup>4</sup>, over the next 5 years, employers plan to hire at least 25,000 occupational safety and health (OSH) professionals, but only about 12,000 new graduates are expected from the academic programs that fill the need. As indicated in the NIOSH report, the above hiring estimates include new or replacement positions. What does this mean to the biotechnology, pharmaceutical, and medical device industry? With venture-capital funding in the life science sector bouncing back,<sup>5</sup> it means two choices – you either recruit away an experienced environmental, health and safety professional from another life science company; or, you hire a new graduate and expect to spend a lot of time training them in the life science industry specifics. For smaller life science companies with limited internal resources, expect to use and budget for consulting support in specialized areas such as [industrial hygiene](#), [occupational toxicology](#), and [potent compound safety](#).
5. **OSHA-Social!** The Occupational Safety and Health Administration, NIOSH and other regulatory agencies will finally get a handle on social media. While many people thought that social media was just a passing trend, by now, most have figured out that social media is not going away. In addition, with the explosive [growth in smartphone usage](#) and younger generations entering the workforce, smartphones will become the preferred communication channel on important environmental, health and safety issues.
6. **Come hangout with us!** In 2011, technology giant Google released Google+. As Google+ began to gain momentum, in late 2011, Google released [Google+ Hangouts](#), which is an incredibly simple way to have a videoconference with anyone in the world – and for free. Recently, it has been reported that Google+ is adding 625,000 new users each day, and will reach 400 million users by the end of 2012<sup>6</sup>. In 2012 expect to see significant growth in the use of Google+

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4 National Institute of Occupational Safety and Health. October, 2011. National Assessment of the Occupational Safety and Health Workforce. Online at: <http://www.cdc.gov/niosh/oshworkforce/>

5 Bloomberg. July 11<sup>th</sup>, 2011. Biotechnology Bounces Back With 46% Rise in Venture Capital. Online at: <http://www.bloomberg.com/news/2011-07-20/biotechnology-bounces-back-with-46-rise-in-venture-capital.html>

6 Computer World. Researcher: Google+ growth accelerating, passes 62M users. Online at: [http://www.computerworld.com/s/article/9223076/Researcher\\_Google\\_growth\\_accelerating\\_passes\\_62M\\_users](http://www.computerworld.com/s/article/9223076/Researcher_Google_growth_accelerating_passes_62M_users)

Hangouts, both internally within an organization and externally by professional organizations.

7. **The merging of occupational health and general wellness programs.** With the continued rise in health care costs, many companies have recognized the benefit in having healthier employees by implementing corporate wellness programs. For example, at Johnson & Johnson, a pharmaceuticals and consumer health products company, a four-year wellness program involving more than 18,000 workers saved the corporation \$8.5 million per year in reduced health-care costs<sup>7</sup>. With the focus of life science companies being disease prevention, and improving the quality and longevity of life, it only makes sense that they start with programs and initiatives for their own employees. Many environmental, health and safety professionals can expect that some of the responsibility for implementing these programs will land in their department.
8. **Growth of continuous biosensing for occupational health.** While the technology is still very early in its development, always-on biosensors are being developed, which will provide us with detailed data about our bodies and their interactions with food, drugs, our activities, and our surroundings. These types of sensors for assessing basic health information are already on the market, and sensors for detecting chemicals have been made in research laboratories.<sup>8</sup> Coupled with health-aware environmental applications, geo-location capabilities, and near field communication devices; biosensors on our bodies and in the environment may provide a more detailed understanding of occupational health risks. The growth opportunities for biosensing devices are almost limitless.
9. **Continued growth in remote EHS training and webinars.** Over the past several years, many companies have experienced significant growth in a distributed workforce – employees that don't report into a physical fixed location<sup>9</sup>. While many of these employees are sales or support staff, there is still the need to provide them with basic environmental, health and safety training. Fortunately, improvements in technology have made remote training and webinars much more cost-effective, efficient, and timely. In addition, enhancements in smartphone apps and tablet computer technology has made it entirely possible to conveniently attend a training course while sitting in your home-office or airport. In 2012, if your organization is not conducting [computer-based EHS training](#), you're already fallen behind.
10. **Continued interest in nanotechnology.** It has been recognized that the use of nanoparticles are promising tools for improving drug delivery, medical imaging,

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7 Pittsburgh Post-Gazette. May 11<sup>th</sup>, 2008. Companies offer wellness programs to cut insurance costs. Online at: <http://www.post-gazette.com/pg/08132/880660-28.stm>

8 Meyyapan, M. Nano chemical and biosensors. NASA Ames Research Center.

9 Fox News. July 5, 2011. Distributed Workforce: More than a Trend. Online at: <http://smallbusiness.foxbusiness.com/entrepreneurs/2011/07/05/evolution-employment-todays-free-agents-core-to-business-growth/>

and in the use of diagnostic sensors<sup>10</sup>. In 2012, this technology demands that we improve our understanding of potential occupational health and safety risks of nanomaterials.

So there you have it, Affygility Solutions' trends to follow it 2012. In 2012, look for Affygility Solutions to present [audio podcasts](#) on each of these important topics.

### **About the Author**

Dean Calhoun, CIH is the President and CEO of Affygility Solutions, and has over 27 years of professional environmental, health and safety experience. Mr. Calhoun is an American Board of Industrial Hygiene Certified Industrial Hygienist. Mr. Calhoun has Masters degrees in Environmental Policy and Management, and Technology Management for the University of Denver. Mr. Calhoun can be contacted at [dcalhoun@affygility.com](mailto:dcalhoun@affygility.com) or by calling 303-884-3028.

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