

## Intelcius European Sales Director Presents at FDA Summit

March 2013

### Steve Healy Talks Risk Assessment & Contingency Planning

March 19, 2013, Bethesda, MD – Steve Healy’s presentation addressed contingency planning and he was the plan for Intelcius. Months ago a representative from FDA News contacted Intelcius Americas CEO, Andrew Mills, about speaking at the summit to which he agreed. Not long after, Andrew and his wife got the news that their second baby was due to arrive at about the same time as the summit. The risk assessment was complete. Not wanting to be out of town at such a time and intending to fulfill the commitment, it was time to develop a contingency plan.

**“Maybe the World Isn’t Coming to an End, But It Sure Seems Like That on Some Days — Contingency Planning Best Practices for**

**Biopharmaceuticals GDPs”** is the topic that Andrew was asked to present. The conference brochure touted, “Risk is your enemy. Risk assessment can be your best friend. Expert Andrew Mills will guide you through the importance of a robust risk

#### Here are the cold, hard facts

- In the U.S. up to 40% of businesses affected by a natural or human-caused disaster never reopen according to the Insurance Information Institute
- Of the 70-80,000 workplaces that experience a serious fire annually, 85% are caused by factors related to human behavior\*
- The bottom line is to prepare for the worst and hope for the best
- And have backup plans for the backup plan for the backup plan



\*<http://www.memun.org/RMS/LC/bestprac/fire.pdf>

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assessment program, and offer a case study analysis of how getting it wrong can damage your company's business plan — and how to fix it before a crisis hits. Learn how to find and fix your company's biggest weaknesses with a triage approach that is prioritized and budget-conscious.

- Learn about the most common problems companies overlook in their risk assessment — and how to find long-term solutions, not just a “patch.”

- Get up-to-the-minute tools and strategies that will keep you ahead of looming risk challenges.”

Instead, Steve Healy stepped in to make the presentation to the “regulators, GDP pioneers, policymakers, risk management experts, consultants and fellow executives from FDA-regulated manufacturing enterprises from coast to coast and around the world.” The audience was very engaged while Steve explained the importance of risk assessment, business impact analysis and contingency planning for every organization.

## Intelsius Contingency Plan Pays Off

He was honored to join fellow executives addressing “50 Solutions to Stability and Security Challenges” they included:

**Michele Johnson**, Supply Chain Advisor, Cubist Pharmaceuticals (Co-Chair)

**Gary Hutchinson**, President, Modality Solutions LLC, formerly Director of Global Transportation, Amgen (Co-Chair)

**Barbara Falco**, President, Barbara Falco Pharma Consulting, former QA Director at Abbott Laboratories

**Ash Patel**, Associate Director, Product Security & Brand Integrity, Biogen Idec

**Rebecca Gentile**, Senior Specialist, Quality, Global Vaccine & Biological Stability, Merck

**B. Brett Heavner**, Partner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

**Kim Egan**, Founder, Saltbox Consulting, formerly Partner, Co-Chair Health Care Sector, Co-Chair, Clinical Trials Working Group, DLA Piper LLP

“I am delighted to fill in for Andrew on this occasion,” said Steve. “The audience got the importance of contingency planning just from me being there.” But the cold, hard facts are what kept the audience interested.

He used recent events to emphasize the importance of risk assessment and business impact analysis by using the damage done to the Carnival Cruise Lines brand during recent events as an example.



## Steve Healy Presents to the Biopharmaceutical Good Distribution Practices Summit Sponsored by FDA News

He also addressed how some in the scientific community were well prepared for Super Storm Sandy last fall and others lost millions of dollars in valuable research animals due to their facilities being swamped before their contingency plans could even be executed.

Steve concluded, “Just when Carnival thought it couldn’t get any worse. The last night of the ship being towed they ran into bad weather and had to slow down even more than the jogging pace of 6 miles per hour they previously enjoyed. That added several more hours to the estimated time of arrival in Alabama. Then the tow line on one of the tugs broke and added several more hours while a new boat and line came out to complete the towing.

The ship finally arrived at 9:15 p.m. EST on Valentine’s Day night. One WEEK after it left on its four day cruise. Some of the ship’s passengers who boarded a bus to New Orleans were stranded on the side of the road when the bus broke down half way there. I think this takes Murphy’s Law to a whole new universe and might rename it ‘Carnival’s Law.’” He also noted that Carnival experienced another blow to its brand last week when another ship, Carnival Dream, became a nightmare while docked in St. Maarten.



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