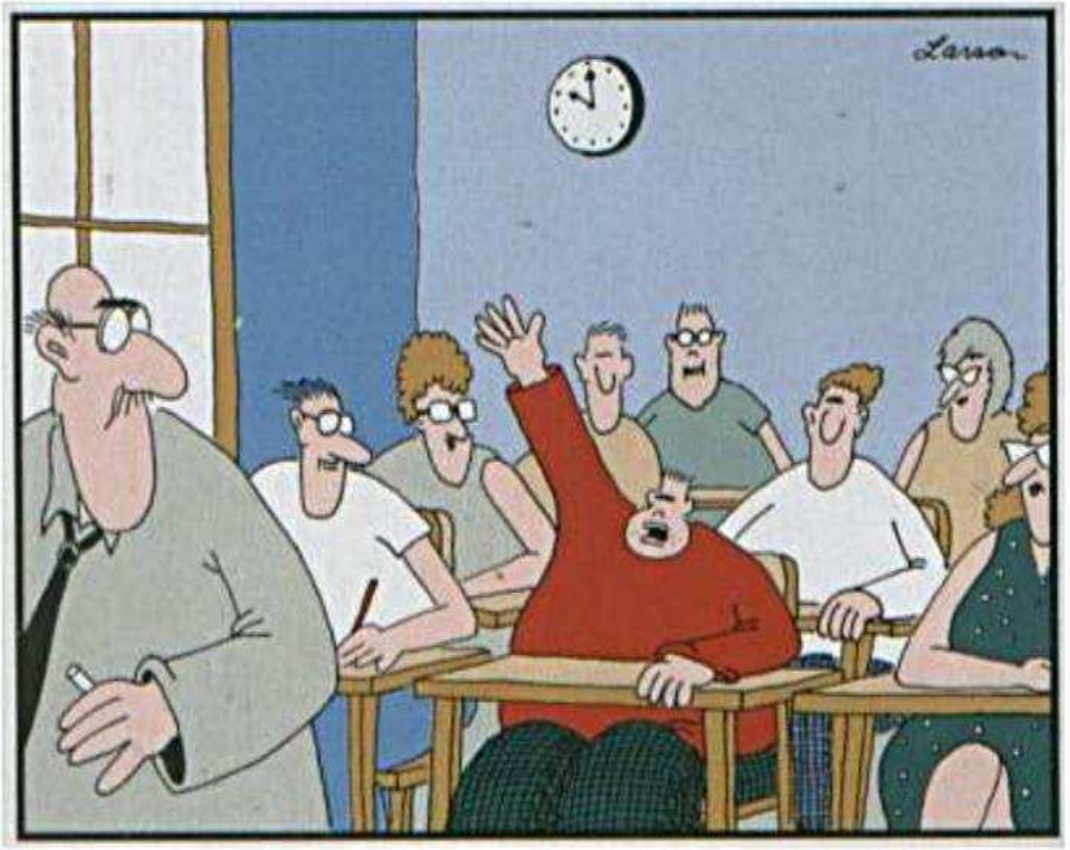
Wrap-Up and Final Questions



"Mr. Wong, may I be excused?
My brain is full."

Summary

- Supplier Management is a complex process
- One valuable source of advice is the GHTF/IMDRF guidance documents
- Supplier risk has two aspects
  - There is risk to the device from the components and services
  - There is risk in the supply chain
- A Supplier Control Plan can help reduce both kinds of risk

Summary

- Initial supplier evaluation and selection uses three tools:
  - Supplier questionnaire
  - Remote due diligence
  - Onsite audits

- All three methods should identify and utilize any QMS-relevant certificates the potential supplier holds

- Virtual suppliers are an increasingly large part of the supply chain
  - Techniques to evaluate, select, and control virtual suppliers may be very different than conventional suppliers

Summary

- Supplier metrics are an important part of re-evaluation
  - The questionnaire, remote audit, and onsite audit help predict future performance
  - Metrics demonstrate results and allow for informed decision-making
  - Be careful about waiting for FDA's metrics….

- Records are a two edged sword
  - Unless there is a record, "it didn't happen"
  - Too many, or the wrong kind of, records can create trouble

More Successful Tips

- Distribute reminders about good supplier oversight principles via quarterly emails
  - example email subject lines:
    - "So you need to pick a new supplier"
    - "What Quality verifies with a supplier and why"
- Obtain an independent audit of your supplier oversight
- Combine an independent audit with management training
- Conduct an annual training refresher for anyone with budgetary authority:
  - review supplier management requirements
  - review your company's processes and program overview

Action Plan to Consider

Write three (3) things that you will do in the next 30 days to improve your supplier oversight

Examples:

- Set up a supplier dossier file for each critical supplier
- Bring in someone independent to assess our processes
- Revise our qualification SOP to handle virtual suppliers
- Summarize my learnings & recommendations from this workshop for my management

About Your Presenter

Dan O'Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.

Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.

He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.

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About Your Presenter

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John Avellanet gives practical, compliance solutions and streamlines quality systems for clients around the world. Winner of the 2009 & 2011 Best of Business Services award by the Small Business Commerce Association, Mr. Avellanet has earned international acclaim for his business-savvy, pragmatic FDA compliance advice.

He most recently served as the industry expert reviewer for the international standard, BSI 10008 *Evidential Weight and Legal Admissibility of Electronic Information* (2015). He is the lead expert for the ISPE GAMP Data Integrity Working Group.

In 2014, he co-authored the book, Pharmaceutical Regulatory Inspections, with several current and former regulatory agency officers, and his industry classic, Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine (2010), was originally featured at BIO 2011 and garnered multiple five-star reviews from industry publications, blogs, Amazon.com readers, and former FDA officials.

He has a breadth of experience designing, implementing, and being accountable for quality systems and compliance programs for FDA, DEA, ICH, GHTF/IMDRF, and ISO. For more than 15 years, John was directly accountable for regulatory compliance, records management, and information technology, most recently as a C-level executive for a *Fortune 50* combination device firm.

In 2006, Mr. Avellanet founded his independent lean compliance consulting and training firm, **Cerulean Associates LLC**.

Final Questions?

thank you

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