Cognizant hosted a January 2015 webinar to discuss trends and issues in the current medical device space, including managing compliance without sacrificing innovation and growth; adapting to regulatory trends; potential changes and trends for 2015; and how companies can effectively use IT solutions.

**EXECUTIVE SUMMARY**

Staying on top of changes and trends in the medical device space is key to bringing products to market and ensuring their success. Given the current state of the industry, companies are always looking for innovative ways to grow, as well as to invest in research and development. As guidelines and mandates are constantly evolving and changing the way both new and updated devices are approved, harnessing IT solutions can help medical device companies better manage compliance issues, as well as manage customer service and complaint issues.

**OUR PANEL OF EXPERTS**

- **RONNIE TODDYWALA**  
  CEO, Nostrum Technologies

- **JANET TRUNZO**  
  Senior Executive Vice President of Technology and Regulatory Affairs, Advamed

- **SRIRAMAN NAGARAJAN**  
  Vice President, Life Sciences Practice, Cognizant Technology Solutions

“Our cloud-based solution truly integrates the sale, the service, and the complaint in a manner that is seamless and enables you to manage your clients and complaints much more efficiently. It’s a game changer.”

– Sriraman Nagarajan
WHAT IS THE BIGGEST COMPLIANCE ISSUE FACING THE MEDICAL DEVICE SPACE TODAY?

*Results from a recent Cognizant webinar poll of medical technology professionals

STAYING ON TOP OF COMPLIANCE ISSUES

1. Implementing technology solutions that enable the tracking and prevention of issues
2. Continuously monitoring the regulatory environment that could affect your business
3. Training employees
4. Staying on top of compliance issues and trends through internal audits

OVERVIEW OF THE MEDICAL DEVICE SPACE TODAY

The medical device space is dynamic; as the industry continues to innovate and develop new technology it’s also faced with a changing regulatory environment. As one example, the FDA Safety and Innovation Act of 2012 reauthorized medical device user fees for another five years, and several regulatory reform provisions were issued around the interpretations of the standard of approval for the investigational device exemption process. Additionally, new regulatory requirements were put in place when making modifications to existing 510(k) products.

While these were positive developments for the medical device industry, the unique device identifier (UDI) program has affected the way many do business. The regulation was finalized in the fall of 2013, and all classifications of devices must now have a UDI within a specific time-frame based on the risk classification of the device. This involves a big investment from companies, and expands their need to best manage compliance issues for new and revised devices.
OVERVIEW OF THE MEDICAL DEVICE SPACE TODAY (cont.)

The FDA continues to issue key guidance documents for other matters within the industry, including ways to improve clinical trials of medical devices, investigational device exemption, promoting expedited access to breakthrough technologies, and pre- and post-market data collection.

Additionally, an increase in mergers and acquisitions and consolidations in hospital systems is putting stress on buyers of medical devices, forcing manufacturers to reevaluate pricing and portfolios.

TODAY’S IT SOLUTIONS

To effectively manage product recalls, regulations or compliance, companies need quality systems that can aid them in these efforts. A cloud-based solution such as MedVantage™ from Cognizant enables companies to manage compliance and complaints more efficiently. It also allows companies to analyze customer issues and determine complaint reportability. The software will then guide users to the forms needed to file and select which countries should get a copy of the forms.

This and other cloud-based solutions are game changers for managing industry challenges.

“IT solutions have a place pretty much in every aspect of our business. They can help better manage the R&D design control process while the product is being developed and from a clinical management perspective there is a huge number of processes that could require and use IT solutions

– Ronnie Toddywala
2015 TRENDS
Trends to watch this year include:

1. Smartphone-based technologies to monitor changes in health or diagnosis
2. Technology to enable patient compliance
3. Technology enablers for the aging population
4. Focus on economic value of the device
5. Continued and/or renewed focus on improving efficiencies
6. Competition from large traditional technology companies such as Apple or Google
7. Increased focus on post-market data collection
8. Extended FDA guidance around medical device technologies

“...I believe we are going to see more [regulatory] trends from FDA because of FDA’s focus on post-market data collection and it’s initiation of the medical device post-market surveillance national initiative.

– Janet Trunzo

WHAT IS THE BIGGEST ISSUE FACING THE MEDICAL DEVICE SPACE IN THE COMING YEAR?

- Increased and more stringent regulations 57%
- Healthcare consolidation 20%
- Emerging markets 10%
- Patient safety 12%

*Results from a recent Cognizant webinar poll of medical technology professionals

LOOKING AHEAD
Experts note to watch for an increased focus on data information security and monitoring as well as protection of sensitive information to ensure patient privacy. Also, the continued evolution of FDA and other regulatory body requirements will increase the breadth and depth of data generated by products. Finally, increased communication among global regulatory agencies will help reduce duplication of requirements in multiple markets.

RESOURCES
- Stay up to date with the breaking news in the medical device space by signing up for AdvaMed SmartBrief.
- Find Solutions:
  - How can Cognizant help you navigate the industry? Click here to learn more.
  - Cognizant’s cloud-based solution helps their clients reach more customers, improves customer satisfaction, and ensure regulatory compliance.
    - Watch this informative video on how MedVantage can help you
    - See MedVantage in action by watching our Demo on Force.com

Hear the full conversation by listening to a replay of the webinar here: http://bit.ly/1AUk3iQ