

LIVE VIRTUAL LEARNING SERIES

# Virtual Safety Systems Seminar 2021

*Week 1: September 14-16, 2021*

*TUESDAY / WEDNESDAY / THURSDAY*

*ALL SESSIONS ARE ONE HOUR UNLESS NOTED OTHERWISE*

*EACH DAY WILL ALSO INCLUDE TIME TO VISIT OUR VIRTUAL EXPO CENTER*

## **TUESDAY, SEPTEMBER 14**

### **WELCOME AND WHAT'S NEW IN ARGUS 8.2.3 // AXEL HAGEL**

Argus and Argus-J, Regulatory background and release approach & roadmap, major enhancements and bug fixes

### **NEW REGULATIONS AND WHAT THESE MEAN FOR YOU // UWE TRINKS**

A look at emerging regulations such as FDA CDER Combo Products, FDA IND Safety reporting via E2B R2, EMA EDQM integration, China, Korea, Japan and the preparation required

## **WEDNESDAY, SEPTEMBER 15**

### **DID YOU KNOW ARGUS COULD DO THIS? // AXEL HAGEL & UWE TRINKS**

Hidden functionalities that you may not be aware of regarding Argus

### **VACCINE VOLUMES AND ARGUS AUTOMATIONS // JANE CARROLL**

With the authorization of COVID 19 Vaccines, manufacturers received an unprecedented volume of adverse events. In order to ensure timely processing and evaluation of any potential safety signals, Moderna implemented a series of automations within their Argus system. Learn how Moderna used automation to drive quality of adverse event case processing as well as ensure compliance with reporting obligations.

### **MANAGING MANAGED SERVICES // ANGELINA GILBERT-SWANN**

## **THURSDAY, SEPTEMBER 16**

### **ASK THE EXPERTS // AXEL HAGEL & UWE TRINKS**

Q&A with audience (90 minutes)

For more information on Safety Systems Seminar,  
visit [safety-systems-seminar.com](https://safety-systems-seminar.com)



LIVE VIRTUAL LEARNING SERIES

# Virtual Safety Systems Seminar 2021

*Week 2: September 21-23, 2021*

**TUESDAY / WEDNESDAY / THURSDAY**

## **TUESDAY, SEPTEMBER 21**

### **REIMAGINING SAFETY AND NEW WAYS OF PRODUCT SURVEILLANCE**

**// UPDESH DOSANJH**

An overview of the latest technologies and tools that help automate and support Safety. Tools like Voice AE detection, automated coding and AE extraction are all helping companies reduce workloads while providing new ways to analyze data

### **TECHNOLOGY INNOVATIONS IN IQVIA VIGILANCE PLATFORM //**

**MIRANDA GREENHALGH & ANDREW MITCHELL**

How IQVIA Vigilance Platform covers the entire safety process, from detecting adverse events through processing, data analysis and Signal Detection. This session will explore some of the key innovations in the platform that allow you to optimize every aspect of Safety

## **WEDNESDAY, SEPTEMBER 22**

### **SAAS SAFETY SYSTEMS: HYPER-RESILIENCE AND SECURITY //**

**BALAJI GOPINATHAN & KEVIN SAYLOR**

Hyper-resilience is common in other industries but unique to IVP in Safety. Understand how a three tier, multi-resilient architecture ensures we can achieve the most reliable system in the industry while managing security and validation

### **DETECTION OF AES IN SOURCE DATA // ALISON SLOANE & AMIRA MODI**

Voice and web are the fastest growing channels for receiving AEs. New technology offers the opportunity to simplify the capture and analysis of everything from patient reporting to automated voice AE identification

## **THURSDAY, SEPTEMBER 23**

### **CASE COLLECTION SYSTEMS // ANDREW DONALDSON & DAVID LEWIS**

Case collection systems allow companies to reduce the space between the AE reporter and the PV Experts. Collection systems allow patients to report in their own language directly into a web site or a mobile device and have their words transferred directly to the safety system. The solution offers the ability to pose questions directly to the reporter as they enter the case, depending on the event and product being entered. This is more efficient than traditional outgoing query processes.

### **USING NATURAL LANGUAGE PROCESSING (NLP) TO CODE AND EVALUATE CASES // JANE REED**

This talk will focus on the use of Natural Language Processing (NLP) to support Medical Coding. When processing adverse events, the verbatim provided by a reporter has coded into a standardized format to allow database processing. Most coding is manual and time consuming, because only an exact match against MedDRA is typically automatic. NLP allows automated recognition of the verbatim and associated coding even when the term is not exact, significantly reducing effort but also improving quality

### **NEW SAFETY PARADIGMS AND THE BUSINESS CASE // UPDESH DOSANJH**

How are these technologies changing the way clients work and what are the benefits they are seeing? We will present some short case studies of how clients have changed their processes and the FTE and Financial Benefits (20 minutes)

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