



## The Conference Program

Fusion 2018 planning is well underway. You can anticipate a program packed with plenty of knowledge sharing, hands-on learning, and countless opportunities to network with fellow SmartSolve users, Pilgrim subject matter experts, and industry authorities. Whether you simply attend the 3-day conference, or extend your stay in the Tampa Bay area before and/or after Fusion to take advantage of additional SmartSolve Training and/or recreational activities, we promise your Fusion 2018 experience will be memorable and worthwhile.

## Agenda

The schedule below provides a comprehensive look at what the Fusion 2018 experience will include before, during, and after the 3-day conference.

### Sunday, Sept 23

8:00am – 1:00pm	<b>Pilgrim Golf Outing (Optional)</b>
1:00pm – 5:00pm	<b>Customer Advisory Board Meeting (Invitation-Only)</b>
2:00pm – 7:00pm	<b>Registration Opens</b>
6:00pm – 9:00pm	<b>Fusion 2018 Welcome Reception</b> Meet your hosts and other conference attendees while enjoying spectacular views of the Tampa skyline from the rooftop deck of the Grand Hyatt. Heavy hors d'oeuvres and cocktails will be served in the Hyatt's acclaimed Armani's restaurant. Pre-registered guests are welcome. <b>Business casual attire is suggested.</b>

### Monday, Sept 24

7:00am – 8:00am	<b>Breakfast</b>
8:00am – 10:00am	<b>General Session</b> <b>Fusion 2018 Welcome</b> Pilgrim will welcome Fusion 2018 attendees to the conference and highlight the improvements made to the event to better suit your needs. We will also share what has been heard from customers and our plans for addressing customer needs into the future. <ul style="list-style-type: none"> <li>• Welcome</li> <li>• Pilgrim Opening Remarks</li> <li>• Delivering Next Generation Value</li> <li>• Global Compliance: From "Concept to Market"</li> <li>• Customer Keynote - Cardinal Health: Global Harmonization of Quality and Compliance</li> </ul>
10:00am – 10:30am	<b>Break</b>
10:00am – 5:00pm	<b>The Quality Zone</b> Visit the new and expanded "Zone," where Pilgrims, partners, analysts, and other thought leaders converge. Meet with some of the industry's best of the best, along with Pilgrim industry and solution experts from Customer Support, Professional Services, Training, Development, Product Management & Regulatory, and Sales & Marketing.
10:30am – 11:30am	<b>General Session</b> <b>Keynote Presentation: Dr. Michio Kaku</b> <b>Next Generation Science &amp; Technology: Shaping the Future</b> (followed by book signing in The Quality Zone)
11:30am – 1:00pm	<b>Lunch</b>

<p>1:00pm – 2:00pm</p>	<p><b>Products &amp; Solutions</b>  <b>The Newest Features and Functionality in SmartSolve</b>          What SmartSolve version are you currently running? When did you last upgrade? Attend this session to get a rundown of all the new SmartSolve features and functionality made available over the last several releases and find out why you should care.</p> <p><b>Products &amp; Solutions</b>  <b>SmartSolve CAPA Management - A Customer Success Story</b>          Pilgrim's Global Services team will walk you through a successful customer implementation and provide related use cases surrounding SmartSolve CAPA Management.</p> <p><b>Thought Leadership</b>  <b>Proactive Post Market Surveillance: Medical Device and IVD</b>          This session will look at the changing needs for post market surveillance for Medical Devices &amp; IVDs. Most of the global regulatory agencies are requiring manufacturers to pro-actively identify different sources of post market data, in addition to the established sources of reactive data (complaints, recalls etc.). We will provide insight how this additional information can be gathered and analyzed.</p> <p><b>Technical &amp; Administration</b>  <b>SmartSolve Platform, Technology, and Administration - The Latest Updates</b>          Take an inside look at the latest platform releases to uncover recent enhancements and new capabilities. In addition, in this session we will discuss the benefits of the quarterly release cycle and how to best plan for your upgrades.</p>
<p>2:15pm – 3:15pm</p>	<p><b>Products &amp; Solutions</b>  <b>Business Process Automation with SmartSolve Studio</b>          This session will examine how requirements-driven development using Pilgrim's low-code platform can enhance your business processes.</p> <p><b>Products &amp; Solutions</b>  <b>SmartSolve Complaint Management and Case Intake Portal - A Customer Success Story</b>          Join our Pilgrim Global Services team to review the key elements of a successful customer implementation and related use cases surrounding Pilgrim's SmartSolve Complaint Management solution.</p> <p><b>Thought Leadership</b>  <b>Predictive Analytics: The Path to True Prevention</b>          How do you find patterns in data around quality issues including product failures, recalls, injuries/deaths, where no one has thought to look? Join this session to learn how to uncover hidden insights that will leave your competition in the rearview mirror.</p> <p><b>Technical &amp; Administration</b>  <b>Application of Organization Hierarchy to Users and Record Management</b>          Join this session to learn how to represent your organization hierarchy within SmartSolve, how to apply organization hierarchy information within users and records, and how to leverage organization hierarchy information in searches and reports to dynamically filter information.</p>
<p>3:15pm – 4:00pm</p>	<p><b>Break - The Quality Zone</b></p>
<p>4:00pm – 5:00pm</p>	<p><b>Products &amp; Solutions</b>  <b>Quality Intelligence, Executive Dashboards, and Data Discovery</b>          Analyzing real time data across multiple quality processes has become critical in making intelligent business decisions. Join us in this session to learn how you can both leverage the new pre-built KPI dashboards and create personalized executive-level dashboards to monitor the quality health of your company.</p> <p><b>Products &amp; Solutions</b>  <b>The Case for Inspection Management</b>          Managing suppliers is key to minimizing risk and improving quality within the supply chain. This session will provide an overview of Inspection Management, the role it plays in Supplier Quality Management, and the new and evolving regulations it supports.</p>

4:00pm – 5:00pm	<p><b>Thought Leadership</b>  <b>Why Is the World So Cloudy?</b>  Come hear about the latest trends in Cloud computing and why those trends are important to you. You'll also get a glimpse into Pilgrim's Next Generation Cloud concepts.</p> <p><b>Regulatory &amp; Compliance</b>  <b>EU MDR – Birds of a Feather Session</b>  The industry's hottest topic, next to ISO 13485 – EU MDR – is coming! Are you ready? This Birds of a Feather (BOF) roundtable session will explore:</p> <ul style="list-style-type: none"> <li>• What is your company doing to prepare for EU MDR?</li> <li>• What is the impact that EU MDR is going to have on your company?</li> <li>• What can IQVIA and Pilgrim do to help you and your company?</li> <li>• Are there any Managed Services areas that your company would consider outsourcing, across any of your company's business process areas?</li> </ul>
6:00pm – 10:00pm	<p><b>South Beach-Themed Dinner Party</b>  Chill out after a productive day of learning in an illuminated South Beach-inspired environment featuring a full buffet of Floridian-infused flavors, cool cocktails, and hot dance music. Pre-registered guests are welcome. <i>All-white attire is suggested.</i></p>

## Tuesday, Sept 25

7:00am – 8:00am	<p><b>Breakfast</b></p>
7:00am – 5:00pm	<p><b>The Quality Zone</b>  Visit the new and expanded "Zone," where Pilgrims, partners, analysts, and other thought leaders converge. Meet with some of the industry's best of the best, along with Pilgrim industry and solution experts from Customer Support, Professional Services, Training, Development, Product Management &amp; Regulatory, and Sales &amp; Marketing.</p>
8:00am – 10:00am	<p><b>General Session</b></p> <ul style="list-style-type: none"> <li>• Technology Forward for Next Generation Quality &amp; Compliance</li> <li>• Products and Regulatory Future for Next Generation Quality Compliance</li> <li>• Customer Keynote Panel: Customer Perspectives Across Life Sciences</li> </ul>
10:30am – 10:45am	<p><b>Break – The Quality Zone</b></p>
10:45am – 11:45am	<p><b>Products &amp; Solutions</b>  <b>End-to-End Supplier Quality Management</b>  This session will review the Supplier Quality Management tools available in SmartSolve and the additional supplier evaluation and selection tools available for supporting on-going supplier management processes. Hear about supplier performance data such as audit records, incoming inspection data, nonconformance records, and CAPA responses, and Pilgrim's new Supplier Quality Portal.</p> <p><b>Products &amp; Solutions</b>  <b>Next Generation Content Management</b></p> <p><b>Regulatory &amp; Compliance</b>  <b>FDA 483s and Warning Letters: Common Observations and Managing Them</b>  By looking at yearly data from the FDA for both Devices and Drugs, we look at the most common observations that FDA find at inspection and some of the common mistakes that companies make in approaching the corrective actions and communicating with FDA.</p> <p><b>Technical &amp; Administration</b>  <b>Configuring and Leveraging SmartSolve Dashboards</b>  Learn from our experts regarding how to modify existing saved searches to support SmartSolve dashboards as well as how to modify common dashboards to support your processes.</p>
11:45am – 1:00pm	<p><b>Lunch</b></p>
1:00pm – 2:00pm	<p><b>Thought Leadership</b>  <b>Data Security and The Cloud</b>  Attend this presentation for a 5,000-foot view of security in the cloud. We will examine where we have been, where we are today, and where we are going with data protection practices and technologies.</p> <p><b>Products &amp; Solutions</b>  <b>Leverage Equipment and Calibration Management to Increase Efficiency</b>  Out-of-service equipment costs significantly more than the cost to maintain it. Join this session to learn how to reduce waste and scrap by leveraging SmartSolve to manage your equipment and tools' accuracy and efficiency.</p>

<p><b>1:00pm – 2:00pm</b></p>	<p><b>Regulatory &amp; Compliance</b>  <b>Upcoming European Regulatory Changes - EU MDR</b>  Join Pilgrim's regulatory experts for an update on recent and upcoming European regulations that will impact you and your organization, such as EU MDR.</p> <p><b>Technical &amp; Administration</b>  <b>Data Migration in Regulated Environments: Challenges and Tips Success</b>  Join our experts to learn best-practice tips for migrating data in a regulated environment. In this session, we will review why the need to perform data migration occurs, what are the alternatives to performing data migrations, why is data migration so challenging, and what are the risks?</p>
<p><b>2:15pm – 3:15pm</b></p>	<p><b>Products &amp; Solutions</b>  <b>What's New in Document and Change Management</b>  Document and Change Management are at the heart of your Quality Management System and Pilgrim continues to evolve these vital processes with new capabilities. Join this session to get a look at planned and upcoming updates to SmartSolve Document Management and Change Management, including enhanced collaboration tools.</p> <p><b>Products &amp; Solutions</b>  <b>Next Generation RID &amp; RIMS for Next Generation Quality</b>  Join this session to learn how your company can start leveraging next-generation Regulatory Intelligence Data (RID) and RIMs to improve the exchange of regulatory information, optimize RA project planning, support global submissions strategy, track products registrations, develop regulatory intelligence, reduce risks related to changes, simplify reporting, and provide insight into regulatory operations.</p> <p><b>Regulatory &amp; Compliance</b>  <b>Impact of EU MDR on Complaints: A Customer Case Study</b>  This presentation is intended to provide an industry perspective of the upcoming EU MDR regulations and its impact on medical device companies. We will discuss implementation challenges associated with the EU MDR regulations. We'll also discuss strategies on how to prepare for implementation of the EU MDR regulations.</p> <p><b>Technical &amp; Administration</b>  <b>Accelerating SmartSolve System Performance</b>  In this session, we will introduce Pilgrim's methodology for improving SmartSolve's system performance and fine tuning application deployment.</p>
<p><b>3:15pm – 4:00pm</b></p>	<p><b>Break - The Quality Zone</b></p>
<p><b>4:00pm – 5:00pm</b></p>	<p><b>Products &amp; Solutions</b>  <b>Why You Should Upgrade and How to Prepare To Do So</b>  Don't miss this session for a look at why you should upgrade and best practices for preparing for upgrades to ensure they are successful within your organization.</p> <p><b>Products &amp; Solutions</b>  <b>Next Generation Document Management</b></p> <p><b>Thought Leadership</b>  <b>Combination Products: Today and Tomorrow's Regulatory Environment</b>  Don't miss this session for a look at the current quality and compliance climate for combination products. We'll review combination products types and processes and the regulatory authority interactions that impact product development and distribution, as well as examine some of the challenges that accompany combination products and what the future holds for this innovative Life Sciences sector.</p> <p><b>Technical &amp; Administration</b>  <b>Integrating SmartSolve with other Enterprise Systems</b>  Join this session to get an overview of SmartSolve integration solutions and capabilities, different integration approaches, and how to choose the right tools. In addition, we will review real-world examples and provide a live demo of SmartSolve integration capabilities.</p>
<p><b>5:30pm – 10:00pm</b></p>	<p><b>Fusion 2018 Beach Party &amp; Dinner</b>  Cap off your final evening at Fusion at this casual poolside buffet and social celebration. You'll enjoy the Hyatt's shoreline overlooking Tampa Bay, accompanied by the tropical flair of steel drum music, beach games, and the opportunity to "make your own" custom flip-flops. Pre-registered guests are welcome. <b>Resort casual attire is suggested.</b></p>

## Wednesday, Sept 26

7:00am – 8:00am	<b>Breakfast</b>
7:00am – 4:00pm	<b>The Quality Zone</b> Visit the new and expanded “Zone,” where Pilgrims, partners, analysts, and other thought leaders converge. Meet with some of the industry’s best of the best, along with Pilgrim industry and solution experts from Customer Support, Professional Services, Training, Development, Product Management & Regulatory, and Sales & Marketing.
8:00am – 9:00am	<b>General Session</b> <ul style="list-style-type: none"><li>• Quality Intelligence</li><li>• Cloud Quality</li></ul>
9:15am – 10:15am	<b>Products &amp; Solutions</b> <b>The Newest Features and Functionality in SmartSolve (Encore Session)</b> What SmartSolve version are you currently running? When did you last upgrade? Attend this session to get a rundown of all the new SmartSolve features and functionality made available over the last several releases and find out why you should care.  <b>Thought Leadership</b> <b>Data Quality Equals Quality Data</b> Data is part and parcel to life today. This session will demonstrate how you can prevent bad data or overlooked information from misguiding your journey to quality excellence.  <b>Regulatory &amp; Compliance</b> <b>Regulatory Strategy and Implementation for US Pre- and Post-Market Submissions</b> This session will explore how to create a regulatory strategy for a medical device and how to put it into action with FDA. We will explore examples for novel devices including use of FDA’s De Novo program.  <b>Thought Leadership</b> <b>Extending QMS Beyond the Four Walls of QA</b> The list of organizational quality stakeholders continues to grow as the value chain expands. Join this session to review key SmartSolve capabilities that enable a quality culture within your organization, moving quality from a departmental responsibility to an organizational responsibility.
10:15am – 10:45am	<b>Break – The Quality Zone</b>
10:45am – 11:45am	<b>Products &amp; Solutions</b> <b>Automation Validation in Today’s Reality</b> Explore Pilgrim’s Automated Validation capability and discover how it differs from traditional automation, including a look at the concept of testing requirements versus design and how Pilgrim uses this automation in our Cloud. A live demonstration will illustrate how to quickly generate and execute PQ for the change with complete traceability and with rich evidence.  <b>Thought Leadership</b> <b>Preparing for Implementation: eQMS Implementation Best Practices</b> Join our Pilgrim Global Services team as they discuss best practices and Pilgrim’s methodology for preparing for implementations of new SmartSolve quality processes.  <b>Regulatory &amp; Compliance</b> <b>ISO 9001:2015 Compliance at Pilgrim Quality Solutions</b> Attend this session for a review of Pilgrim’s Software Development Life Cycle (SDLC) that guides the development of new products and the enhancement and maintenance of existing products. Discover how our SDLC ensures that we consistently deliver software to our customers that conforms to established and contracted technical requirements.  <b>Thought Leadership</b> <b>Industry 4.0: Why Quality Cares and How to Prepare</b> The impact of Industry 4.0 on our manufacturing, supply chains and quality management will be felt sooner than we think, and as quality professionals, we need to be planning for it now. Join this session to gain an understanding of Industry 4.0, its expected impact on our organizations’ products and processes, and the role technology will play in reshaping the way we work.
11:45am – 1:00pm	<b>Lunch</b>

1:00am – 2:00pm

**Products & Solutions**

**Business Process Automation with SmartSolve Studio (Encore Session)**

This session will examine how requirements-driven development using Pilgrim's low-code platform can enhance your business processes.

**Products & Solutions**

**Machine Learning for Social Signal Case Creation**

Is your organization tracking adverse events and off-label use from digital/social marketing sources? Would your organization like to avoid unexpected fines from global regulators for underreporting of adverse events? Join this session to learn about AETracker, and our plans to allow for automatic detection of adverse events and other potential risks in structured and unstructured data using artificial intelligence to report complaints/adverse events within minutes.

**Regulatory & Compliance**

**A Look Inside the Pilgrim Validation Pack**

This overview will walk you through the documents included in a SmartSolve Validation Pack, as well as some additional ones that can assist you in your Pilgrim Quality Solutions validation project. We will look at the Getting Started Guide, Release Notes, Validation Matrix, and more.

**Thought Leadership**

**Reduce Organizational Risk: The Impact of Supplier Management and the Role of Quality**

If the Life Science industry wants to improve patient outcomes, then its enterprises have to manage risk. One of the largest sources of organizational risk is dependence on third-party suppliers. Today's global economy has added complexity to supply chains, and longer supply chains are making it increasingly difficult to manage suppliers, and in many cases, suppliers' suppliers, thereby increasing overall risk. The plethora of regulatory requirements reflect this new reality. How can you reduce supplier risk and what is the role of quality in that process? Join this session to better understand:

- Supplier risk and its role in the broader enterprise risk ecosystem
- The regulatory landscape regarding Supplier Control
- How Supplier Management processes reduce risk and the criticality of Quality Management to those processes
- Effective monitoring and measurement tools for Supplier Risk Management
- The business benefits of an effective Supplier Management program

2:15pm – 3:15pm

**Products & Solutions**

**Let's Talk about Recall Management**

Managing product removals and corrections is a complex process that touches many aspects of your extended value chain. In this session, we will discuss how Pilgrim views Recall Management and how we can help automate and control the end-to-end process. Opportunity for you and your organization to be part of the Recall Advisory Board.

**Products & Solutions**

**Why You Should Upgrade and How to Prepare To Do So (Encore Session)**

Don't miss this session for a look at why you should upgrade and best practices for preparing for upgrades to ensure they are successful within your organization.

**Products & Solutions**

**Quality Intelligence, Executive Dashboards, and Data Discovery (Encore Session)**

Analyzing real time data across multiple quality processes has become critical in making intelligent business decisions. Join us in this session to learn how you can both leverage the new pre-built KPI dashboards and create personalized executive-level dashboards to monitor the quality health of your company.

**Technical & Administration**

**SmartSolve Platform, Technology, and Administration - The Latest Updates (Encore Session)**

Take an inside look at the latest platform releases to uncover recent enhancements and new capabilities. In addition, in this session we will discuss the benefits of the quarterly release cycle and how to best plan for your upgrades.