SeerPharma Symposium 2018 Program

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September 6th & 7th 2018
Park Hyatt Sydney
7 Hickson Road, The Rocks, Sydney NSW

PRESENTED BY SEERPHARMA

WELCOME

Welcome to SeerPharma's Symposium for 2018.

This year's event is aimed towards Medical Device and Pharmaceutical professionals that are involved in Quality Assurance (QA) and Compliance.

Day 1 will focus on QA/Compliance needs for the Medical Device industry. We'll take on topics such as managing Design History Files (DHF), Risk Management and Post Market Responsibilities. We're also excited to bring you the latest on Cybersecurity from UL and their work with the US FDA, and implications towards connected Medical Devices. We're thrilled to also have the Australian regulatory body for therapeutic goods - the TGA - present on Market responsibilities for Medical Device Sponsors. Plus we're privileged to have Notified Body - BSI, discuss what they consider to be "Effective Implementation of ISO13485:2016" , sharing their experience of auditing and certifying Medical Device companies to this standard.

Day 2 will address topics on QA/Compliance for those of you dealing with Pharmaceuticals. We'll look to address topics such as managing your CAPA's, Computer System Validation (CSV) and Supplier Qualification / Supplier Assurance. Leaning on our 30 years of industry experience, we're excited to also address how you should best prepare for a Regulatory GMP Inspection. We'll look at the approaches and differences between a TGA(PIC/S) and a US FDA GMP Inspection, and hopefully provide you with some ideas on how best to prepare your staff for managing a regulator on site. We're also honoured to have GS1 present on the latest standards and work that they've been putting in with the US FDA on securing drug supply through Track and Trace, which we will look to tie in to our presentation on Supplier Quality Assurance.

In addition to all this, we're really excited about holding the Symposium at the Park Hyatt, in Sydney. Situated at The Rocks, below the Sydney Harbour Bridge, you'll have spectacular views of the Harbour and Sydney Opera House during this 2-day event.

We look forward to hosting you at this wonderful location and hopefully at the end of it, you will have achieved greater **Confidence In Compliance.**

EVENT PARTNERS

UL

Australian Government
Department of Health
Therapeutic Goods Administration

bsi.

GS1 Australia

SeerPharma®
CONFIDENCE IN COMPLIANCE

MEDICAL DEVICES PROGRAM DAY 1

SeerPharma®
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MEDICAL DEVICES

DAY 1

Thursday, September 6, Medical Devices

8:00 AM - 8:30 AM **ARRIVAL AND REGISTRATION**

8:30 AM - 8:45 AM

BIJU KISHOR, SALES & MARKETING MANAGER, SEERPHARMA

Introduction and Welcome

8:45 AM - 9:45 AM

TONY ROWLAND, PARTNER, SEERPHARMA

Achieving Quality Management System Certification

The backbone of achieving compliance is ensuring you have a sound Quality Management System that works for your organisation. This presentation will talk about how to plan out a Quality System, the ideal document hierarchy to use, the responsibility of Management, how to integrate the key elements of a Quality System, and the importance of how language should be used for procedures and defining Quality System elements.

9:45 AM - 10:45 AM

DUSHYANT SANATHARA, TEAM MANAGER, MEDICAL DEVICES AND PRODUCT CERTIFICATION, BSI

Effective Implementation of ISO13485: 2016

ISO 13485 is the best internationally-accepted model a medical device organization can implement to help demonstrate compliance to laws and regulations of the medical device industry. Increasingly, ISO 13485 is being required, or is at least beneficial, in supporting regulations around the world although it is not a direct requirement. Adopting ISO 13485 demonstrates commitment to the safety and quality of medical devices. This presentation will focus on effective implementation to the latest version of this standard - ISO13485:2016

10:45 AM - 11:00 AM **MORNING TEA BREAK**

11:00 AM - 12:00 PM

JACQUELINE BERRY, SENIOR CONSULTANT, SEERPHARMA

Addressing the Culture of Quality in your Organisation

The culture in your organisation influences the behaviour and actions of individuals. It is critical that companies have appropriate systems in place to influence and support a culture that embraces Quality Assurance so that achieving compliance is just part of normal business operations.

MEDICAL DEVICES

DAY 1

Thursday, September 6, Medical Devices

12:00 PM - 1:00 PM

ANDREW JAMIESON, TECHNOLOGY AND SECURITY DIRECTOR, IDENTITY MANAGEMENT & SECURITY, UL

Cybersecurity for Medical Devices

In an ever connected world, and the emergence of the Internet of Things (IoT), it is critical that Medical Device companies address Cybersecurity threats. UL helps manufacturers comply with regulatory requirements as healthcare IoT and cyberthreats grow. The US FDA have officially recognised UL2900-1 as the standard for Medical Device companies to follow to help ensure they are well prepared.

1:00 PM - 2:00 PM

LUNCH BREAK

2:00 PM - 3:00 PM

DANIEL FLEWELLEN, SENIOR CONSULTANT, SEERPHARMA

Design History Files and Risk Management for Medical Device Companies (ISO14971)

When designing and developing a Medical Device, companies must ensure that the risk to patients is constantly evaluated and monitored, and in addition capture any changes made using Design History Files (DHF's). This presentation will look to capture best practices for achieving this.

3:00 PM - 3:45 PM

PAUL KERR, PARTNER AND ROHAN BHATIA, BUSINESS SYSTEMS PROJECT MANAGER, SEERPHARMA

Electronic Quality Management Systems for Medical Device Companies

Presentation and examples of how Medical Device companies can automate their Quality Management System and processes to help manage responsibilities such as Document Control, CAPA's, Risk Management and Design History Files

3:45 PM - 4:00 PM

AFTERNOON TEA BREAK

MEDICAL DEVICES

DAY 1

Thursday, September 6, Medical Devices

4:00 PM - 5:00 PM

KELLY TSANG, ASSISTANT DIRECTOR, TGA - MEDICAL DEVICES BRANCH

Post Market Responsibilities for Medical Device Sponsors

Once you have a product in the market, there are responsibilities that you have as a Sponsor to constantly monitor and evaluate the performance of your device and its risk to the general population.

5:00 PM

CLOSING REMARKS

6:00 PM - 9:00 PM

DINE & DEMO

Presented by MasterControl

You are invited to attend an evening Dine & Demo event by MasterControl. Join your fellow attendees at The Cut Bar & Grill from 18:00-21:00 for a delicious, three-course meal where you can network and unwind. You'll enjoy the best cuisine that Sydney has to offer and see a brief demo of MasterControl's electronic Quality Management System. Registration details will be provided to all Symposium Ticket holders.

MasterControl™
Compliance Accelerated

PHARMACEUTICALS PROGRAM DAY 2

SeerPharma®
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PHARMACEUTICALS

DAY 2

Friday, September 7, Pharmaceuticals

8:00 AM - 8:30 AM — **ARRIVAL AND REGISTRATION**

8:30 AM - 8:45 AM — **BIJU KISHOR, SALES AND MARKETING MANAGER, SEERPHARMA**

Introduction and Welcome

8:45 AM - 9:45 AM — **TONY ROWLAND, PARTNER, SEERPHARMA**

Your Quality Management System and Managing your CAPA's.

The backbone of achieving compliance is ensuring you have a sound Quality Management System that works for your organisation. This presentation will talk about how to plan out a Quality System, how to integrate the key elements of a Quality System, and how to best manage your CAPA's, the central component of your Quality Management System.

9:45 AM - 10:45 AM — **JACQUELINE BERRY, SENIOR CONSULTANT, SEERPHARMA**

Addressing the Culture of Quality in your organisation

The culture in your organisation influences the behaviour and actions of individuals. It is critical that companies have appropriate systems in place to influence and support a culture that embraces Quality Assurance and ensure that human error is understood and minimised.

10:45 AM - 11:00 AM — **MORNING TEA BREAK**

11:00 AM - 12:00 PM — **ANDREW GILES, SENIOR CONSULTANT, SEERPHARMA**

How to best prepare for and manage the outcomes of a Regulatory GMP Inspection.

This presentation will address the key areas that you must focus on when preparing for a regulatory inspection. We will also dive in to the differences between approaches of the US FDA and the TGA, and how to best handle a response to observations/findings from a GMP Inspection.

PHARMACEUTICALS

DAY 2

Friday, September 7, Pharmaceuticals

12:00 PM - 1:00 PM

LOUISE WHITE, PARTNER, SEERPHARMA

How to best prepare for PIC/S Guide to GMP version 13 (PE 009-13).

Compliance with PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009-13) requires a company-wide Pharmaceutical Quality System (PQS) across the entire product life cycle. There is a clear need for more cross-functional collaboration and improvements in data management and data integrity. This presentation will provide some guidance on how to best adopt these principles.

1:00 PM - 2:00 PM

LUNCH BREAK

2:00 PM - 3:00 PM

JACQUELINE BERRY, SENIOR CONSULTANT, SEERPHARMA

Best practices for your Supplier Quality Assurance Program

This presentation will provide an overview on how to best establish and maintain your supplier Quality Assurance program acknowledging an ever changing regulatory framework and dealing with a complex supply chain.

3:00 PM - 3:45 PM

CATHERINE KOETZ, INDUSTRY MANAGER - HEALTHCARE, GS1

Track and Trace - Securing Drug Supply

GS1 have been working hard on developing standards , and working alongside the US FDA on adopting Track and Trace, to help ensure the safe supply of pharmaceuticals. This presentation will discuss the latest developments on this front.

3:45 PM - 4:00 PM

AFTERNOON TEA BREAK

PHARMACEUTICALS

DAY 2

Friday, September 7, Pharmaceuticals

4:00 PM - 5:00 PM

PAUL KERR, PARTNER, SEERPHARMA

A Pragmatic Approach to Computer System Validation

Companies are continually looking to upgrade and/or bring in new IT infrastructure to assist with their operations, with an ever growing trend of adopting SaaS platforms. However decisions to adopt new IT technology can be hampered by a conservative / risk averse Quality department. This presentation will discuss the importance of approaching Computer System Validation in a pragmatic way, so that businesses don't see QA as a roadblock, and instead work hand in hand to ensure that operational efficiencies and compliance can be achieved in tandem.

5:00 PM

CLOSING REMARKS