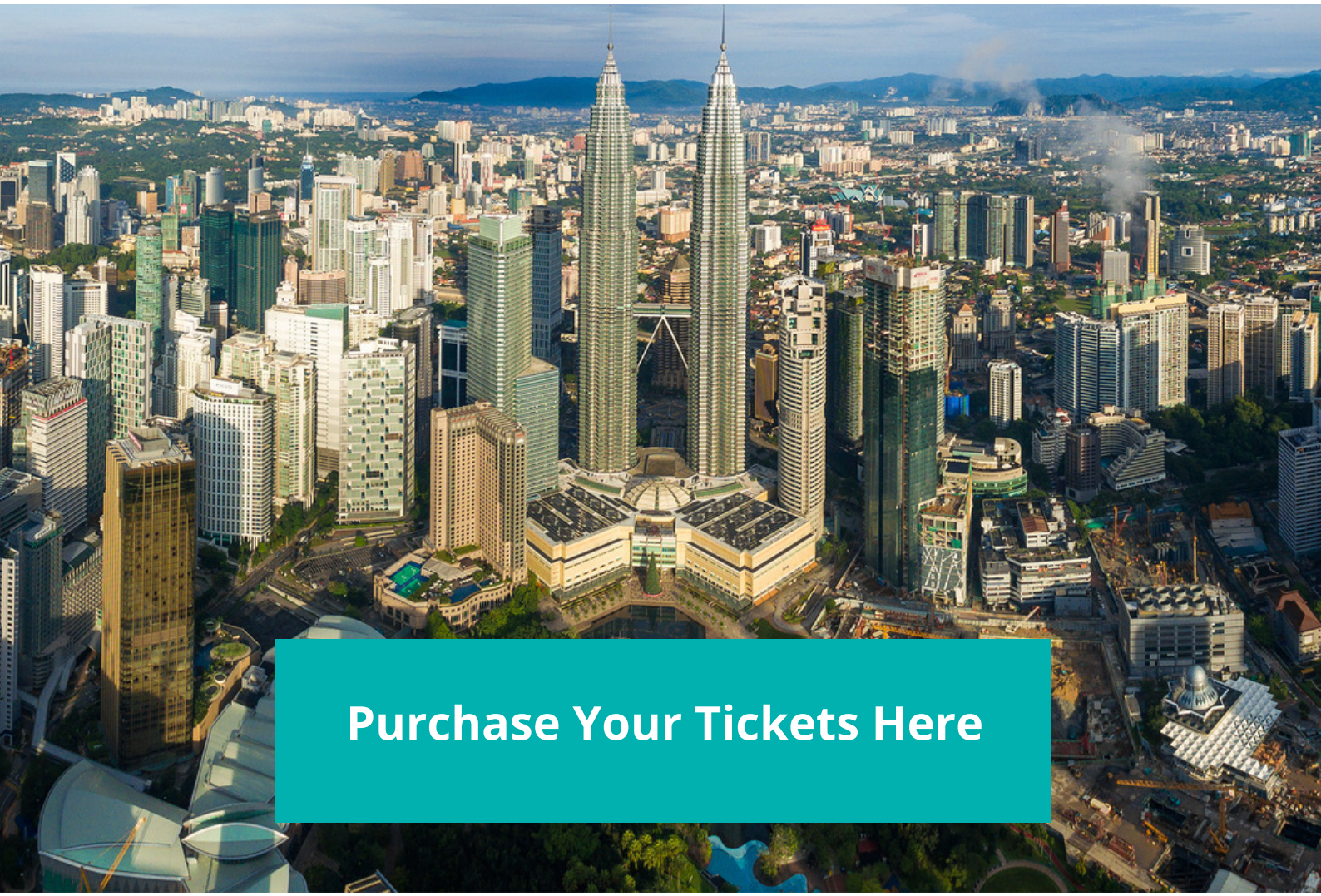
SeerPharma®
CONFIDENCE IN COMPLIANCE

Symposium 2019



July 8th & 9th 2019

Mandarin Oriental
Kuala Lumpur, Malaysia

Event Partners

MasterControl™

bsi.

Medical Devices
Monday, July 8th 2019

8:30 - 8:45 **Biju Kishor, Sales and Marketing Manager, SeerPharma**
Welcome and Introduction

8:45 - 9:45 **Kenny Chong, BSI**
ISO 13485:2016 – Show or Performance?
Companies involved with Medical Devices must look and consider obtaining ISO 13485 Certification – For SHOW or to enhance organizational PERFORMANCE? BSI are a well-recognised notified body that certifies companies to this standard. This presentation will focus on the myth, intention and benefits of ISO 13485, leaning on BSI's experience of training as well as auditing and certifying companies to the latest version of this standard - ISO 13485:2016.

9:45 - 10:45 **Jacqueline Berry, Senior Consultant, SeerPharma**
Addressing the Culture of Quality - Part I
Influencing and supporting a culture that embraces quality assurance
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 simply an afterthought.

10:45 - 11:00 **Morning Tea Break**

11:00 - 12:00 **Paul Kerr, Director, SeerPharma**
Cybersecurity
In an ever connected world, and the emergence of the Internet of Things (IoT), it is critical that Medical Device companies address Cybersecurity threats. The US FDA have officially recognised UL2900-1 as the standard for Medical Device companies to follow to help ensure they are well prepared.

Medical Devices
Monday, July 8th 2019

12:00 - 1:00

Bryant Headley, MasterControl

Former FDA Manager Spills Beans on Making Compliance Easier

Most medical device firms tend to establish over complicated processes, but simplification is actually the key to effective compliance, according to Bryant Headley, former program manager at the FDA's Office of Regulatory Affairs.

1:00 - 2:00

Lunch Break

2:00 - 3:00

Kenny Chong, BSI

Latest on MDSAP and EU MDR

Preparing for the Medical Device Single Audit Program (MDSAP) will allow companies to enter markets such as the US, Canada and Australia with a single inspection. Meanwhile Europe has adopted the EU MDR, as more stringent requirements are placed on companies to access the EU. Hear the latest developments on both fronts from Notified Body - BSI.

3:00 - 3:45

Rohan Bhatia, Project Manager, SeerPharma

Automating Document Management

Managing Quality documents can be a time consuming and error prone process. Issues with keeping documents up to date with changing regulations and processes is a common problem for many companies. Learn how these problems can be eliminated by automating your document management processes.

3:45 - 4:00

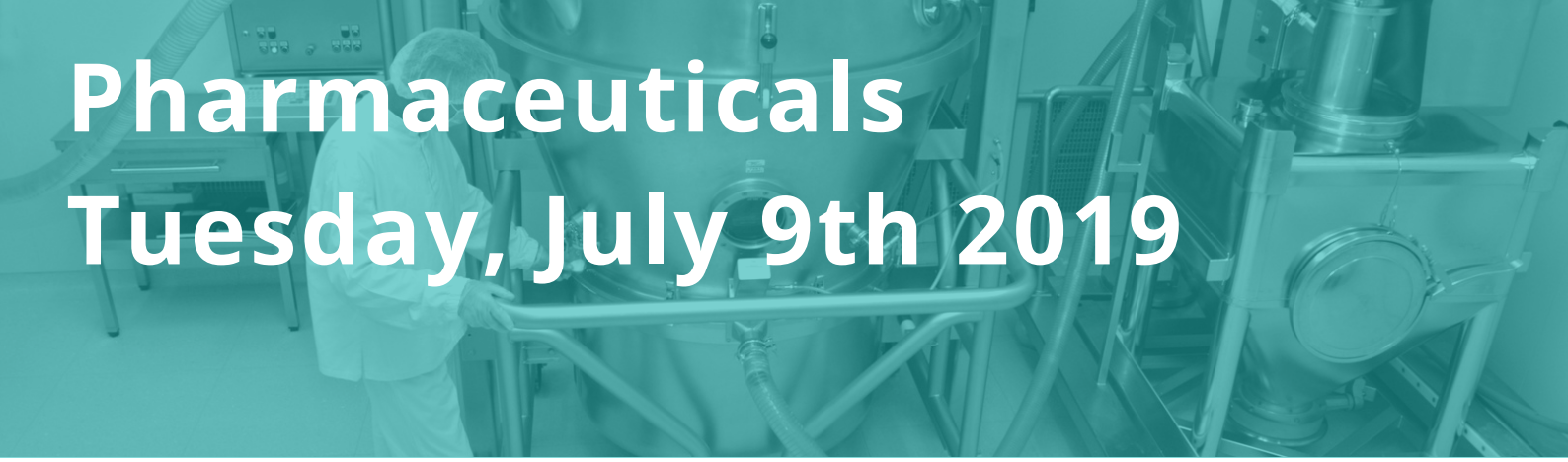
Afternoon Tea Break

4:00 - 5:00

David Spaulding, Director and Training Manager, SeerPharma

Conducting Internal Audits

Internal audits are a fundamental part of implementing, maintaining and improving your quality system which is critical to your business' success. A critical requirement of ISO1485: 2016, learn how you should best manage and handle internal audits.



Pharmaceuticals
Tuesday, July 9th 2019

8:30 - 8:45

Biju Kishor, Sales and Marketing Manager, SeerPharma

Welcome and Introduction

8:45 - 9:45

Gloria Pang, Senior Consultant, SeerPharma

Pharmaceutical Quality Management System

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.

9:45 - 10:45

Jacqueline Berry, Senior Consultant, SeerPharma

Addressing the Culture of Quality - Part II

Influencing and supporting a culture that ensures human error is understood and minimised

Behavioural GMP acknowledges that human error is human and will occur, and looks to systems and processes that will reduce the likelihood and impact of human error rather than relying on re-training as the only corrective action.

10:45 - 11:00

Morning Tea Break

11:00 - 12:00

Andrew Giles, Senior Consultant and ex- GMP Inspector, SeerPharma

Preparing for a GMP Inspection

Leaning on Andrew's experience as a lead inspector for the TGA, and having worked alongside other Inspectors, this presentation will address the key areas that you must focus on when preparing for an inspection. Diving 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
Tuesday, July 9th 2019

12:00 - 1:00

Rohan Bhatia, Project Manager, SeerPharma

Automating CAPA Workflow

The CAPA process is central to all Quality Management Systems. This session will showcase how the process can be automated providing Quality professionals the ability to easily track and manage their CAPA's

1:00 - 2:00

Lunch Break

2:00 - 3:00

Bryant Headley, MasterControl

Former FDA Insider Reveals One Thing You Need to Maintain Data Integrity

Given the FDA's new guidance document on data integrity, pharmaceutical companies are concerned about increased documentation burden. And yet, there's really only one thing you need to remember to maintain data integrity—simplicity

3:00 - 3:45

Lee Choon Keat, Executive, GS1 Malaysia Berhad

Fulfilling the National Healthcare & Pharmaceutical Track & Trace Roadmap using GS1 Standards

The usage of GS1 standards in Healthcare increases patient safety, drives supply chain efficiencies, improves the traceability of medicines and reduces medication errors. Learn how to reduce operational and inventory costs whilst increasing service quality and better healthcare management

3:45 - 4:00

Afternoon Tea Break

4:00 - 5:00

Paul Kerr, Director, SeerPharma

Computer System Validation

Companies are continually looking to upgrade and/or bring in new IT infrastructure to assist with their operations. However decisions to adopt new IT technology (eg: EQMS, ERP, LIMS) 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.