



Symposium 2024

New Frontiers in Quality and Manufacturing

25-26 March 2024
In-Person and Online
Melbourne



SeerPharma Symposium 2024

New Frontiers in Quality and Manufacturing

In-Person

Pearl Riverfront

1–5 Spencer Street
Melbourne VIC 3008

Pearl Riverfront is one of Melbourne's premier event destinations. Located right on the Yarra River, this specially designed venue is situated beneath one of Melbourne's iconic buildings; Crowne Plaza Melbourne.

Online

Details will be provided to ticket holders closer to the event.

Purchase Tickets

Event Partners



Day 1

Monday 25th March 2024

INTRODUCTIONS

08:45 - 09:00 **Welcome and Introduction**
Biju Kishor: Director / General Manager Asia, SeerPharma

QUALITY

09:00 - 09:45 **Total Quality Management - Best Practices**
Louise White: Director / Senior Consultant, SeerPharma
Michelle Peake: Senior Consultant, SeerPharma
SeerPharma has over 35 years of experience implementing, updating and improving Quality Systems. Hear from SeerPharma on best practices in designing a QMS for your operation. Some insights from what we've observed in industry.

09:45 - 10:15 **Large Language Models (LLMs) / Artificial Intelligence (AI) in Quality Management**
Elahe Haghsheno: Master of Biotechnology, University of Melbourne
Melbourne University Master of Biotechnology students partnered with SeerPharma to assess the potential use of Large Language Models (LLMs) on GMP Quality Management Systems. The team interviewed a range of industry professionals across different disciplines, levels of expertise, and organisations including the TGA. The presentation will cover key discoveries from their project, including how LLMs are likely to impact GMP and Quality over the short, medium and long term.

10:15 - 10:30 **Morning Tea**

Day 1 Continued

Monday 25th March 2024

QUALITY CONTINUED

10:30 - 11:15 **Intelligent Automation**

John Valastro: CEO, Simply AI

AI-infused automation is today's cutting edge automation technology, enabling businesses to dramatically reduce operating costs whilst also improving process accuracy & speed. Hear how this technology continues to evolve with the rise of Generative AI and see how it could streamline Quality/Manufacturing operations in our industry.

11:15 - 12:00 **MasterControl (Qx) – AQEM and Advanced Documents & Training**

Matt Lowe: Chief Strategy MasterControl

Ciaran O'Keefe: Director, Business Development & Channel Sales, Asia Pacific, MasterControl

Advanced Process for Quality Event Management (AQEM) from MasterControl allows users unprecedented flexibility and configurability to design processes, build forms and capture data around their quality events. AQEM is part of a MasterControl's new suite of advanced quality management applications, including Advanced Document & Training management which will also be presented. Learn about latest advancements from market leading software provider MasterControl.

IMPLEMENTATION OF DIGITAL TECHNOLOGIES

12:00 - 13:00 **Pfizer to NovaCina: Transitioning & Digitising Quality Workflows**

Simon Vandenberg: Site Quality Head at NovaCina

NovaCina is a leading supplier of sterile liquid pharmaceutical contract manufacturing services in Perth, WA. The site was formerly owned by Pfizer and has recently transitioned its operations. This presentation walks through the transitioning from legacy systems to digitising Quality workflows with MasterControl, including topics such as securing budget, project management, managing stakeholder expectations. In addition, it spotlights how issues/challenges were addressed provides some insights on the roadmap for the future.

Day 1 Continued

Monday 25th March 2024

13:00 - 13:45 Lunch

13:45 - 14:15 UTS Information Session and Interactive Session

Jacqueline Berry: Senior Consultant / Lecturer, SeerPharma

SeerPharma and the University of Technology Sydney have partnered to deliver innovative and university-accredited graduate programs in Good Manufacturing Practice (GMP). Unique to Australia and the Asia-Pacific region, the programs are centered around being practice-based and contemporary. This presentation will walk you through the various qualifications on offer, plus showcase an interactive learning experience used in the program.

IMPLEMENTATION OF DIGITAL TECHNOLOGIES

14:15 - 15:00 **Lessons Learned from Digitalisation Deployments: A Failure and a Success**

Gerry McKiernan: Director / Principal Consultant, Increment4

This presentation shall look at two separate deployments of digital platforms within a GMP company, where one failed to meet project timelines consistently and was constantly hindered by bottlenecks and the other, although an even greater transformational change, went smoothly and was deployed on schedule, within budget and with full employee engagement.

15:00 - 15:15 Afternoon Tea

VALIDATION

15:15 - 16:00 **Computer Software Assurance (CSA)**

Ian Lucas: Director / Training Manager, SeerPharma

Learn that Computer Software Assurance (CSA) is really a 'Common Sense Approach' to CSV, Understand the importance of proper risk assessment, vendor collaboration and critical thinking, walk through a system validation with examples. Learn how CSA forces you to know more about your processes and that the true output is not documentation but knowledge.

Day 1 Continued

Monday 25th March 2024

VALIDATION CONTINUED

16:00 - 16:45 **Computer System Validation Master Planning (CSVMP)**

Paul Kerr: Director / General Manager Australia, SeerPharma

Daniel Flewelen: Senior Consultant, SeerPharma

SeerPharma shares insights on developing a Computer System Validation Master Plan (CSVMP) to support governance and provide overall robustness to processes and procedures related to IT systems and infrastructure impacting product quality.

CLOSE

16:45 - 17:00 **Closing Remarks**

Biju Kishor: Director / General Manager Asia, SeerPharma

17:30 - 19:30 **Cocktail Event @ Byblos Bar + Restaurant**

In-person ticket holders are invited to join us for a complimentary cocktail mixer event at [Byblos Bar + Restaurant](#) from 5:30pm to 7:30pm; Sponsored by MasterControl.



Day 2

Tuesday 26th March 2024

INTRODUCTIONS

08:45 - 09:00 Welcome and Introduction

Biju Kishor: Director / General Manager Asia, SeerPharma

TRAINING

09:00 - 09:45 Why Re-training Staff as a Corrective Action Does Not Solve Anything

Andrew Giles: Director / Senior Consultant, SeerPharma

Why do manufacturers who regularly re-train staff to correct deviations get serious deficiencies from the regulators? For some manufacturers, when a deviation occurs, the regulators observe that the root cause is repeatably listed as *"the staff member did not follow procedures"* with corrective action listed as being re-training (or removal from organisation). This shows a failure to conduct a proper root-cause analysis. This presentation from SeerPharma Director - Andrew Giles, will dive into expectations of the code and regulators on the training of staff. That training is not a tick box exercise, re-training of staff is not a cure all and that competency to work in a GMP environment, must be the aim of training provided to staff.

09:45 - 10:15 Assessing and Measuring Competency Using a Chatbot Assessor

Sharaf Goussous: CEO, XponixAI

XponixAI is a premier provider of Exponential Artificial Intelligence solutions, leveraging the power of OpenAI's GPT and other state-of-the-art technologies to deliver unrivalled AI as a Service (AlaaS). Learn about a Chatbot Assessor that has been developed in conjunction with input from SeerPharma that can help enhance training and provide greater insights on training effectiveness.

10:15 - 10:30 Morning Tea

Day 2 Continued

Tuesday 26th March 2024

TRAINING CONTINUED

10:30 - 11:00 **Use of Augmented Reality (AR) Technology in Industry Training**

Ralf Muhlberger: CEO & Co-Founder, Ardacious

Learn about the Ardacious Training Platform - an Augmented Reality training and assessment software. Built with over 20 years of hands-on education experience, Ardacious delivers immersive and experiential learning outcomes that allow participants to immerse themselves in realistic scenarios, without needing to leave the classroom.

11:00 - 11:30 **An Autonomous Tool to Enhance Your Training Programs**

Thomas Van Petegeh: Immersive Learning Expert, Uptale

Uptale offers a game-changing solution for training programs, enabling organizations to train their workforce at scale and digital speed. Uptale's autonomous platform offers a simple way to create Immersive Learning experiences and provides robust progress tracking. Discover how Uptale has been revolutionizing training in industries like pharmaceuticals.

TECHNOLOGIES IN INDUSTRY

11:30 - 12:00 **Case Study: Use of Hololens Technology in Tech Transfer Training**

Pushpa Kotharu: Senior Scientist, CSL

Microsoft's Hololens technology has proven to be a highly effective hands-free solution for ensuring accurate and timely transfer of technologies between global sites of CSL Behring. Using mixed reality hands-free smart glasses, the subject matter experts were able to showcase a complete manufacturing process of a life-saving biotherapeutic.

Day 2 Continued

Tuesday 26th March 2024

TECHNOLOGIES IN INDUSTRY CONTINUED

12:00 - 13:00 **Case Study: AI Fuelled Compliance Management**

Omar Elsermagawy: Manager - Manufacturing and Life Sciences, KPMG

Tim Plenderleith: Partner and National Sector Lead Manufacturing and Life Sciences, KPMG

Learn about how AI and generative AI can be used as part of QA Compliance activities to accelerate and improve cGMP compliance. Find out how KPMG Australia has undertaken this in a regulated industry to produce a company-specific genAI tool that helps to track the existing controls in place and their effectiveness in meeting compliance requirements.

13:00 - 13:45 **Lunch**

13:45 - 14:15 **UTS Information Session and Interactive Session**

Jacqueline Berry: Senior Consultant / Lecturer, SeerPharma

SeerPharma and the University of Technology Sydney have partnered to deliver innovative and university-accredited graduate programs in Good Manufacturing Practice (GMP). Unique to Australia and the Asia-Pacific region, the programs are centered around being practice-based and contemporary. This presentation will walk you through the various qualifications on offer, plus showcase an interactive learning experience used in the program.

FACILITIES & MANUFACTURING

14:15 - 15:00 **Best Practices in GMP Facility Design**

Jo Sherriff: Senior Consultant, SeerPharma

SeerPharma has over 30 years of experience supporting clients with reviewing facility designs. Senior Consultant - Jo Sherriff, shares her insights on best practices, and what to look out for when designing a GMP facility.

Day 2 Continued

Tuesday 26th March 2024

15:00 - 15:15 Afternoon Tea

FACILITIES & MANUFACTURING CONTINUED

15:15 - 16:00 **Roll of Visualisation in the Design Process of a GMP Facility**

Hamish Hunt: Arista Process Design

Manufacturing facilities are expensive to build. The better the capacity to visualise the plant early on, the better the correlation between budget & cost – rectification is extremely expensive in these situations – so detail counts. 3D visualisation is an exercise in communication. Every viewer of a proposed design has knowledge that is specific to their training and natural aptitude. Never assume all parties in the review process can interpret all the aspects of a 3D rendering – often new viewers will initially find large format displays disorienting. This presentation from 40-year industry veteran, Hamish Hunt dives into dealing with various stakeholders when designing a GMP facility.

16:00 - 16:45 **MasterControl (Mx) – Electronic Production Records & eLogbooks**

Matt Lowe: Chief Strategy MasterControl

Ciaran O'Keefe: Director, Business Development & Channel Sales, Asia Pacific, MasterControl

MasterControl's Manufacturing Excellence (Mx) provides 100% paperless data input and documentation, as well as unique automation capabilities that enable in-line quality event management, built-in limits, integrated training, review by exception and a unique data set that enables personnel and supplier optimisation. In 2024, Electronic Logbooks will be released as part of MasterControl's digital manufacturing suite, providing a highly-configurable solution to digitize logbooks, purpose-built for life sciences. Learn how this unique solution can remove paper from production.

CLOSE

16:45 - 17:00 **Closing Remarks**

Biju Kishor: Director / General Manager Asia, SeerPharma