Speaker Bios & Abstracts

CAPA Investigations – Identifying the right CAPA and CAPA process

Maria Mylonas – PharmOut

Maria has over 20 years' experience in pharmaceutical, consulting, and learning space. Maria is PharmOut's Learning & Development Director and has an unhealthy passion regarding CAPA processes, specifically how to avoid the CAPA death spiral by using tools and techniques to identify issues, investigate to determine root cause, implement corrective and/or preventive actions and conduct effectiveness checks.

"*We have attributed the root cause of issues to human error and implemented retraining as the only corrective action one too many times, hence why the regulations have been updated to specifically state "Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked, if present."* – Maria Mylonas

Compliance issues surrounding Data Integrity and Data Management

Andrew Giles – SeerPharma

Andrew has over 30 years of experience in the pharmaceutical industry, including more than 11 years as a Medicines Inspector with the Therapeutic Goods Administration (TGA) of Australia. During his time, Andrew was a lead inspector for initial, routine and specialized inspections of Australian and international facilities which produced sterile and non-sterile medicines as prescription medicines, Over the Counter (OTC) medicines, complementary medicines, sunscreens, veterinary products and Active Pharmaceutical Ingredients (APIs). Andrew has had experience in dosage forms, including injectable, biologicals, radiopharmaceuticals, compounding, oral dosage forms, and sprays. Andrew has had experience working with inspectors from other agencies and be part of, and lead for, multinational inspection teams.

Andrew Giles will cover:

- Typical data integrity finding from regulatory inspections.
- How to address data integrity deficiencies.
- How to avoid data integrity deficiencies.

An Industry perspective - Insight to Site Preparedness for Inspections

Andrew Hodder – Pfizer (Mulgrave)

Andrew has over 25 years of experience in the pharmaceutical industry. Andrew is currently Vice President of Operations and Site Head at Pfizer Australia (Mulgrave).

Andrew has been working in pharmaceuticals with experience in manufacturing operations through the product lifecycle from API manufacture through to the end of life product in a range of management and senior leadership positions.

As Site Head at Pfizer Mulgrave, Andrew has been responsible for site transformation, facility expansion and leadership of one of Pfizer Australia's flagship sterile manufacturing sites. Andrew and his team

have been heavily involved in management and facilitation of regulatory inspections from both local and international regulators.

Andrew Hodder will discuss:

- Experience in preparing a site for a regulatory inspection
- Facilitating the inspection process
- Post inspection reflection.