



# Does your IT Speak Medical Compliance?

05 September 2019 @ Glenhove

## Who should attend?

- ☒ Heads of IT
- ☒ Heads of Compliance Portfolios: RA, QA, PV, etc.
- ☒ Company Executives & Senior Managers

## Overview

This 1-day workshop aims to inform participants on and outline the critical importance of:-

1. Data Governance, including
  - 1.1. Data Integrity
  - 1.2. Computer System Validation (CSV)
  - 1.3. Regulatory Information Management (RIM)
2. the elements that form part of the Information Management System for which, the Senior Management, RP and the Head of IT, are responsible.
3. the interrelationships across the management teams that are essential for the successful implementation and maintenance of a compliant Information Management System.

## Outcomes

At the end of the course attendees will have:

- an overview of the scope and current GxP requirements related to Data Governance.
- insight into the legislation and GxP requirements that form the fabric of the IT and regulatory systems and expectations for a Health Products company.
- an understanding of the elements within the compliance system that need to be supported in terms of resources for the implementation and maintenance thereof.

## Presenters

Henriette Vienings (GxP Consultant) & Andrew Gilchrist (IT Expert) – MRA Regulatory Consultants (Pty) Ltd