Centre for **Biopharmaceutical** Excellence

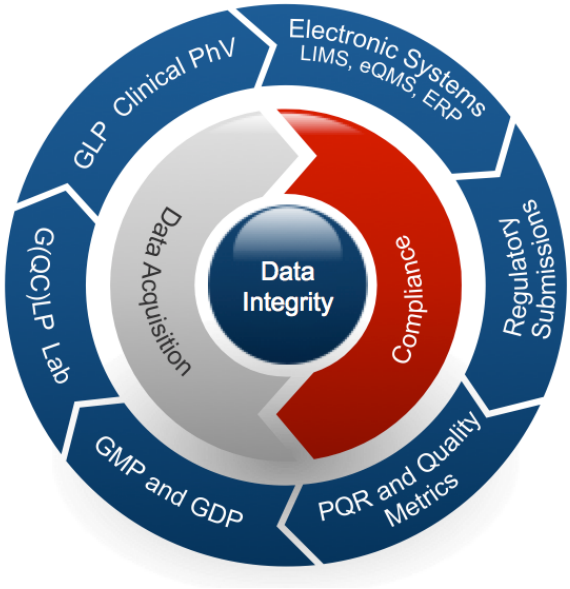
GMP- Consulting

Data Integrity and Quality Metrics

Quality Culture

"Quality culture is the collection of values, beliefs, thinking, and behaviours …... that contribute to creating a quality culture to assure data integrity."

PICs Guidance – Good Practices for Data Management and integrity



Governance

"Data governance systems should be integral to the pharmaceutical quality system described in PIC/S GMP/GDP."

PICs Guidance – Good Practices for Data Management and integrity

PICs, EMA, FDA, MHRA and **WHO** are currently updating their Guidance's to include specific requirements for Data Integrity Governance and Compliance. ICH Q10 and FDA have also signaled increased emphasis on the importance of establishing and monitoring Quality Metrics as part of Quality Systems oversight of manufacturing.

Data integrity (DI) issues, once identified by regulatory agencies, undermine trust in the companies quality system, regulatory submissions and product development programs. Recent MHRA, TGA, EMA and WHO non-conformances and FDA warning letters have highlighted the potential significance of this issue. Over the last 3 years DI issues have emerged in multiple countries, including Australia, USA, India and China and as a result regulatory agencies have published draft guidance, soon to be finalized, setting out the Rules and Regulations expected from industry.

Our Offer

CBE and Delta offer a comprehensive assessment of your Data Integrity and Quality Metrics status. We provide a comprehensive gap analysis and CAPA report on the following areas:

- Overall Data Integrity health check – where are your gaps and how compliant are your procedures
- Development Programs and Regulatory Submission integrity
- Manufacturing in-process controls, particularly around your CPPs and CQAs
- Laboratory controls, with emphasis on Data Acquisition Systems, OOS and reporting of results
- Lifecycle security, access and audit trail over your GxP computerized systems and data
- Health status of your Quality Metrics Oversight programs

Our Data Integrity / Quality Metrics Team

Steve Williams (CBE) BSc, Grad Dip Quality Management

Steve has over 40 years' experience in the Biotechnology, Pharmaceutical and Medical Device industries in quality and manufacturing, including 25+ years consulting in GxP Quality Management and Regulatory Compliance. Steve conducts FDA and EU/TGA/PICs compliance audits and gap analyses, assists companies in remediation programs and prepares companies for regulatory inspection. He has developed multiple training courses in PQS, GMP, GLP, Process Validation, Risk Management, Sterile Manufacture and Medical Device Quality Systems. He specializes in sterile products, risk management and compliance training solutions for the Life Sciences Industry. Steve is a registered auditor for the Australian Pesticides and Veterinary Manufacturing Authority (APVMA) and in this role, conducts GMP licensing audits on behalf of the Australian government. He is a past member of International Board of Directors for ISPE (voluntary position). He is also a director SWA Biopharm Pty Ltd.

Rai Karklins (Delta) Member of Royal Society of Chemistry, MRSC CChem

Rai has over 30 years' experience in Chemical, Pharmaceutical, and Biotech, occupying senior management roles such as;

- VP Quality
- Site Operations Director
- QA and QC Managers
- Senior Project Manager/Technology Transfer Manager
- Development Manager

In quality roles, Rai has conducted multiple compliance audits and gap analysis, within the vendor assurance/supply chain, due diligence, routine internal and intra-company audit landscape. He has performed business process re-engineering with both Operations and Quality units using Quality Best Practice methods such as LEAN/SMED/TQM.

Our Affiliate Network

CBE works closely with a small team of trusted regional associates and affiliates who support our core team in specific projects including regulatory compliance, product registration, medical devices diagnostics, qualification, training and bio-processing technology.

In Asia CBE has partnered with the Hong Kong Institute of Biotechnology (HKIB) to support our regional operations.

Where we consult

CBE consultants are based in Australia and New Zealand and support clients throughout the Asia Pacific region. Our consulting experience includes countries such as Australia, New Zealand, China, Hong Kong, Taiwan, Korea, Malaysia and Singapore.

Contact

Steve Williams: steve.williams@cbe-ap.com.au

Rai Karklins: raikark@internode.on.net