Centre for **Biopharmaceutical Excellence**

Company Profile

CBE brings together a team of senior industry consultants and associates with extensive and practical industry experience in key areas of biopharmaceutical operations.

Our team of professionals offers broad, deep and diverse experience in the key areas of Quality, Engineering, Manufacturing Operations, Supply Chain and R&D. We offer a range of strategic consulting services to assist customers across Australia and the Asia Pacific Region.

CBE's mission is to ensure our customers are successful, efficient, compliant and can competitively manufacture safe and effective products.

CBE has capability across many sectors including biologicals, human and animal medicines, blood products, natural products/traditional medicines, vaccines, diagnostics and medical devices.

Our core skills are focused in the following areas:

- Compliance and quality systems gap analysis to FDA, EMA, PICs, TGA and other international standards
- Facility and cleanroom design, engineering solutions, commissioning and qualification/validation oversight
- Manufacture of sterile and non-sterile medicinal and biological products
- Development of R&D and operational strategies for the registration of biologics, medicines, blood products and new entities
- Operational excellence and process improvement
- Organizational improvement strategies

Within these areas the services we offer include:

- Consulting, planning and project management
- Quality Improvement and enhanced compliance
- Technical and scientific due diligence
- Client services and representation
- Technology transfer, plant expansion and scale-up
- Knowledge management and capability development

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, Brazil, Taiwan, Korea, Malaysia, India, Vietnam, Japan** and **Singapore.**

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Our Core Team

Steve Williams (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.

Jeff Davies PhD (Biochemistry)

Jeff is a Biopharmaceutical Executive with over 30 years' experience. He has 8 years of general management experience with CSL with oversight of the manufacture and supply of plasma products, influenza vaccines, anti-venoms and diagnostic products, and the in-licensing of pharmaceuticals and vaccines.

From 2000 to 2005 Jeff was Global Head of Plasma Products Research and Development responsible for R&D strategy and programs conducted in Switzerland, Australia, the USA and Japan. Prior to this his roles included Director of Clinical and Regulatory Affairs-plasma products (1997-2000) and R&D Management of Albumin, Immunoglobulin and Virology.

Jeff has had a number of advisory roles including industry representative on Pharmaceutical Industry Council, a member of the Australian Red Cross Advisory Board and CSL representative on European Plasma Fractionation Association.

Andrew Watson (Bachelor of Engineering - Chemical)

Andrew has over 20 years' experience in the design, construction, commissioning/validation and operation of a wide range high tech facilities, including pharmaceutical manufacturing, high containment, industrial cleanroom, hospital pharmacy and specialist research facilities.

This experience extends to facility layout, building fabric design, construction, and HVAC, utility and purified water specification. His project management experience encompasses all aspects of FDA, EU-TGA-PIC/s and associated regulations, local and international standards and general quality practices.

He has performed gap analyses on many pharmaceutical manufacturing facilities and sterile/cytotoxic dispensing suites to assess aspects of compliance, safety, design and rectification.

Andrew is a past president of ISPE (Australasia) and is active in establishing ISO standards. He is Independent Chair of ME-060 (Cleanroom Standards) for Standards Australia and committee member for TC-209 – (ISO 14644 and 14698 suite of standards).

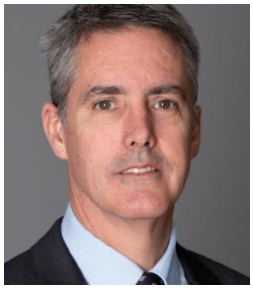
Maurice Parlane (B Tech MIT (Hons), NZCE (Mech); MIPENZ, MNZIFST - ISPE Member of the Year 2016)

Maurice is a professional engineer with 28 years' experience in manufacturing management operational and technical roles within the human and animal health, biotechnology and medical device sectors including 18 years in consulting roles.

He is an expert in management of technical operations under GMP regulations and specializes in biopharmaceutical process scale up, optimization and validation. He has a thorough understanding of operational and quality policies, procedures and international regulations; having managed over 350 compliance and operational projects of varying scale for clients nationally and internationally.

Maurice is a former President of ISPE (Australasia) and Chair of the ISPE Asia Pacific Affiliate Council. He is a member of ISPE's Asia Pacific Regulatory Committee and PQLI Process Validation Team. Maurice is also Principal/Director of NewWayz Consulting Ltd based in New Zealand.

Paul Fletcher (Dip. Engineering (Mech), Bachelor of Technology - Manuf. Eng.



Paul has over 25 years' experience in the Pharmaceutical and Life sciences industry as a Manufacturing/Operations Manager, Engineer and Consultant.

Most recently, he was the Manufacturing Manager for the Australian Red Cross Blood Service with overall responsibility for processing, testing and distributing of therapeutic blood products to the public and private hospitals within the states of NSW and ACT, Australia. Prior to this, his career included roles in project management, qualification and validation, production/manufacturing and operations management with Sandoz, AstraZeneca, Schering-Plough and iNova (previously 3M).

Paul has extensive industry experience in compliance, interpretation and practical application of TGA/PICs and FDA GMPs. He has extensive experience in continuous improvement, change management and productivity improvement. Paul has also worked on behalf of clients to obtain GMP licensing and remediate compliance gaps.

Alison Mew (MSc Hons)

Alison has extensive experience in the bio-pharmaceutical and diagnostic industry in operations and general management roles - both in Australia and overseas. Her corporate experience includes 13 years with CSL Ltd., in senior executive positions across the Animal Health, Biosciences and Pharmaceutical Divisions - managing vaccines, diagnostics and other biologicals and pharmaceuticals manufacture. Her tenure at CSL included direct involvement in acquisitions and establishment of new sites, as well as divestments – in particular, the divestment of the Animal Health business to Pfizer.

Alison was the Chief Executive Officer of Genetic Technologies Limited, a publicly listed genetic testing services company operating in both Australia and the US, from December 2012 until December 31st 2014. Prior to that, Alison held the position of Chief Operating Officer of Genetic Technologies Limited, responsible for the testing laboratories, IT and Customer Service functions. During this period, she provided the operational evaluation in the due diligence of a US asset acquisition and subsequently was instrumental in the validation and launch of a new genomic test into the US market. She then assumed responsibility for the US reimbursement program. Alison has spent several years providing consulting services in both operational and strategic planning to both local and international organizations.

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. Key associates include expertise in:

- Regulatory Affairs and Product Registration
- Pharmacovigilance
- Commercialisation Strategies and Market Analysis
- Due Diligence and M&A Strategies
- Quality Systems Implementation and Quality Improvement Strategies
- Energy Analysis and Energy Savings