**STUART SUTTON**

**Executive Summary**

Practical solutions to support operations for controlled business environments. My career has spanned, MNC, Pharmaceuticals, Regulatory Agency, Government – Military, International Banking and Consulting. I have a range of experiences that have broadened my perspective and the offering I bring to managing a team for excellence as part of a global matrix/virtual team. I thoroughly enjoy the adventure of travel, meeting new colleagues and collaborating on new projects and this has been a significant portion of my most recent career. I have delivered on projects for Quality Operations within MNC, CMO and Consulting within the Quality Operations space, QC, QA, Validation and advisory. I further expanded my horizons, by undertaking a Global MBA at Manchester Business School with a focus on Risk and Strategy. I bring a unique perspective for Quality Risk Management/Operational Risk with my experience in Therapeutics (Drug and Device), Military and the Banking sector with an emphasis on data management/governance and data integrity.

I enjoy delivering practical solutions to complex situations and find this type of challenge will enthuse me. Throughout my career several themes have emerged, starting with QC at a MNC with the quick adoption of computing and automation (robotics) to improve operations within a QC environment. Developing a fast pace high growth medium size contract manufacturer (CMO) to develop efficient and scalable processes to support the recent listing of the entity. A site closure project was my most challenging, with people issues of redundancy, coupled with compliance and technical transfer of processes and methods, including complete systems, training and validation to various locations in Asia. Also, during this time, we significantly improved service levels using an open/transparent data driven approach to bring stellar results to the group. Experience at Corporate Global Quality as a Regional Quality Systems Lead for systems, ranging from Quality Management Systems to Logistics and Distribution partners, has lent me great insight to the larger organisation and how it operates. I was fortunate that I also had Quality Validation Systems overview responsibility for a significant Greenfield site in China. I was one of the lead designers on a new concept for a Regional Surveillance Laboratory, where a small global team designed, built and fitted out for surveillance testing, validation and compliance to provide Quality input to the supply of contract manufactured products into the US market.

My view of QRM was shaken and adjusted when I developed processes and systems for an International Bank as part of the Basel II requirements for the banking sector. This led me to think differently and more structured about how to view Operational Risk. This experience showed me a world that was less structured than the therapeutics I was most familiar with and how to manage the fast pace of change. Following this I decided to move into consulting where I have experienced the dynamics of working on significant global projects in various locations, ranging from China, Japan, Greece, Russia, South Korea, Singapore and Malaysia. Consulting has given me a unique perspective into how to quickly determine the practical approach to solve a client’s pressing problems with balancing, delivering of a solution in a highly political environment that is usually cost constrained and with limited resources. Most recently I have been providing consulting support on QRM and CSV training as well as onsite projects related to computerised systems validation and quality systems. I was also fortunate to speak at two ISPE conference within the SEA region on topics I am familiar with.

**Career Highlights**

* Validation/Qualification Consulting for Computerised Systems for Automation, Data Integrity and Control. ERP, MES, CDS, Automation and Quality related systems, including Analytical instruments. QRM and CSV training programs developed and delivered to various clients. GMP audit with associated action plans for improvement.
* Market research on consumer perception of indoor farming to develop a Strategy for Marketing of Intensive Indoor farmed vegetables - Ang, R., Chan, K., Ito, Y., & Sutton, S (2016).
* Audit preparation, Systems for Self-Governance for a Biologics facility startup in Suzhou China. Development of and maturation of SOP’s, Metrics Scorecard, Quality processes, Qualification/Validation of Analytical Systems.
* Operational Risk Training for Client, Malaysia. Developed and delivered training course for Retail banking and Assurance staff at Standard Chartered bank.
* Developed Systems for Quality Assurance process and Scorecard/Metrics for Operational Risk Management (ORM) performance and effectiveness. Document Management and Publishing (e-signing), Operational Risk Intranet Site (SharePoint), including Communications with feedback, Process Universe library portal, Systems to administer and scale Assurance across the Group as well as Assurance Self Review and measurement. Risk Management mentor and training for business and functions.
* Assurance Reviews: Group, Business and Function review of ORM processes and practices as part of the first Assurance review in 2014. This pilot led to the development of broader Assurance reviews, with new scalable processes for Assurance in Group and Countries (tope nine) for all business/functions.
* Quality Authority for Global Systems: Advise, mentor provide guidance, best practice support to sites during period of rapid Asia expansion with Global Merger and Acquisition changes concurrent. Identify areas for Improvements and

**Key Skills:**

* Asia/EU Experience –lived and worked in Singapore, Malaysia, Philippines, China, South Korea, Japan and EU (Greece/Russia) for the past 10+ years.
* Business Administration – Strategy development, Scorecard, Research, Training, Mentor and Coaching.
* Operational Risk (Basel II / III, PRA) - Quality Assurance/Control GMP, EMA, PICs, US FDA, TGA, China FDA, Korea FDA;
* Training development and delivery
* Process Development & Standardization - Cost Leadership/Efficiency;
* Risk Assessment/Mitigation - cGxP - Risk based - Audit Preparedness;
* Global & APAC experience - Leadership / Management (MNC & Military) - Matrix & Virtual Team Management - Staff Training & Development;
* Quality / System Design Implementation & Management - Validation – Process/Cleaning/Aseptic/Computerised Systems/Review/Audit - Critical Information Accuracy ISO9000, 10002, 14000;
* Balanced Score Card - Communication tool to all levels of Management and Staff;
* Technical Transfer Inter/Intra company - Risk Operations / Compliance / Policy/Procedure;
* Global and Strategic Focused – Culturally adept – Matrix and Virtual skilled;
* MBA (Strategy focus), Bachelor of Science, Diploma in Military Operations (Capt. retired);
* Interpret Ambiguity to develop Standardisation;
* Realise BIG picture through the lens of cause and effect, resulting in Cost/Operational Effectiveness.

**PROFESSIONAL EXPERIENCE**

**Consulting, Singapore 2016 to Current**

**Operational Risk Training and Pharmaceutical Consulting.**

Malaysia - Independent consulting Operational Risk training for Ratings Agency Malaysia (RAM) to Standard Chartered Bank.

China - Innovent Biologics Suzhou. Pharmaceutical consulting, Validation and Audit preparation. QC Audit review and preparation for first startup Clinical Manufacturing Audit.

Analytical Equipment and Method Validation Speaker at ISPE Philippines Manila 2017.

Singapore - Lonza Biologics collaboration with NIKON CeLL innovation Co., Ltd Japan develop Operations SOP’s.

Singapore - Novartis Biopharmaceutical Singapore Laboratory Equipment Qualification/Validation of Computerised system (6 months).

Japan - Nikon Cell Innovation – Tokyo (6 months) Cell Therapy – Operational Process development (Supply Chain/Warehouse/Quality), SOP development and Advice work.

Europe & South Korea - Swiss Multinational Client – Site support in Athens Greece (6 months), Saint Petersburg, Russia (4 months), South Korea (6 months). Analytical Equipment and Computerised systems Qualification (CSV) for In-Line instruments, Primary Control System and Process Supervisory Systems.

Singapore – MSD Biologics, Validation consultation for Automation and lifecycle document writing.

Singapore - ThermoFisher, Manufacturing Execution System (MES) Full lifecycle Computerised System Validation of Servers and System (Medical Device Class I&II).

Quality Systems Audit of Pharmaceutical facility in South Korea Sept 2019

Computer Systems Validation Keynote Speaker at ISPE DaNanag, Vietnam 2019

Computer Systems Validation Training course development and presentation including full day workshop for Medical Device Manufacturer in Malaysia Nov 2019

Quality Risk Management and Risk Management techniques Training course development and Workshop at South Korea for Pharmaceutical manufacturer, Dec 2019

Malaysia – Site Validation Consultant. Develop Governance framework, Processes, SOP’s, and systems validation for a US FDA Medical Device Audit 2020.

**Standard Chartered PLC, Singapore 2013 to 2016**

**Group Operational Risk, Executive Director - Operational Risk Assurance team. Group assurance and process excellence***.*

Strategic Review of ORM and Audits resulting in developing systems to support, standardize, deliver on audit findings for Document Management and Publishing (e-signing), Operational Risk Intranet Site (SharePoint), including Communications with feedback measurement, Process Universe library portal, and Systems to administer and scale Assurance across the Group as well as Assurance Self Review and measurement.

Strategic paper for ORM future direction, use of common language across business groups via Scorecard cause and effect with linkage of Performance to Remuneration / Bonus.

**MERCK PHARMACEUTICALS,** Singapore **2013 to 2013**

**Head of Subsidiaries Quality, APAC**

Develop APAC staff, systems, quality reporting, coordinate APAC quality issues with Regulatory and Development.

PFIZER (legacy WYETH) PHARMACEUTICALS, Singapore 2009 to 2013

*Pfizer Global Supply, Global Quality Operations Quality Assurance team.*

Senior Quality Operations Manager - Global Quality Operations QSTS-SLS – Design, Build, Equip and Operate: Multi-function matrixed global team of specialists designed a new Global facility in 3 months, then construction (6 weeks), followed by fit out, staff and validate of processes and systems. The site was considered groundbreaking in design for size and cost.

Senior Quality Operations Manager - Global Quality Operations QSTS-V – Mentor, Corporate Feedback/Review/Regulatory guidance and assessments on Systems (computer, cleaning, process, computerised) Validation – assuring appropriate Risk Based Compliance / Validation Documentation is produced and available. Site Strategy and Audit preparedness review.

**SCHERING PLOUGH, Sydney, NSW (now MSD) 2006 to Nov 2008**

**Global supply chain location, supply site for Asia Pacific countries.**

Quality Control Manager - Led turnaround of manufacturing operation plagued with poor productivity, delivery rate, and compliance performance. Managed all aspects of in-house and third-party chemistry, microbiology and QC, including analytical/cleaning/method development/validation, in-process/finished product testing, and technical transfers. Developed and maintained relationships with internal and global operations, regulatory affairs, manufacturing, and maintenance groups to enable successful completion of tasks. Member, Site Quality Council.

* + Improve location’s global rank from #28 in 2004 to #1 in 2007
  + Systems re-engineering service levels from 40% to high 90% over 18-month period.
  + Reduction in team staffing.
  + 100% on-time customer delivery, with reduced Investigations and significant improvement in quality of investigation.
* Coordinated site closure activities for all QC and analytical matters
* Developed Global Regulatory Compliance report tool

**LIPA PHARMACEUTICALS LTD, Sydney, NSW 2005 to 2006**

**One of Australia’s top publicly listed manufacturers of OTC products, and complimentary/herbal medicines & nutritional supplements.**

Quality Operations Manager - Strategic Initiative for growth / expansion as the company transitions from privately owned to publicly owned organization. Main challenges included realigning quality processes with requirements of a large organization, improving internal compliance operations, and providing a level of technical competence to customers who required multinational corporation (MNC) compliance. Heightened company’s credibility and developed new business by implementing technology advancements and state-of-the-art equipment. 50 direct reports.

**THERAPUETIC GOODS ADMINISTRATION (TGA), Canberra, ACT 1992 to 1992**

*Physical Chemistry Evaluator for Change to Route of Synthesis, Packaging, Stability or Registered specification.*

**ELI LILLY, Sydney, NSW 1988 to 2005**

*Global pharmaceutical company; manufacturer of tablets capsules, liquids, suspensions, drug devices, and medical feed for animals.*

**Quality Control Manager, Laboratory** (1999–2005) | **Senior Chemist, Quality Assurance** (1996–1998)

**Associate, Quality Assurance** (1993–1996) | **Analyst, Quality Control** (1988–1993) — Delivered strong and sustainable results, **achieving/surpassing all growth objectives:**

**First time performing Computerised Systems Validation.** QA, and Inventory Modules for **ERP** system. **Robotic** Sample preparatory instrument. **Quality Systems**, Document Control, Training, Change Control and Deviation Management.

***Prior:*** *Analyst, Quality Control,* ***Sterling/Winthrop Pharmaceuticals,*** *(now Glaxo Smith Kline)* ***1987-1988***

**EDUCATION:**

Global MBA, Manchester Business School, Manchester University, U.K.

Bachelor of Applied Science (Chemistry), University of Technology, Sydney NSW, 1994

Diploma in Operations Management, Royal Military College, Duntroon, 1998-1999 Graduate Lieutenant Australian Army, current rank Captain (Retired).

**CERTIFICATION:**

Chartered Chemist, Australia.

AFFILIATION: Member - Royal Australian Chemical Institute and International Society for Pharmaceutical Engineers