PLENARY SESSION

National GMP & Validation Forum 2016

11-12 July

DAY 1

09.00 – 09:05

Welcome and Introduction

Trevor Schoerie, Managing Director, PharmOut

09.05 – 09:20

Forum Opening

Mr Frank McGuire MP, Member for Broadmeadows, Parliamentary Secretary for Medical Research

09.20 – 9:50

Gmp & Validation – From Disaster, Via Overkill, To Common Sense

Gordon Farquharson, Executive Consultant, PharmOut

9:50 – 10:20

FDA Regulatory Update – New Guidance's and Warning Letter Trends

Roy Cherris, BAI Associates

10:20 – 10:30

Conference Overview & Interactivity Tool

Ashley Isbel, PharmOut

10.30 – 11:00

Tea / Coffee

11.00 – 11:30

EU Regulatory Update

Bryan Wright, ex Head of GMP/GDP at the MHRA, UK, Executive Consultant, PharmOut

11.30 – 12:00

International Regulatory Convergence – Is Enough Being Done

Bob Tribe ex Head TGA GMP section, Executive Consultant PharmOut

12:00 – 12:30

Data Integrity & Blockchain Technology and The "Internet Of Things" (IoT)

Eoin Hanley, Technical Manager, PharmOut

12:30 – 13:30

Lunch

PharmOut®

Regulatory Knowledge, Practically Applied

TRACK 1 (Track leads: Eoin Hanley & Alison Tennent)

Non Sterile & Sterile Manufacturing GMP Compliance & Validation

DAY 1

Regulation & Implementation

13.30 - 14.00 Impact of EU GMPs on Australian GMP - Trevor Schoerie, PharmOut

14.00 - 14.30 Keep the Faith: Ageing Plant Compliance - John Montalto, CSL

14.30 - 15.00 Is Knowledge Management part of your Pharmaceutical Quality System? - Eoin Hanley, PharmOut

15.00 - 15.30 Tea/Coffee

QA Lifecycle

15.30 - 16.00 Case Study: FDA ANDAs and legacy QbD approach - Deb Cailes, IDT Australia

16.00 - 16.30 Product Quallity Review - Clare Schwarz, CSL

16.30 - 17.00 A practical approach for implementing product lifecycle and control strategy for an API manufacturing process - Ahsan SyedAli, Qbiotics

DAY 2

Electronic Quality Management Systems

09.00 - 09.30 GMP Considerations Transitioning to an eQMS - Kathy Walsh, PharmOut

09.30 - 10.00 A Cost Effective EQMS Solution - Matt Schoerie, QikSolve

10.00 - 10.30 EQMS Implementation Case Study - Sean Pitt, QikSolve

10.30 - 11.00 Tea/Coffee

Session Title - Process & Equipment Validation

11.00 - 11.30 Process Validation: Measuring what Matters - Trevor Schoerie, PharmOut

11.30 - 12.00 Using Data Analysis to Improve Quality, Save Money & Increase Productivity - Ming Dong, Minitab

12.00 - 12.30 EMS Project Management - From URS to Handover - Matt Kennett, Laftech

12.30 - 13.30 Lunch

GMP Hot Topics

13.30 - 14.00 CSL Behring – Aligning Quality Processes - Ed Jones, CSL

14.00 - 14.30 DI - A Study of Thinking and Regulatory Action - Eoin Hanley, PharmOut

14.30 - 15.00 Data Integrity - Practical Applications - Marc Fini, PharmOut

15.00 - 15.30 Tea/Coffee

Storage and distribution (GDP)

15.30 - 16.00 Wholesaling & Distribution & the GMPs - Bryan Wright

16.00 - 16.30 Introduction to Temperature Mapping of Controlled Temperature Storage Areas – Temperature Mapping 101 - Grant South, PharmOut

16.30 - 17.00 Q & A Session & Panel Discussion

TRACK 2 (Track leads: Ashley Isbel & Marc Fini)

Sterile & Aseptic Manufacturing
GMP Compliance & Validation

DAY 1

Emerging Trends in Sterile Manufacture

13.30 - 14.00 RABS & Isolators Barrier Technology - Gordon Farquharson, PharmOut

14.00 - 14.30 Advanced Therapy Medicinal Products and GMP - Ashley Isbel, PharmOut

14.30 - 15.00 Rapid Decontamination Systems - Brett Cole, Biosafety

15.00 - 15.30 Tea/Coffee

Pharmaceutical Water

15.30 - 16.00 WFI – New Ph Eur Production Specification

16.00 - 16.30 WFI – New Ph Eur Selecting the best production option - Gordon Farquharson, PharmOut

16.30 - 17.00 Rapid Micro Detection Systems - Roger Strebel, Mettler Toledo

DAY 2

Annex 1

09.00 - 09.30 Update on revision of Annex 1 - Bryan Wright, PharmOut

09.30 - 10.00 Impact of new ISO 14644-1&2:2015 0n GMP Annex 1 - Gordon Farquharson, PharmOut

10.00 - 10.30 Sterile Processing – Current Challenges in Annex 1 - Ashley Isbel, PharmOut

10.30 - 11.00 Tea/Coffee

Sterile Manufacturing Hot Topics

11.00 - 11.30 Sterile Compounding - Regulations, Application & The Future, Ashley Isbel, PharmOut

11.30 - 12.30 Particle Determination: Guidance for Parenteral Products - Roy Cherris, BAI Associates

12.30 - 13.30 Lunch

Sterile Manufacturing Tools

13.30 - 14.00 Sterilization Liquid Loads Description - Daniel Clifford, Getinge

14.00 - 14.30 Disposable Technology - Qualified Disposable Materials - Andreas Kokourek, Sartorius Stedim

14.30 - 15.00 Microbiological monitoring of clean rooms – A New Approach - David Felici, Thermofisher Scientific

15.00 - 15.30 Tea/Coffee

Sterile Manufacturing Practice

15.30 - 16.00 Best practice in environmental monitoring - Annette Grundy, Baxter Healthcare

16.00 - 16.30 Bio-contamination control PHSS Technical Monograph No. 20 - Gordon Farquharson, PharmOut

16.30 - 17.00 Q & A Session & Panel Discussion

TRACK 3 (Track leads: Jacob MacDonald & Nic van der Nol)

Facility Design & Equipment

DAY 1

Innovative Technology

13.30 - 14.00 Innovation in Automation - Barry Hendy, ADDE

14.00 - 14.30 Advancements in Isolation Technology for Aseptic Filling - Marco Preus, IMA

14.30 - 15.00 RFID and barcode technology in GMP - John Nesbitt, Wayahead Systems

15.00 - 15.30 Tea/Coffee

Session Title - Warehousing & Facilities Monitoring

15.30 - 16.00 Wireless Technology Update - Craig Abbott, Emerson Process Management

16.00 - 16.30 Scientific Approach to Cool Room Validation - Gary Ward, IPI

16.30 - 17.00 Warehousing case study - Michael Lawrence, CHS

DAY 2

Facility Design & Construction

09.00 - 09.30 Efficiency in Facility Design - Nic van der Nol, PharmOut

09.30 - 10.00 Clean room construction - Keiron Smith, Kingspan

10.00 - 10.30 Engineering a blood processing facility for viral safety - Cameron Roberts, PharmOut

10.30 - 11.00 Tea/Coffee

Facility Design & Critical Measurement

11.00 - 11.30 Particle Counting Systems - Design, Installation & Qualification Challenges - Bradley Thomas, Kenelec

11.30 - 12.00 Flow Measurement with FLOWave flowmeters in clean utility applications - Ryan Orbell, Burkert Controls

12.00 - 12.30 Modular Cleanrooms - Jason Kavanagh, G-Con Manufacturing

12.30 - 13.30 Lunch

Containment & Isolation

13.30 - 14.00 Case Studies: Demonstrated advantages of RABS/Isolators - Marco Preus, IMA

14.00 - 14.30 Facility design for containment - Gordon Farquharson, PharmOut

14.30 - 15.00 Contained processes and equipment - Gordon Farquharson, PharmOut

15.00 - 15.30 Continuous Manufacturing & Other OSD Technological Advancements - Jacob MacDonald, PharmOut

15.30 - 16:00 Tea/Coffee

PLEASE NOTE: Sessions and times are subject to change