Centre for Biopharmaceutical Excellence

CBE Consulting Team – Industry Presentations

Title	Consultant	Conference	Date
Challenges in Implementing the New PICs/ EMA Chapter 1 PQS	Steve Williams	ISPE - Singapore	Aug 17
Practical Risk Management Tools for Different Situations	Steve Williams	ARCS - Sydney	Aug 17
Caution in Using the Cpk Statistic in PQR Assessments	Steve Williams	Paper download	<here>
Media Fills: A Rational for Number of Units Processed	Steve Williams	Paper download	<here>
ISO 14644 – Current Update and regulatory Interpretation - TGA	Andrew Watson	TGA- Canberra	May 17
Data Integrity Webinar	Steve Williams	Download	<here>
Does industry really have a problem with Data Integrity DI ?	Steve Williams	ARCS /ISPE - Canberra	Aug 16
Defects, Deviation Investigations and Root Cause Analysis	Steve Williams	ARCS - Sydney	Aug 15
Engineering QbD Principles into Commercial Product (Leveraging CPPs and CQAs)	Steve Williams	ISPE – Kuala Lumpur	May 14
Validation of Viral Inactivation / Scale Up into GMP Manufacturing	Steve Williams	ISPE – Kuala Lumpur	May 14
Technical challenges in Partnering Biotech projects	Maurice Parlane	NZBio - Auckland	Sept 15
Process Validation *An update on the ISPE PV initiative and application of lifecycle PV principles*	Maurice Parlane	ISPE China Spring Conference	April 2015
Process Validation for Legacy Products Strategies for implementing lifecycle validation to legacy products	Maurice Parlane	ISPE India Conference	May 2016
ISPE PQLI PV Team - Introduction and PV Discussion documents	Maurice Parlane	CFDA/ISPE	April 2015

QUALITY BY DESIGN (QbD) *A Paradigm shift in the regulation of the pharmaceutical product life-cycle*	Maurice Parlane	ARCS - Sydney	Sept 2014
Update on GMP and PIC/S in the Asia Pacific Region	Maurice Parlane/Bob Tribe	ISPE Annual Meeting – Washington DC	Nov 2013
Current Status of PV in the Asia Pacific region	Maurice Parlane	ISPE Process Validation Conference – Washington DC	Sept 2016
Process Validation trends in the Asia Pacific region	Maurice Parlane	ISPE Process Validation Conference – Silver Spring USA	Oct 2015
Planning and Managing Expansion Projects - Balancing the Risks and Opportunities	Maurice Parlane	Natural Products NZ - Auckland	May 2016
New Pharma Manufacturing Technology Trends	Maurice Parlane	ISPE Indonesia - Jakarta	May 2017
ISPE Drug Shortages PREVENTION Initiative *Preparedness Assessment, Gap Analysis and Remediation Guidance*	Maurice Parlane	ARCS - Canberra	Aug 2016
Challenges in Scale Up/Technology Transfer to Commercial Manufacture	Steve Williams	Workshop - Taiwan	Aug. 16
Due Diligence – **A** Case Study	Dr. Jeff Davies	Workshop - Taiwan	Aug. 16
Compliance Trends and Data Integrity	Steve Williams	Workshop - Taiwan	Aug. 16
Challenges in Regulatory Pathways (From Clinic to Market)	Dr. Jeff Davies	Workshop - Taiwan	Aug. 16
Medical Device Current Global Landscape	Steve Williams	Workshop – Hong Kong	Aug. 16
Developing and Managing a Cleanroom Microbiological Monitoring Program for Sterile Products	Steve Williams	ISPE – Brisbane Melbourne Adelaide	Sept. 14
Applications of Cleanroom regulations and standards – present and future	Andrew Watson	ISPE – Brisbane Melbourne Adelaide	Sept. 14
Building Offshore Collaborations – A Case Study	Alison Mew	NZBio	Sep 16
Data Integrity – What is it and does industry have a problem?	Alison Mew	BioMelbourne Network	Feb 17