

Ispe Good Practice Guide Good Engineering Practice

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ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry PROJECT TYPE MATRIX : Key Activities per Life Cycle Phase Phase Aspects within phase Facility - New Build / Revamps / Upgrades Product Transfer Process Improvement / Development IT Automation

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Cold Chain 101 The First Steps Andrew Gibson Quality Director CoolPac Pty Ltd V01 Compliance • TGA's GWP (Good Wholesaling Practice) • ISO 13485 (Medical Device) • Pharma's GMP • ISO 9001 • GDP (Good Distribution Practice) • ICH •ISPE Good Practice Guide: Cold Chain Management •USP 1079 / 1083

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Guidlines for Good Engineering (GEP)

Guidlines for Good Engineering (GEP) Author: Unknown Created Date: Thursday, November 18, 1999 1:26:36 PM

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In accordance with PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE 009-10 - Annex 11 (Computerised Systems), roles and responsibilities (eg Business Process Owner, System Owner, Supplier, IT, etc) must be clearly defined and documented for the life cycle of a

Commissioning and Qualification (Verification) in ... - ISPE

6based on maturity ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment, Inter-national Society for Pharmaceutical Engineering (ISPE), June 2011, www.ispe.org 7 ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification, International

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Tony was joint-editor of the ISPE Guide to Ozone Sanitization of Pharmaceutical Water Systems⁸ and was also chief editor of the PHSS Best Practice Guide for Cleanroom Monitoring⁹ Tony is a well-known international speaker and has provided educational seminars on TOC, liquid particle counting,