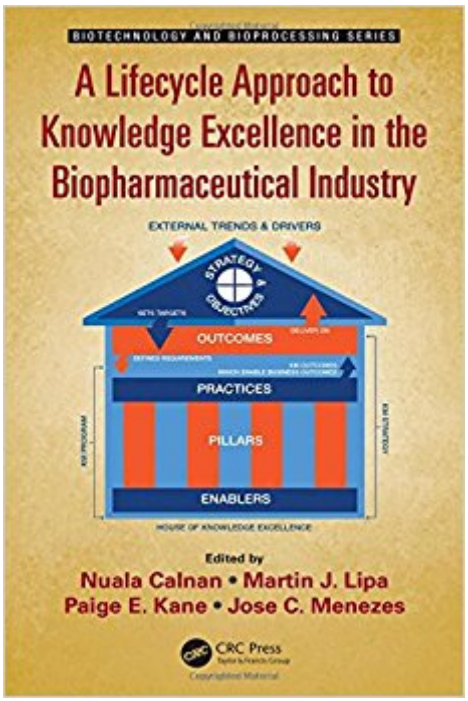
A Lifecycle Approach To Knowledge Excellence In The Biopharmaceutical Industry (Biotechnology And Bioprocessing)



Synopsis

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisationÃ¢â ¬â„¢s knowledge assets can provide a path towards business excellence.

Book Information

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Customer Reviews

Nuala Calnan, PhD has over 20 yearsÃ¢â ¬â„¢ experience in the pharmaceutical industry and is currently an adjunct Research Fellow with the Pharmaceutical Regulatory Science Team at DIT, Ireland, where she leads a number of patient focused regulatory science research projects at Masters and PhD level. Dr. Calnan’s focus is on the integration of Knowledge Excellence, Operational Excellence, & Cultural Excellence in delivering enhanced quality outcomes for the patient and has led a recent Irish Industry research study in this field examining the Product Recall and Quality Defect data at the Irish medicines regulator, HPRA. She is currently a member of the St. Gallen University led team who were awarded a one-year research grant by FDA examining the role of Quality Metrics in determining risk-based inspection planning. Dr. Calnan also works closely with industry in the areas of Quality Excellence and Metrics, Data Integrity and Quality Culture development. Dr. CalnanÃ Â co-leads the ISPE Quality Culture Team and the ISPE/ PQLI Task Team on Knowledge Management. Martin Lipa is an Executive Director in Merck Manufacturing

(MMD) and leader of the MMD Knowledge Management Center of Excellence (Knowledge Management CoE). For the past 8 years he has worked to create Knowledge Management strategy for Merck Manufacturing and other functions across the Merck enterprise and to build capabilities and competency in Knowledge Management as an enabler of the companyÃ¢â ¬â„¢s strategy. Lipa has over 20 yearsÃ¢â ¬â„¢ experience in the biopharmaceutical industry. Prior to focusing on Knowledge Management, he started his career as a Technical Operations engineer and then progressed through roles in shop floor automation, computer systems validation, new GxP facility startup, project management and clinical supplies. He is also a certified LSS Black Belt and specializes in change management techniques. Lipa is a recognized industry Knowledge Management thought leader and has helped organize multiple Knowledge Management conferences. He has also published industry specific works and features as a regular speaker sharing his experience and learnings. Paige E. Kane, CPIP, is a Director in the Merck Manufacturing Division Knowledge Management Center of Excellence. In addition she is a regulatory science researcher at Dublin Institute of Technology in Dublin, Ireland where she is pursuing a PhD focusing in the realization of the ICH Q10 enabler Ã¢â ¬â œ Knowledge Management. For the past 10 years, she has been involved in developing and implementing Knowledge Management Strategies for Wyeth and Pfizer Global Supply with a strong focus on people, collaboration, and processes.Ã Â Kane has over 25 yearsÃ¢â ¬â„¢ experience working in a regulated environment (including Genetics Institute, Wyeth, Pfizer, Monsanto, and the US Government).Ã Â Kane has been responsible for developing and implementing Quality Systems for GLP, GCP and GMP, as well as Computer System Validation programs. In addition, she provided leadership and Subject Matter Expertise for multiple biotech startups in the US and Europe. Kane is the Co-Chair of the ISPE/ PQLI Task Team on Knowledge Management.and serves locally as co-chair of the Boston ISPE Student Development Committee. Jose Menezes, PhDÃ Â is founder and director of one of the earliest Pharmaceutical Engineering programs in Europe and a pioneer on the use of PAT and QbD tools in bioprocessing. He is the recipient of a Presidential Award for Excellence in University-Industry collaborations. Dr. Menezes is a Professor at the University of Lisbon since 2005. He has published extensively on the subject of manufacturing sciences and technologies applied to pharma and biotech products. He earned Chemical Engineering BSc and MSc degrees and a PhD in Bioengineering from ULisbon. He worked for Ciba-Geigy in Switzerland and the nuclear industry also in Switzerland, before embarking on an academic career. During his 20 years at ULisbon, he spent multiple sabbatical periods in industry at different pharma companies in Europe, where he built, trained or managed

several PATÃ Â and QbD teams. He is an active member of several societies and a Senior Member of AIChE, ISPE, PDA and IFPAC among other organizations. Dr. Menezes co-founded 4Tune Engineering Ltd in 2004 Ã¢â ¬â œ an award-winning ISO 9001:2008 engineering services company Ã¢â ¬â œ developing and implementing worldwide state-of-the-art manufacturing sciencesÃ Â and technologies solutions, to deliver quality risk management and excellence in corporate Knowledge Management over life-cycle.

A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry (Biotechnology and Bioprocessing) Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing) Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation (Publication / United States Catholic Conference) Building Biotechnology: Biotechnology Business, Regulations, Patents, Law, Policy and Science The Ethics of Biotechnology (Biotechnology in the 21st Century)**OUT OF PRINT** Bioprocessing Piping and Equipment Design: A Companion Guide for the ASME BPE Standard (Wiley-ASME Press Series) Organising Knowledge: Taxonomies, Knowledge and Organisational Effectiveness (Chandos Knowledge Management) Scale-Up and Optimization in Preparative Chromatography: Principles and Biopharmaceutical Applications (Chromatographic Science Series) Preclinical Development Handbook: ADME and Biopharmaceutical Properties Biopharmaceutical Production Technology, 2 Volume Set Advances in Fungal Biotechnology for Industry, Agriculture, and Medicine Bonds of Blood: Gender, Lifecycle, and Sacrifice in Aztec Culture (Early Modern History: Society and Culture) Engineering Documentation Control Handbook, Fourth Edition: Configuration Management and Product Lifecycle Management Virtually Perfect: Driving Innovative and Lean Products through Product Lifecycle Management God’s Appointed Customs: A Messianic Jewish Guide to the Biblical Lifecycle and Lifestyle UX Lifecycle: The Business Guide to Implementing Great Software User Experiences Business Intelligence Roadmap: The Complete Project Lifecycle for Decision-Support Applications W21PR - Standard of Excellence Book 1 Drums and Mallet Percussion - Book Only (Standard of Excellence Comprehensive Band Method) W21CL - Standard of Excellence Book 1 Clarinet - Book Only (Standard of Excellence Comprehensive Band Method) W22FL - Standard of Excellence Book 2 Book Only - Flute (Standard of Excellence - Comprehensive Band Method)

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