Pharmaceutical Consulting Israel, Ltd

Tax Reg. No. 51-250658-5

PCI

Resume

Name	Karen Ginsbury
Current Employment	President, PCI, Pharmaceutical Consulting Israel (1994 – current)
Education	MSc, Microbiology, University of London, ENGLAND
	BPharm (Hons), University of London, ENGLAND
Previous Employment	1987 - 1994 TEVA Pharmaceutical IndustriesLtd Quality Assurance Department Compliance Officer (reporting to Director, Quality Assurance) Other positions held in Teva: Quality Assurance, Sterile Production 1985 - 1986 SMITH & NEPHEW Pharmaceuticals Ltd. England Research & Development Pharmacist

Areas of Expertise

Quality Systems, GxP and Management of Outsourced Activities	Preparation and negotiation of Technical / Quality Agreements; audits and investigation of deviations / non-conformances / dispute resolution Setting up and continuous improvement of Q10 compliant Pharmaceutical Quality Systems tailored to meet a company's strategic goals: trim, slim, no-nonsense SOPs with performance metrics built-in to ensure continuous improvement Inspection Readiness Management: FDA, MHRA and other EU inspectorates, mock inspections and in-depth compliance audits to provide management with an accurate picture of the current state of compliance and regulatory risk areas. Preparation of response to regulatory inspection deficiencies
Validation	All aspects of facility, system, equipment and process validation in compliance with ICH Q8, 9, 10 lifecycle model. Hands-on validation experience.
Investigational Products	All aspects of GMPs for products in development, working with companies to develop flexible but controlled approaches to Quality Operations in product development. Use of Risk Management to develop a Product Control Strategy.
Aseptic Processing	Start-up, validation, operation and monitoring of cleanrooms, media fills, environmental control programs, risk assessment
Microbiology	Sterile and non-sterile operations; water microbiology; bioburden and IPC
APIs	GMPs and supplier qualification / auditing, implementation of Q7
Training	Managers; production and QA staff as well as R&D personnel; tailored in-house courses; set-up formal training programs with efficacy metrics
Biotechnology	Product and Process Lifecycle Quality System: upstream / downstream from early R&D through pre-clinical, phase I, II and III to commercial production, blood products including risk assessments and audits from starting material through final fill and finish

Recent Publications / Activities

IVT Validation Week EU Amsterdam, 2019: Digital Maturity and Data Integrity + Pharma 4.0 workshops, Chair, PDA Outsourcing Conference, Berlin December 2014

Pharmaceutical Outsourcing: Quality Management and Project Delivery, 2013

Editors: Trevor Deeks, Karen Ginsbury, Susan Schniepp

Chapters on Investigations, Use of Risk Management in EM Program, Microbial Control Strategy

in Environmental Monitoring, edited by Jeanne Moldenhauer Published by DHI, USA

Compliance Auditing for Pharmaceutical Manufacturers

Published by Interpharm Press, USA 1994.

Professional Affiliations

Former co-chair of PDA Interest Group on Ousourced Operations and Pharmacopoeial Interest Group

Karen Ginsbury set up the Compliance Division at Teva Pharmaceuticals and co-authored a book on compliance auditing which is still available worldwide, including being purchased by FDA. Karen has extensive auditing experience and is frequently called upon to manage inspection readiness programs for companies around the world. In this role, she has performed mock inspections as part of international teams and has successfully steered several reputable companies through regulatory pre-approval inspections including US FDA, EU inspection authorities (including MHRA, IMB now HPRA and others), Health Canada and others. At the 2014 PDA/FDA Conference, Karen facilitated a session for the Inspection Trends Interest Group on "Showcasing your Quality System" – How to present a company's quality system in the best possible light during the short time available in an inspection. FDA inspectors and industry representatives discussed "do's and don'ts" prior to, during and after the inspection.

Karen's major areas of expertise relates to quality systems, compliance and validation activities using a risk based, cost-effective approach and integrating risk assessment for lifecycle management of validation of facilities, equipment, critical systems and processes as well as analytical methods and computerized systems. She lectures regularly on Quality and GMP – related topics at different meetings around the world allowing her to benchmark best practices.

Through her membership in PDA's prestigious Regulatory Affairs and Quality Advisory Board Karen led task forces commenting on guidance-in-the-making. Karen led the commenting team on the EUs shared facilities guidance and represented PDA at the EMA meeting with industry. She was active in the task force commenting on the draft process validation guidance and since issuance of the finalized FDA Process Validation guidance in January 2011, has moderated two interactive question and answer sessions at conferences with FDA representatives.

In 1994, Karen Ginsbury set up her own company providing consultancy services in Israel and around the world. The company serves companies wishing to pass pre-approval and ongoing compliance GMP inspections in order to sell / export medicinal products to the USA or European Community. Recently PCI has extended its client database to include any company or service provider wishing to embed a quality culture of defects prevention rather than continuing to react to failures.