Trish Melton

Managing Director

MIME Solutions Ltd

Trish launched ***MIME Solutions*** in November 2003 – her vision being to support companies through identification & implementation of projects & business strategies.

Trish is a ***Chartered Chemical Engineer*** who has worked world-wide as a Project Manager & Project Management Consultant within both engineering & non-engineering Projects, predominantly within the ***Pharmaceutical Industry***.

Trish has extensive experience of Project Management, Product Development, Change Management & also the ***regulatory needs*** of the Pharmaceutical Industry. She has worked as both a service provider & an end user and uses an ***innovative approach*** to the development of appropriate strategies, which considers both technical & business needs whilst meeting Client requirements

Trish was recently given an award for her role in the launch of the ***ISPE API Baseline Guide***

Name	**Trish Melton**
Date of Birth	**1963**
Qualifications	**BSc (hons), PhD, MBA, CEng, CSci, FIChemE**

SUMMARY

- Project Management (EPC, product launch/development, engineering & non engineering projects, PM Training and PM Publications)
- Pharmaceutical Engineering, Validation & Compliance
- Management Consultancy, Business Management/Improvement, Lean 6 Sigma

RELEVANT EXPERIENCE

- 2003 to present – Director of an Engineering & Management Consultancy delivering project management, business change management (including deployment of lean six sigma), regulatory and GMP consultancy assignments for Clients in the Pharma, Chemicals & Healthcare Industries. Current & past Clients include Astrazeneca, Barts NHS Trust, GSK, Britest and ISPE.
- 2002 to 2003 – Divisional Head of Atkins PharmaChem delivering project & consultancy services to the Pharma and Chemical Industries. Regulatory Consultancy assignments with key Pharma Clients, Set-up of the Validation & Compliance Department, Compliance Risk Reviews of "live" projects such as the £30M BioPharma Project for Avecia Biologics, Responsible for divisional operational Improvements using lean thinking & applied this to the project delivery process as well as to other internal business processes.
- 2000 to 2002 – As a Project Consultant, development of the concept of a generic structured approach to Project Management in GSK through active involvement in non-engineering projects such as Product Development within R&D (managing the regulatory lifecycle/compliance risk) & corporate Facility Rationalisation/Relocation. Management of the implementation of "lean manufacturing" on GSK's largest pharma manufacturing site involving the deployment of lean sigma training, management of the improvement project programme and overall review of the benefits of the deployment.
- 1999 to 2000– Overview project management of a major new Primary Manufacturing Facility in the Asia Pacific Region.. Overview project management of the conceptual design of a major new Secondary Manufacturing & Packaging Facility in India.
- 1997 to 1999 - Manager of Projects - Overall responsibility for coordinating all projects across the company – including resource management. This role also extended to project performance monitoring, management of Client relationships and line management of the Project Managers, Project and Mechanical Engineering Departments.
- 1997 to 1999 - Manager of QA & Validation - Management of the QA System (in line with ISO9000) which was flexible enough to cater for a varied Client base via use of Quality Plans, i.e. Project Specific Quality Manuals.
- 1998 to 1999 - BPC Plant, Korea **-** Project Director & Validation Director leading the Client/Consultant Project Management & Validation Team that delivered the 1st plant in Korea to be designed, installed & commissioned to FDA Standards. During the project further support was provided to the Client in managing the regulatory & product development strategy. This work was in partnership with a major UK based pharma company (SKB) & involved the development of a fast track strategy to take a new drug from clinical trial, through registration to launch.
- 1995 to 1998 – Major Antibiotic Facility (SKB) –Installation of primary manufacturing capability all validated to FDA standards, GMP Plant Upgrade & Antibiotic Facility Commissioning Support (GW) plus various conceptual design consultancy assignments
- 1991 to 1994 – Project Engineer/Manager & Validation Engineer for a £5 Million Human Hormone Facility. Scale-up of fermentation, purification (chromatography) & freeze drying process in compliance with MCA & FDA (Eli Lilly).

SELECTED PUBLICATIONS

Melton P M (June 2005), ChERD, 83(a6): 662-673***, "The Benefits of Lean Manufacturing: what lean thinking has to offer the process industries"*** – as presented at the World Congress in Chemical Engineering, July 2005

Melton P M (March 2005), DIA 17th Annual Euro Meeting, Lisbon, Portugal, ***"Agile Project Management in a Pharma Environment: How "best practice" project management can support lean compliance"***

Melton P M (Sept 2004), The Chemical Engineer***, "To Lean or not to Lean (that is the question)"*** A paper which examines the benefits on using lean thinking on business processes and project management