## Mark Shal

28581 Springfield Drive
Laguna Niguel, CA 92677
- Tel. (949) 363-6047
- Email mark@fb2c.com
- Offers a feedback driven program that removes roadblocks to Useful and User-Friendly Compliance (UUC). Speeds up Design & Realization of Devices & Combination Products

## Employment

- **January 2008 - Present, Program Manager, Insight Technology, Laguna Niguel, CA**
- **Nov-1998 - June 2007, Senior VP QA/RA, and Supply Chain**

**Curlin Medical, Huntington Beach, CA**

## Achievements

I have played a leadership role and contributed to the success of:
- Curlin pumps and Admin Sets
- Accufusers (elastomeric pump)
- BeeLines (syringe pump)
- McKinley Pos-Op kits
- FMS Easy-Flow (elastomeric pump)
- FMS Regional Anesthesia Kits

## Work Experience

Sixteen (16) years of hands-on Program Management experience leading
- QA/RA and NPD activities
- Obtaining 510 (k) clearance & CE Marking
- ISO implementation, audit & improvement
- Software Validation (embedded & Part 11)
- Post-Market Sustenance (suppliers included)
- Devices: electronic pumps (hardware/software) sterile disposable pumps, catheters & sets.

## Work Experience (cont.)

Have provided leadership in applying quantitative techniques to
- Analysis of MDR's, Complaints, and CAPA's
- Definition of deliverables in the DHF
- Test Method and Measurement Validation
- Process Control and V & V (IQ/OQ/PQ)
- Raw Materials, and Components Qualification
- Contract Manufacturing and Vendor surveillance
- Organization of Remediation efforts
- Leverage technical and managerial resources

## Education

- Ph. D Probability and Statistics (quantitative techniques)
- M. S. Stochastic Control (control of variations)
- M. S. Engineering Mathematics (electro-mechanics)
- Bilingual English, French
- Fluent in German

## Sample of Projects I contributed to succeed

Curlin Pump and Set

This was the first pump in the market with data management capability, allowing providers to monitor infusion and check for compliance.

*Accufuser and Beeline pumps*

*McKinley Post-OP Kits*

Easy-Flow

2009 US sales reached $2M; the product line was acquired by a third party

*2000* *2006* *2009*

## Sample of Projects I contributed to succeed

*Designed, developed, and marketed a family of reliable pain management kits*

*Successfully led the Remediation efforts for a class II medical device company, closing a Warning Letter reflecting concerns in Design Control, MDR/Complaint , and CAPA*

*2010* *2012* *2014*

## A Window into the Future

My mission, if you accept it, is to optimize your compliance efforts

I apply quantitative and engineering techniques to speed up design, validation, submissions, ECO's, remediation efforts, and manage risk with present and future products

## Value Proposition

I offer to guide a feedback driven program that removes roadblocks to Useful and User-Friendly Compliance (UUC)

I provide engineering and QA/RA support to medical device/pharmaceutical companies wanting to meet the regulatory requirements for Combination Products within budget and schedule

I provide assurance of process optimization, so safe and effective devices and combination products are delivered on time, to spec, and cost-effectively

## Who I am

I am an expert in quantitative techniques

An engineer with background in design, development, and manufacturing of electro-mechanical and sterile disposable FDA/ISO compliant medical infusion devices.

I have a track record of performance in rapid NPD & Mfg of high quality, trouble free, FDA/ISO compliant, low-cost infusion devices

I have obtained 510 (k) clearance, and CE Marking for 4 families of infusion pumps, and accessories

## What I do well

I save you time and money. I shorten your time to market. I guide you in identifying, and organizing the deliverables for compliance in:

- Design
- Development
- V&V
- Production; and
- Post-Market sustenance

## What I do well

- Perform a Gap Analysis/Audit of the DHF Deliverables, and guide remediation
- Provide insight to management for a risk-based approach to NPD
- Provide design input to manage risk and engineer quality in design
- Speed up, and improve design transfer - (re)validation, IQ/OQ/PQ

## What I do well

- Develop PMA/510 (k)/Technical files for submission
- Interface with Regulatory agencies (FDA, ISO, TUV)
- Perform compliance audits (CFR 820/ISO 13485)
- Identify, qualify, and maintain suppliers

## What I do well

- Improve change control, and reduce ECO processing time
- Focus complaint, MDR, and CAPA investigations where it is warranted
- Customize training in engineering, and manufacturing
- Provide feedback to manufacturing for performance improvement

## What I do well

- Coach/train staff to focus resources on critical areas
- Reduce MDR's complaints, and non-conforming materials
- Guide performance metrics using quantitative techniques

## Leading Six-Sigma Classes

## With Dr Deming, 1988