Lifescience Business Solutions
IMPROVING PATIENTS LIVES

*Case Summary*

# CONTROL STRATEGY - COMBINATION DRUG DEVICE

## Subject Matter Expert and Management Consultant

**TECHNOLOGY**

*Single dose prefilled autoinjector drug delivery device for use with TNF (Tumor Necrosis Factor) inhibitor.*

**COMPANY**

*US-based multinational biotechnology company and associated contract manufacturing organization(s).*

**CHALLENGE**

*Legacy device field complaints called for assessment and re-engineering of insufficient Design Controls to improve new technology platform development and qualification for manufacturing transfer and user adaptation.*

**ENGAGEMENT**

*Multi-phased engagement designed to benchmark best-in-class industry standards and provide clear assessment of QMS effectiveness in terms of management controls, global QSR compliance and commercial device-use integrity.*

- ***Phase 1*** *– Demonstrate core elements affecting best-in-class control strategies among relevant respondents.*
- ***Phase 2*** *– Rationalize end-to-end gap assessment spanning QMS structure and regulatory alignment through control processes for design and development through supply chain.*

**OUTCOMES**

- *Established a baseline perspective among benchmarked industry respondents on best-in-class drug-device QMS applications.*
- *Improved next-generation approach for design requirements planning, phase reviews and CMO design transfer thru gap assessment across legacy design history files, device history records, supplier qualifications, validations and comprehensive review of procedural QMS documentation.*
- *Reconciled and prioritized corrective measures in response to existing customer field complaints and reportable MDRs.*
- *Increased focus on next generation consumer-targeted auto-inject device safety and efficacy emphasized thru improved integration of risk management and usability engineering.*

**LESSONS**

- *As pharmaceutical companies embrace strategies to include device and drug-device platforms, so to must development and operational strategies evolve around changes in Quality System Regulations and Quality Management System requirements.*
- *When outsourcing manufacturing, best in class development life cycle management integrates CMO accountabilities at design input phase through validation production/commercial release. This positions CMOs as a strategic lever for effective delivery of innovative devices and therapies to market.*
- *Complex therapeutics often face overlapping Quality System Regulations between device, drugs, combination and markets and therefore demand cultural mindsets and behaviors that begins with executive sponsorship and governance of a well-adapted QMS framework.*

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