MEDCON CONFERENCE
COLUMBUS, OH · APRIL 23–25, 2025

Due Diligence & QS Integration Methodology

COLUMBUS, OH • APRIL 23-25, 2025

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Due Diligence

Objectives of today's session

- Understand that Due Diligence (DD) is one of several critical elements of a Strategic Alliance or Acquisition
- Understand who may need to be involved and what deliverables are needed for a DD
- Highlight the key focus areas for quality/regulatory compliance to execute DD

Due Diligence Overview

- Basic elements of Mergers and Acquisitions: **Due Diligence,** Integration planning, Integration Execution and Transition to Business
- **Due Diligence** is a collaboration with business development and other functions to assess a target to identify potential fit for acquiring organization, and if so, what success looks like
- **Quality** and **Regulatory** focus is the identification and estimation of risk associated with an acquisition
  - Some factors to consider:
    - Bias
    - Timelines
    - Prioritization
    - How deep can you go?
    - Risk

Due Diligence Activity*

- Supercool Devices Inc.," a leading provider of medical imaging technology, is considering acquiring “**TechMed Dynamics**," a U.S.-based company with a groundbreaking technology for non-invasive blood glucose monitoring.
- Flagship product uses advanced optical sensors and AI-driven algorithms to provide real-time data, potentially revolutionizing diabetes care.
- Led by a small, highly specialized team: two physicians with extensive clinical experience and an engineer with deep expertise in the target application area of the technology.
- In the early stages of early feasibility studies with the FDA.
- Contractor/consultant manages their Quality Management System (QMS) and regulatory activities, and their manufacturing is outsourced to a contract manufacturer.

A meticulous due diligence process is essential to evaluate this unique opportunity and target timeline for completion is 2 months.

*Fictional companies and scenario to allow for interactive discussions

Due Diligence Activity*:
Part 1: Stakeholder Identification (10-15 minutes)

Discuss which stakeholders from “Supercool Devices Inc." need to be involved in the due diligence process.

1) Identify key stakeholders to include in the Due Diligence activities and be ready to discuss your list.
2) Identify any 2-3 functions from your list and define/describe the role each perform.
3) 1 spokesperson from each group will read-off 1 or 2 roles definition

*Fictional companies and scenario to allow for interactive discussions

Due Diligence Activity*
Diligence Team – Potential Stakeholders

- Strategy / Opportunity
- Technical (incl. R&D)
- Medical Affairs
- Clinical
- Clinical Compliance
- Regulatory
- Operations / Supply Chain
- Quality
- Legal
- Tax
- Finance
- BU Finance
- Intellectual Property
- HR
- Privacy
- Compliance
- Facility
- IT
- Government Affairs
- Comms

*Fictional companies and scenario to allow for interactive discussions

Stakeholders- Scorecard

Market Potential	Technology	Clinical	Regulatory	Supply Chain	Facilities	Quality	HR
Ease of Use	Concept	Clinical Strategy	Non-clinical Test Strategy	Mfg. Process	Fixed Assets	QMS / Mgmt Controls	Culture
Population	Design Process	Trial Prep	Clinical Trial Design	Capacity	Environmental Control	Change / Document Ctrl	Talent
Timing	Usability	Trial Execution	Regulatory Strategy & Path	Vendor Performance	Facility Layout	Design Controls	Compensation / Benefits
	Development Portfolio	Clinical Suitability	Regulatory Change Mgmt.	Inventory Management		Production / Process Controls	HR Compliance
		Safety		COGS		Purchasing / Supplier Controls	
		Efficacy		Supply Chain Risk		CAPA/FCA	
						Resource Management	
						SW Quality / Cybersecurity	

Acceptable risk: little-to-no action required
Medium risk: moderate action required
Large risk: large investment required
Pending diligence

Stakeholders - Scorecard

Commercial	Reimburse	Finance	Compliance	Legal	Privacy	IP	IT
Market Opportunity	US Coverage	Tax	Corporate Comms	Corporate Structure	Privacy Governance	Patents	IT Assets
Differentiation	Coding and Payment	Financial Reporting	Ethical Standards	Minutes, Records, Coms	Data Management	Trademarks	Infrastructure
Pricing	OUS Reimbursement	Assets & Liabilities	Govt & 3P Interactions	Stakeholders & Shareholders	Vendor / 3PL	Software / other copyright	IT Services
KOL/Advisors		Budgeting	Compliance	Litigation	Incidents & Claims	Trade Secrets	Process & Procedures
Training & Procedure Sup.		Financial Services	HCP Relations	Contracts & Agreements	Workforce	Contracts / agreements	Cybersecurity
Global Launch Strategy		Insurance		Misc.	Risk Management	Litigation / disputes	IT Resources

Acceptable risk: little-to-no action required
Medium risk: moderate action required
Large risk: large investment required
Pending diligence

Due Diligence Activity*
Part 2: Key Questions that must be answered (15 min)

Brainstorm 5 or more critical questions for TechMed Dynamics that must be answered to complete a successful due diligence exercise, which includes making a recommendation to leadership on whether to proceed or stop.

Take 10 minutes to develop your questions.

Each group to provide one (or more if time permits) questions they developed

*Fictional companies and scenario to allow for interactive discussions

Due Diligence Activity*
Part 2: Some Suggestions

Answer Key

- Are there any pending actions that would suggest inappropriate regulatory or quality compliance decisions?
- How robust is the contractor/consultant's management of the QMS system and regulatory compliance?
- What progress has been made in the early feasibility studies, and what feedback has the FDA provided so far?
- How secure is the intellectual property for the technology?
- What are the capabilities, capacity, and risks associated with the contract manufacturer?
- Would we want to transfer manufacturing in-house at some point as part of the business strategy? If so, are any of the Contract Manufacturer's mfg. processes proprietary?
- How do the leaders' backgrounds translate to operational effectiveness? As part of their growth strategy do they have a Staffing or infrastructure plan?

*Fictional companies and scenario to allow for interactive discussions

Due Diligence Activity*
Part 3: Prioritizing Activities (Take Home Exercise)

Prioritize the list below in order of importance to complete and present a timeline. A volunteer from each group to present.

Note: Place a number by each task in order of progression and approximate duration

- Evaluating the FDA documentation and feasibility study data.
- Assessing the contractor/consultant's processes and track record with QMS and regulatory activities.
- Auditing the contract manufacturer for compliance, capacity, and risks.
- Verifying design robustness and design for manufacturing potential.
- Interviewing the leadership team to assess their vision, capabilities, and alignment with your company culture.
- Identify potential staffing and infrastructure needs

*Fictional companies and scenario to allow for interactive discussions

Due Diligence Activity*
Part 3: Prioritizing Activities (15 minutes)

Answer Key

A possible order of priority and duration:

1) Verifying design robustness and design for manufacturing potential. 1 week
2) Evaluating the FDA documentation and feasibility study data. 1 week
3) Auditing the contract manufacturer for compliance, capacity, and risks. 1 week (2 days onsite + visit key suppliers)
4) Interviewing the leadership team to assess their vision, capabilities, and alignment with company culture. 2 days
5) Assessing the contractor/consultant's processes and track record with QMS and regulatory activities. 1 week
6) Identify potential staffing and infrastructure needs. 2 days

*Fictional companies and scenario to allow for interactive discussions

Example: Quality Deep Dive

Categories	Status	Key Issues/Findings	Recommendations
Production / Process Controls		**Purpose: *Verify that the organization's processes can ensure that products will meet specifications*.** Objective evidence will show whether the organization has: ▪ Defined, documented and implemented procedures to ensure production and service processes are planned, developed, conducted, controlled, and monitored to ensure conformity to specified requirements ▪ Developed production and service process controls commensurate with the potential effect of the process on product risk ▪ Ensured that when the results of a process cannot be verified by subsequent monitoring or measurement, the process is validated with a high degree of assurance that the process will consistently achieve the planned result ▪ Implemented procedures for the validation of the application of computer software for production and service processes that affect the ability of the product to conform to specified requirements, including validation of computer software used in the quality management system ▪ Maintained records for each batch of medical devices that provides information for traceability and confirmation that the batch meets specified requirements ▪ Implemented controls to protect customer property, including intellectual property, confidential health information, and other forms of customer property that is used or incorporated into products ▪ Critical control points (commensurate with high severity dFMEA risks) are identified and properly managed	

Open Items / Next Steps / Final Recommendation

Example: Supply Chain Deep Dive

Categories	Status	Key Issues/Findings	Recommendation
Process		**Purpose: *Verify processes used to manufacture & inspect devices.*** Objective evidence will show: ▪ Flow chart of manufacturing / Inspection processes from Receiving-Inspection through Distribution ▪ Manufacturing and inspection procedures for each Product P/N process ▪ DHR Requirements verified: Bill of materials, Process Sheets / routers, Verify product labels and IFU, component drawing standards and template, verify material specs for solvents, chemicals and all materials used in the products (BOM and non-BOM items) ▪ Identification of Critical tools / equipment and management (ie preventive maintenance system) ▪ Gowning and line clearance practices ▪ Packaging testing and verification ▪ Critical Process lists (including definition of critical processes and where it is performed; internal or supplier) ▪ Verify Special Processes performed (Heat Treat, Welding, Plating, etc.) ▪ Calibration SOP (inventory) ▪ List of NCMRs and disposition, Open / Closed CAPAs in last 24 months (highlights those that resulted in design/manufacturing process changes) ▪ Verify quality assurance procedures for measuring and monitoring, specifications, and equipment used ▪ Current Shelf Life for all products and any extension plans ▪ Sterilization requirements ▪ Silicon, water, latex use	
Open Items / Next Steps / Final Recommendation			

Acceptable risk: little-to-no action required

Key risks identified: important actions required

Major risks: substantial / extensive actions required

Quality Systems Integration (QSI) Overview

Objectives

- What are typical goals of Integration
- Methodology used with leading clients
- Lessons Learned
- Recommendations for success

Quality Systems Integration Scenarios

Scenario	Pros	Cons
1) "Slow Roll" i.e. allow business acquired to continue with their QS as-is for 12-18 mo.	• Minimal disruption to business continuity • Allows more strategic planning / preparation for QSI activities	• Significant Compliance and Product Quality vulnerability issues found too late to prevent / mitigate • Encumbers any required Quality culture change
2) "Ninja" i.e. Integrate w/ Corp Entity QS policies and procedures in 6-12 mo.	• Faster adoption to Corp. Entity QS and Quality Culture • Faster data migration and Corp visibility to QS records and product quality issues	• Max disruption to business continuity • Likely not enough time for in-depth gap assessments and remediation
3) "Methodical" i.e. Integrate w/ Corp Entity QS policies and procedures over 24 mo. period including execution performance improvements	• Allows in-depth gap assessment and QS record sampling and identification and planning of required remediation activities • More effective in understanding product performance, maturity of the organization and establishing the culture	• More investment cost • Quality culture change slower than "Ninja".

Typical goals of Quality Systems Integration

Participant Audience Polling – Individual exercise (5 min)

Name top 3-5 goals for QSI	How does it differ from Due Diligence
1) …	
2) …	
3) …	
4) …	
5) …	

Typical goals of Quality Systems Integration

Answer Key

Name top 3-5 goals for QSI	How does it differ from Due Diligence
1) Integrate QMS structure and processes w/ corporate policies and standards. Also, assess quality maturity of the organization	• DD should determine “what”, QSI determines “how”, “resources”, and “timing” (i.e. plan and execution)
2) Improve state of quality and compliance by reducing regulatory compliance & process and product quality vulnerability	• DD short duration, limited transparency; personnel interviews, and QS records review may not uncover all significant issues.
3) Data migration and/or access for Corporate and/or business unit visibility and oversight.	• DD rarely addresses

Typical goals of Quality Systems Integration

Answer Key

Name top 3-5 goals for QSI	How does it differ from Due Diligence
4) Lean processes by eliminating waste prior to completion of integration	• DD sometimes will ID early on some waste removal opportunities, QSI further deep dives and discovers others
5) Change Quality Culture as needed to align with new Corporate/Company expectations and improve quality maturity and skills of the organization	• Good QSI may uncover Quality Culture changes required throughout organization

Program Management

Phased Model

Kickoff → Phase 1 review → Phase 2 review → Phase 3 review → Project Closure

Analyze	Plan	Update Policies & Train	Execute	Complete
Phase 0 Create Transition Strategy and Business Plan	**Phase 1** Complete gap assessment and program planning	**Phase 2** Achieve Readiness state, QS **ownership / accountability,** train your workforce	**Phase 3** New Process Effectiveness check, Remediation of records, processes & products as necessary	**Phase 4** Complete program, transition to sustaining & monitor effectiveness

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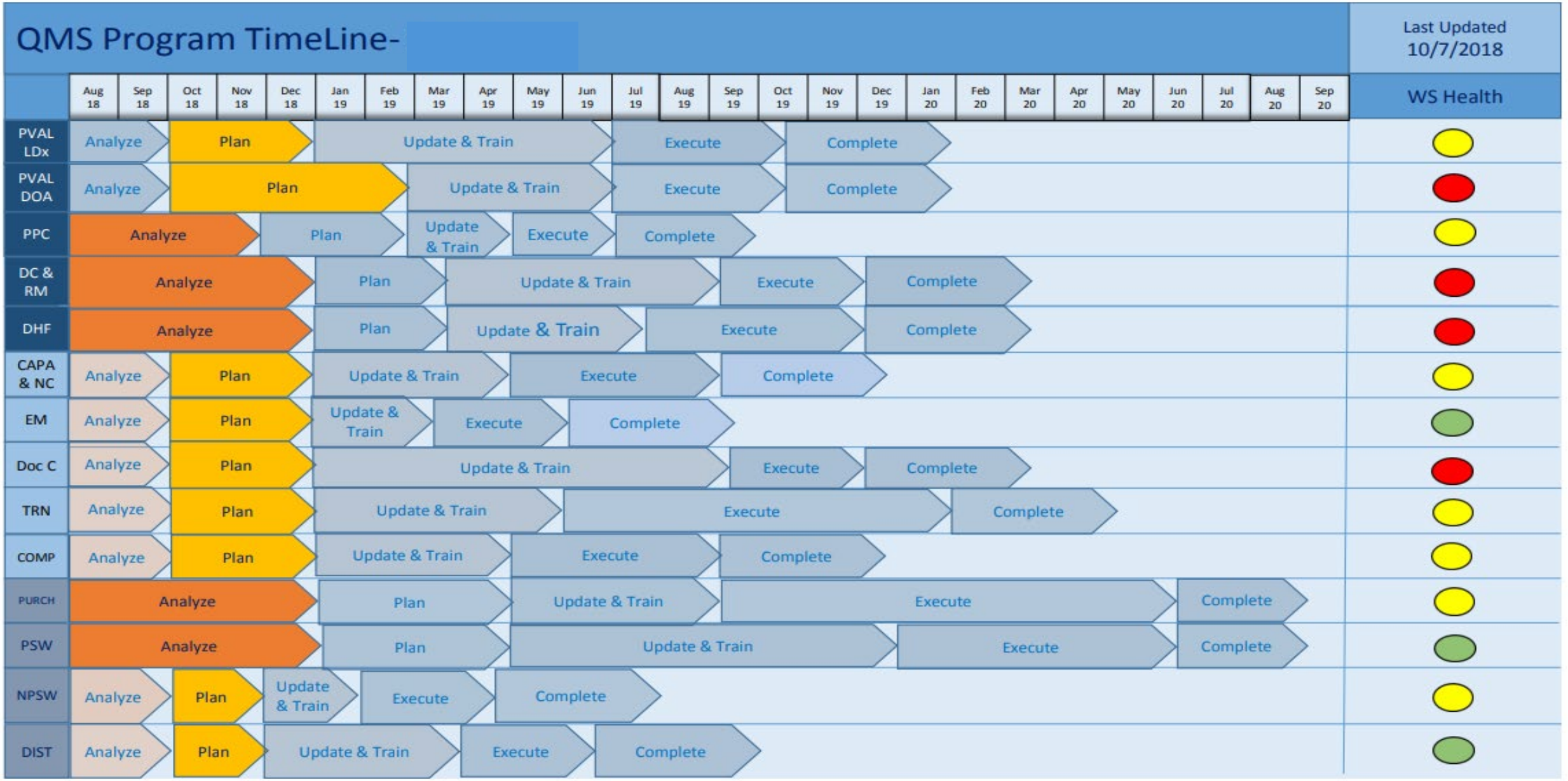
Integrated Program Management (IPM)

- Emphasizes sharing and standardization of processes across the organization
- Improves accountability
- Focuses on teams meeting regularly, increasing transparency
- Works best in environments where resources from multiple teams and departments interface with each other

Integration & Remediation WS

Workstream (WS)	
Quality Management (Training, Mgmt Resp)	Document and Change Control
CAPA & Non-Conformances	Risk Management
Production & Process Controls	Complaint Handling
Process Validation	Environmental Controls
Design Controls	Product Software
Distribution & Warehousing (Pkg Validation)	Non-Product Software
Purchasing Controls	Statistical Techniques

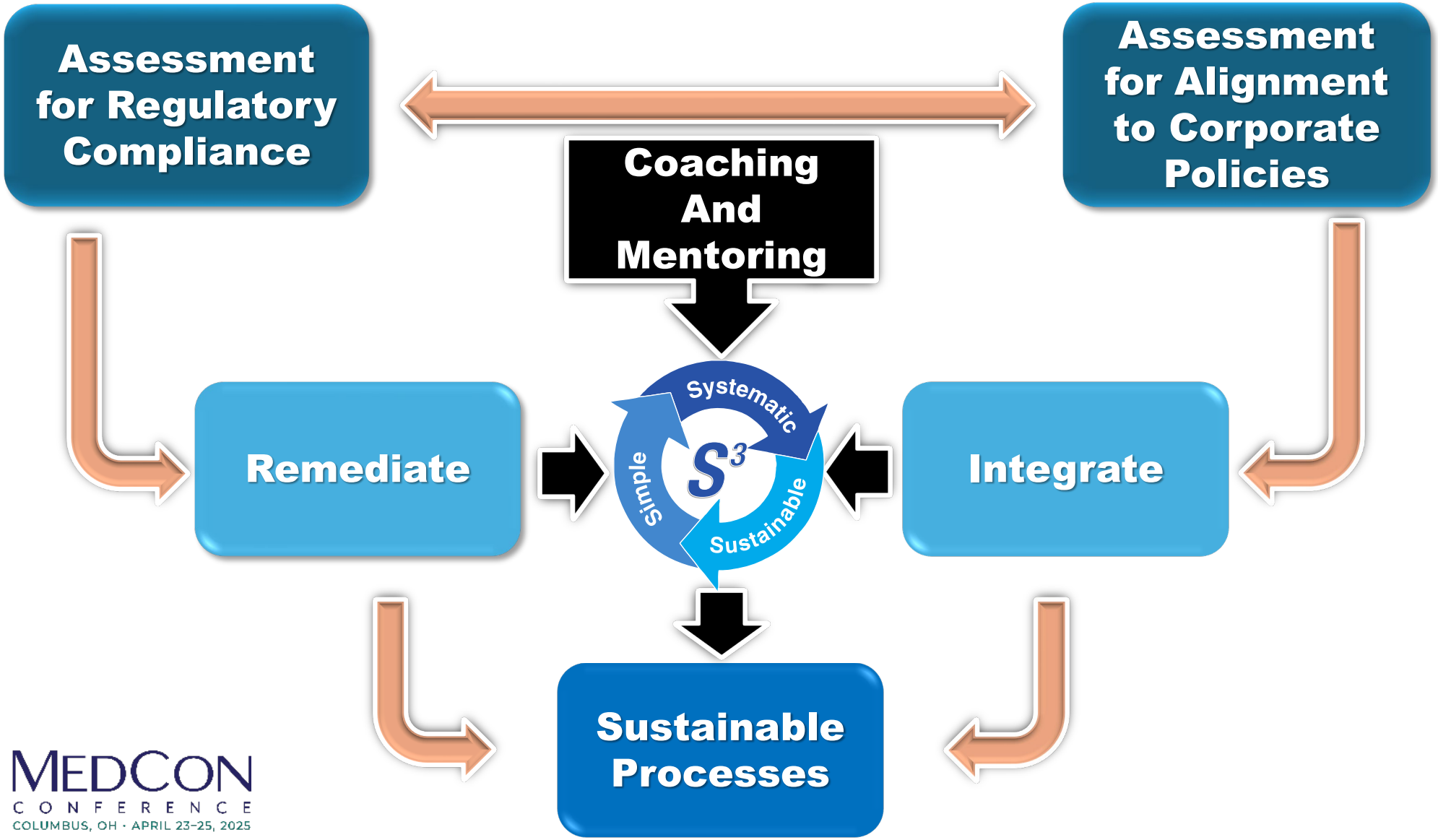
Integration / Remediation Project Plan



Program Resource Types

- Cross Functional Steering Committee (typically heads of R&D, Engineering, Operations, and Quality)
- Site Subject Matter Experts (SME) and additional team members by WS
- Consultant Engagement Manager
- Project / Program Manager
- Senior Quality Consultants
- Quality Engineers
- Technicians
- Sr. Software Quality Consultants
- Software Quality Engineers

Project Macro Model

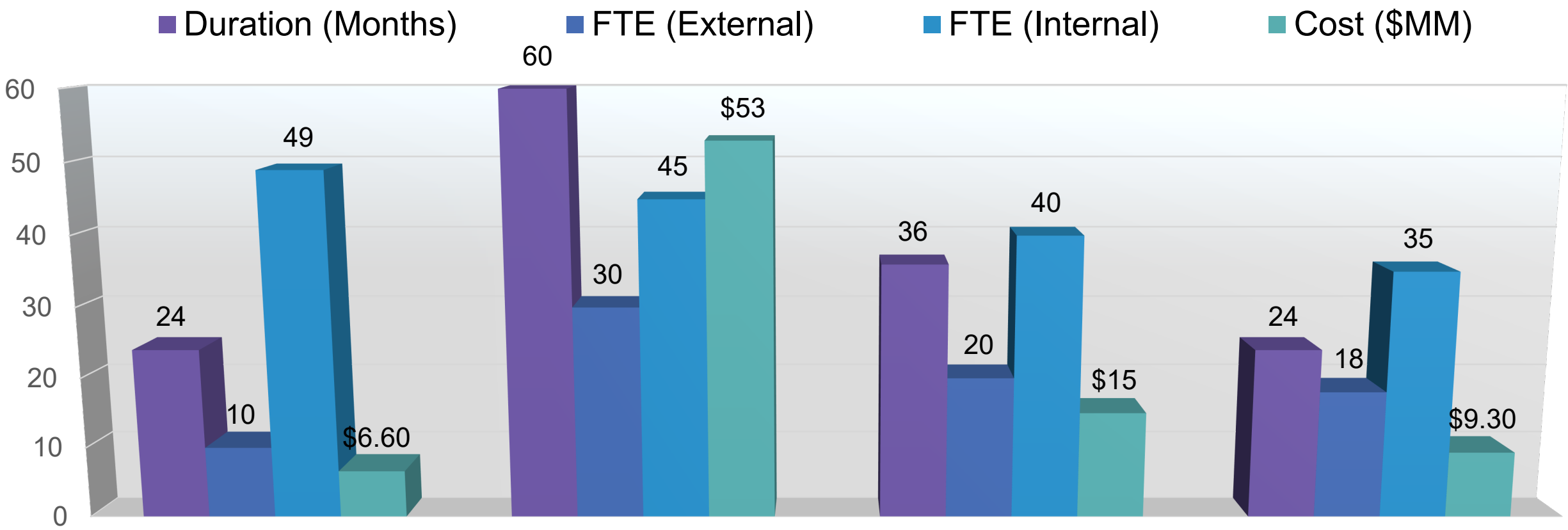


Typical QSI Duration and Cost

Participant Audience Polling – Electronic polling via some QR Code or other link (2 min)

Avg. Duration	Avg. Cost
1) ~ 6 months	1) $500K - $1MM
2) 12 – 24 months	2) $1 – 3 MM
3) 2 – 3 years	3) $3 - 5 MM
4) 3 – 5 yrs	4) > $5 MM

RECENT EXPERIENCES



Post acquisition Gap Assessments Class III Medical Device across 6 mfg sites

Led integration / remediation efforts new BU acquisition for Fortune 100 Class II Medical Device across 10 mfg. sites & 7 countries

Pre-divestiture remediation of Class III Medical Device across 4 mfg. sites& 3 countries.

Conduct Gap Assessment and coaching/mentoring for QSI at 8 mfg. sites in 5 countries for Class I and II Medical Device

Why Use Consultants and/or Contractors

Consultants	Contractors
1) Corporate regulatory compliance resources sometimes have limited availability	1) Backfilling acquired firm's resources assigned to QSI teams
2) Provide Subject Matter Expertise and mentoring skills	2) Lower level and/or local resources lower cost
3) Leverage QSI experience of Consulting firm	3) Transition into employees if talented and now have Site / QMS and/or product knowledge
4) Special technical expertise (ex. engineering, design, software, validation, etc.)	
5) Manage contractor resources assigned to WS	

Workstream LEAD Roles & Traits

Client	Consultants
• **Process Owner** • Assigns Tasks to Resources • Monitors/reports progress • Prepares WS Decks • Presents during SC Meetings • Co-develops methodologies, delivers training and coaching*	• **Facilitates Solutions development** • Supports WS • Co-develops Methodologies • Co-delivers Training • **Provides Coaching & Mentoring**

*Note: Integration projects roles are a continuum depending on strength or skills of Client lead and team members. Clients must own system being developed

Workstream LEAD Roles & Traits

Client	Consultants
• **Change Agent** • **Out-of-Box Thinker** • **Excels in Communication Skills** • Versed in PM Tools • Navigates Challenges • Visionary, Fixing Know-How & Knowledge Transfer*	• WS Lead Experience • WS SME • Visionary • Fixing Know-How • **Knowledge Transfer**

*Note: Integration projects roles are a continuum depending on strength or skills of Client lead and team members. Clients must own system being developed

QSI Project Typical Pitfalls

Pitfalls	Remedy
• Insufficient QSI team member expertise	• Bring in Corporate and/or Consulting experts
• Lack of transparency	• Encourage QSI team members time to “fix” old issues and reward proactive behavior
• Inadequate record sampling => lack of discovery of significant vulnerabilities	• Protocol defines how many records and period of sampling commensurate with product quality / compliance risk
• Too many issues and lack of prioritization => poor Mgmt decisions on key areas to address	• Establish method to group opportunities for improvement and prioritization tool

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Gap Assessment Phase

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Gap Assessment Phase

Item	Description	Client	Consultant
1.	Interview site SMEs *("Open Kimono")*	P	L
2.	Site / Area Walk-throughs & Tours	L	P
3.	Procedures / Templates Review		L
4.	Records Review	P	L
5.	Identify Potential Gaps & Discuss with SMEs	P	L
6	Observation Write-ups		L
7.	Observation Risk Rankings		L
8.	Daily Debriefs	P	L

L = Lead P = Participate

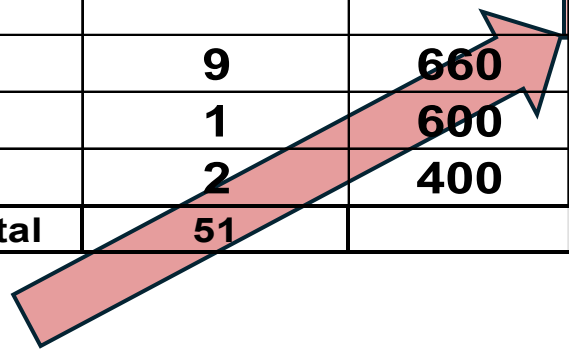
Prioritization

Item	Description	Client	Consultant
1.	Affinity Grouping *Scoring Factors* • Compliance Rank (# Issues/Findings) • Focus for Inspection / High Product Quality Impact Rank • Timeline to Remediate • Enabler		L
2.	Develop Pareto Diagrams of Top Opportunities	L	P
3.	Final Prioritization	L	P
4.	Identify Site Workstreams	L	P
5.	Corporate Leadership Review / Approval	L	
6.	Site Communication	L	P

L = Lead P = Participate

Prioritization – Affinity Grouping

% of Children per Parent	Quality Sub System	Potential Project No.	Parent (Affinity Group)	Sites impacted	Total # of "Children"	Affinity Group Score	Affinity Group Priority	Lookback may be needed?
19.6%	CAPA- 51 Children	p.CAPA-01	CAPA Risk Assessment	M	10	5940	A	Y
15.7%		p.CAPA-02	CAPA Investigation	M	8	5940	A	Y
7.8%		p.CAPA-03	CAPA Effectiveness Check	M	4	5400	A	Y
9.8%		p.CAPA-04	Verification / Validation	M	5	5400	A	Y
3.9%		p.CAPA-05	CAPA Sources and Input	M	2	3600	A	Y
13.7%		p.CAPA-06	Trend Analysis	M	7	2640	A	Y
3.9%		p.CAPA-07	Containment	M	2	2400	A	Y
2.0%		p.CAPA-08	Corrective / Preventive Action	M	1	1800	A	Y
17.6%		p.CAPA-09	Objective Evidence	M	9	660	B	Y
2.0%		p.CAPA-10	Dissemination	M	1	600	B	Y
3.9%		p.CAPA-11	Timeliness	M	2	400	C	N
100.0%				Subtotal	51			



Integration Focus

Root Cause Analysis

Item	Description	Client	Consultant
1.	Use Six Sigma Tools to Identify Root Cause • DMAIC • Fishbone Diagrams • Cause & Effect • Fishbone	P	L
2.	Define Preliminary Remediation Scope for each WS • High Business Impact Products • Input from Quality Indicators to identify problem areas • Post Market Input	L	P
3.	Steering Committee Approval	L	

L = Lead P = Participate

Solutions Development

Item	Description	Client	Consultant
1.	Develop Process Maps of New Methodology for each WS	L	L
2.	Develop Procedures, Templates, Forms	L	L
3.	Develop High Level Program Project Plan	L	P
4.	Steering Committee Project Plan Approval	L	P

L = Lead P = Participate

Implementation

Item	Description	Client	Consultant
1.	Exercise new QS process(es) for each WS (ex. Pilot)	L	P
2.	Solution & Timeline Adjusted as required	L	P
3.	GO Live Phase Completed	L	P
4.	Remediation Completed	L	P

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WS Closure Phase

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WS Closure

Item	Description	Client	Consultant
1.	Develop Trace Matrix showing Observations have been addressed	L	
2.	Develop Effectiveness Check (EC) Protocol	L	L
3.	Execute EC Protocol • Review Procedures • Review Records • Interviews	P	L
4.	Determine if EC Pass/Fail • WS Closure • Conditional Closure • WS Failure	L	L
5.	Develop WS Closure Deck	L	P
6.	Steering Committee WS Closure Presentation	L	P

L = Lead P = Participate

Key Lessons Learned & Recommendations

- Encourage transparency
- Integration team members freed from the day-to-day operations
- WS or day-to-day operation Lead - personnel development opportunity
- Additional resources for Change Management
- Remediation of RM prior to or in parallel with Design Control and Process Validation

Key Lessons Learned & Recommendations

- Assessments and/or remediation under an overall protocol
  - ✓ Criteria and process followed;
  - ✓ Documentation
  - ✓ Report summarizing the overall findings, actions completed, and risk profile
- High Risk areas: Risk Mgmt, PVal, Design Contrl, Change Mgmt, CAPA, Complaints, and MDRs
- Process for maintenance and retention of objective evidence

Thank You!

How did we do?

Any Questions?

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Dennett Kouri

- Over 25 years of experience in the Medical Device and Biologics industries.
- Edwards Lifesciences, SVP Corporate Quality, Regulatory and Clinical, responsible for establishing and ensuring compliance with global regulatory requirements.
- Responsible for QA activities in Alliance Management and Due Diligence activities by providing the required quality leadership and assessment support.
- UC Santa Barbara; Southwestern University School of Law in Los Angeles.

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- 40+ Years of industry experience
- Director of Engineering, Quality Systems, and Operations at Baxter Healthcare
- Principal and Founder of BioTeknica, Inc.
- B.S. in Chemical Engineering, Cornell University
- MBA, University of Miami
- Expert in Regulatory Compliance & Engineering

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