M&A - Mission Amplified

A Practical **Approach** for Medical Device Integrations

Webinar - June 25, 2026

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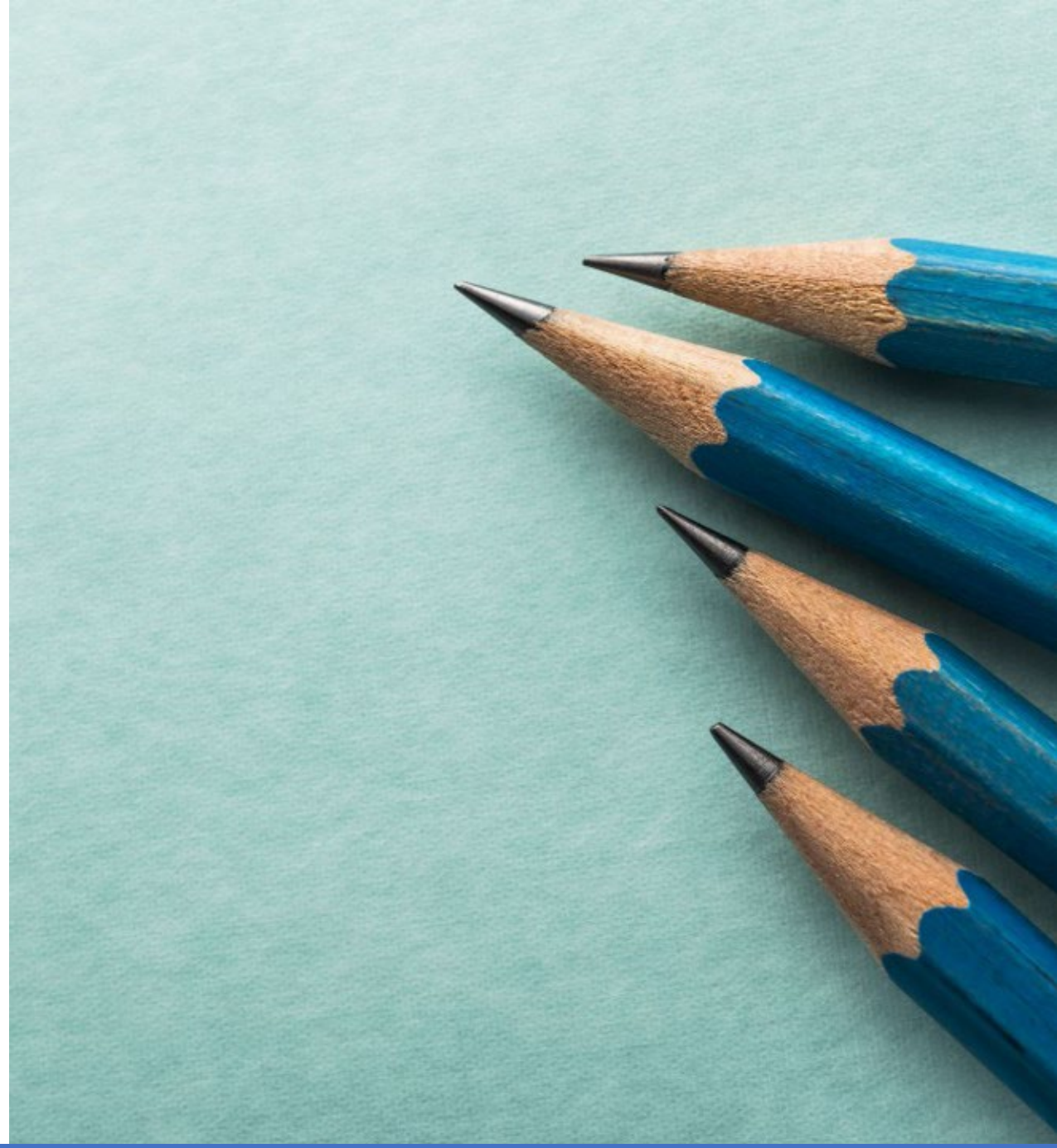
Housekeeping

A few things before we start…

- This Webinar is being recorded and will be available on the MEC website: ***www.medicalengineeringconsultants.com***
- The Presentation deck will be sent to registered participants and will also be available on the MEC website.
- **During the live Webinar:**
  - Please use Teams “Chat” for questions.
    - We will review questions at the end.
    - We will also follow-up directly with participants on any questions not covered, where possible.



WEBINAR OBJECTIVES

Today's session will cover:

- Why medical device integrations miss the mark
- The biggest post-acquisition risks
- Structured M&A integration approach
- The importance of managing integration, remediation, and operations simultaneously
- Best practices for achieving sustainable, audit-ready operations

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WHAT WE DO

Medical Engineering Consultants (MEC) is dedicated to helping our clients provide safe and effective medical devices, diagnostic devices and pharmaceutical products.

MEC offers contracting & staffing resources, consulting services and training to deliver operational excellence.

MEC achieves client service excellence by utilizing

- Effective talent acquisition processes
- Consistent solution delivery resources
- Efficient operations infrastructure

Every MEC resource has access to our full suite of internal resources and to the expertise of the full MEC team.

About the Presenter

Rachel Chase is a consultant and Director of Mergers & Acquisitions at Medical Engineering Consultants. She believes we can achieve more together by working with whole people to shape highly effective teams. Rachel translates compliance, patient, and employee needs into business impacting change. Shepherding teams through the integration process to achieve goals and the necessary cultural change. With this approach she helps Medical Device and Pharmaceutical organizations successfully acquire and integrate targets. This allows Target products to reach untapped markets and provide therapies to those that would not otherwise have the benefit of these novel technologies. With 15+ years spanning Quality and Operational Excellence, Rachel brings a dual lens — helping companies build compliant and efficient solutions with QMS rigor that keeps them audit ready.

Participant Poll

Have you participated in any Acquisition or Integration?

Response	Results
Yes	33%
No	67%

Participant Poll

Have you ever worked at a company that was acquired?

Response	Results
Yes	43%
No	57%

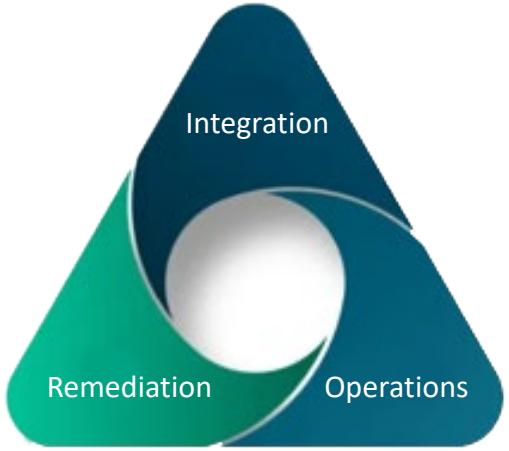
THE REALITY OF MEDTECH M&A

Why Most Integrations Miss The Mark

In medical device acquisitions, the greatest risk emerges after the deal closes.

✓ Integration Goal

- Integrate the acquired company into the corporate QMS
- Maintain production and business continuity
- Ramp manufacturing and supply
- Align procedures, systems, and supplier controls



! Critical Unknowns

- Limited visibility into post-market product performance and reliability trends
- Unforeseen remediation efforts required to close compliance gaps
- Misalignment between practice vs procedure
- Unclear maturity of the acquired company's talent and quality systems
- Hidden CAPA, validation, or supplier risks

Without structured integration governance:

- Remediation scope expands
- Operational disruption increases
- Regulatory exposure grows

Integration risk becomes business risk.

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COMMON FAILURE POINTS

- Weak governance structure
- Underestimated remediation scope
- Poor CAPA execution
- Operations competing with remediation
- Competition with new product launches or expansions
- No centralized ownership
- Inadequate resource planning
- Lack of audit readiness strategy

Result

Delays | Regulatory exposure | Operational disruption | Increased integration cost

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KEY INTEGRATION ELEMENTS

MEC Integrates While Strengthening Operations

						
REMEDIATION	**OPERATIONAL STABILIZATION**	**LEAN MANUFACTURING**	**KAIZEN**	**PROCESS OPTIMIZATION**	**TRAIN-THE-TRAINER PROGRAMS**	**SUSTAINABLE EXECUTION MODELS**
Closing compliance and operational gaps	Maintaining continuity during transition	Reducing waste and improving efficiency	Driving sustainable process optimization	Streamlining workflows and improving execution efficiency	Building internal capability and sustainable knowledge transfer	Building long-term compliant execution

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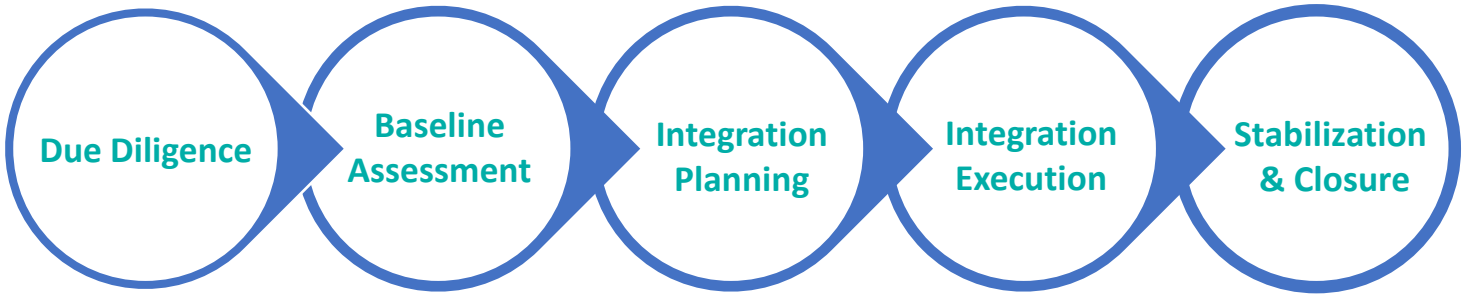
M&A LIFECYCLE



MEC teams operate directly within client **integration framework** which governs:

- Due diligence assessments
- Target Baseline Assessments
- Integration planning and execution
- Risk classification and remediation strategy

Continuous Audit Readiness

During integration MEC ensures the organization remains inspection ready at all times, including for:

- FDA inspections
- Notified Body audits
- International regulatory authority inspections
- Internal corporate audits

The areas of Expertise required:

- ✓ Integration leadership
- ✓ Remediation experts
- ✓ Lean & process improvement specialists
- ✓ Cultural integration partners
- ✓ Long-term operational strength

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PHASE 1: DUE DILIGENCE

Objective:

Identify hidden integration risk BEFORE deal close

MEC Focus Areas, if available:

- QMS maturity
- CAPA health
- Supplier robustness
- Risk Management systems
- Validation exposure
- Field performance trends
- Talent capability

Deliverables:

- Risk assessment
- Integration complexity estimate
- Resource forecast
- Remediation strategy

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PHASE 2: BASELINE ASSESSMENT

Objective:

Identify integration and remediation gaps against requisite standards and OPAs

Assessment Areas:

- Design Controls
- Risk Management
- CAPA
- Validation
- Supplier Quality
- Organizational Process Assets (OPA) (Policies, SOPs, WIs, etc)
- Production & Process Controls
- Software / Part 11
- Practice vs Procedure

Deliverables:

- Target Baseline Assessment
- Risk-based Report reflecting gaps to standards and/or Corporate OPAs

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PHASE 3: INTEGRATION PLANNING

Centralized Program Leadership

- Single governance structure
- Technical PM leadership
- Cross-functional coordination
- Sprint-based execution

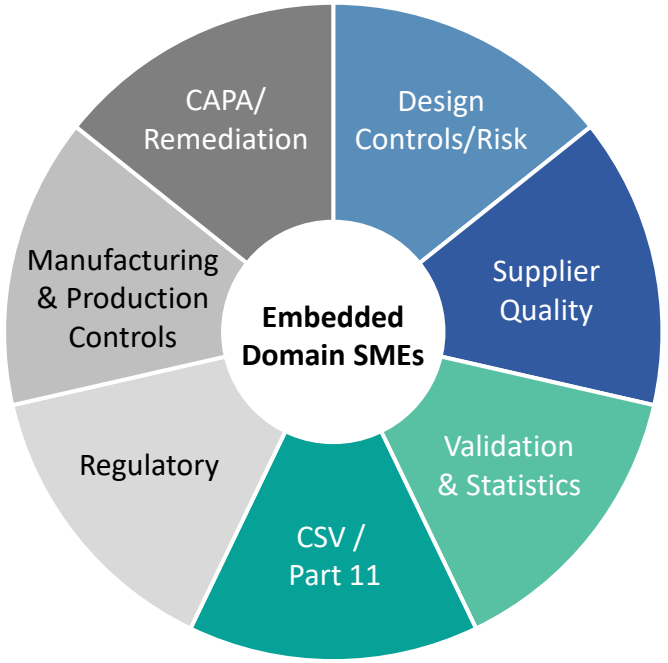
One command structure. No silos.

Planned Execution Areas:

- Assessment Finding resolution
- Remediation
- QMS Integration
- Interim Target Assessments
- Acquisition Documentation Maintenance

Deliverables:

- Resource Planning
- Risk based prioritized project planning
- Communications / Governance established



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PHASE 4: INTEGRATION EXECUTION

Rapid SME Deployment

When issues surface:

- CAPA escalations
- Supplier instability
- Validation gaps
- Audit findings
- Field performance concerns

MEC deploys specialized experts immediately.

Benefits:

- Faster remediation
- Reduced disruption
- Accelerated closure
- Improved execution quality

Deliverables:

- Compliance Improvements and Corrective Actions, as needed
- Remediated Elements
- Integrated QMS and Systems

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AUDIT READINESS DURING INTEGRATION EXECUTION

Integration Should Never Compromise Compliance

We must Maintain:

- FDA readiness
- Notified Body readiness
- Internal audit readiness
- Inspection-ready documentation
- Sustainable compliance execution

During Integration:

- Procedures change rapidly
- CAPAs increase
- Documentation evolves
- Operational pressure grows

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PHASE 5: STABILIZATION & CLOSURE

Stabilization Objective:

Execution of the Closure Target Assessment and resolution of any deficiencies.

Assessment Areas:

- Full Scope of Integration Plan
  - Remediation
  - QMS Integration
  - Finding Resolution
  - System Integration
  - Regulatory and Clinical Integration

Deliverables:

- Closure Target Assessment Report

Closure Objective:

Completion and approval of Acquisition/ Integration Report and project closure.

Deliverables:

Released Acquisition/Integration Report Recognition, lessons learned, archival and project closure.

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BEYOND INTEGRATION: OPERATIONAL STRENGTHENING

We must integrate while improving operational performance.

- Lean Manufacturing implementation
- Kaizen facilitation
- Process flow optimization
- Waste reduction initiatives
- Production cell improvements
- Statistical process control
- Train-the-trainer capability development
- Leadership training for sustainable quality systems

We address practice vs procedure gaps to ensure:

Processes operate as designed	Documentation reflects actual operations	Systems remain sustainable after integration

Remediation becomes operational improvement.

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IN SUMMARY - FROM DUE DILIGENCE TO STABILIZATION

MEC supports the entire M&A lifecycle.

Pre-Acquisition **Post-Close**

- QMS maturity
- CAPA health
- Risk Management systems
- Supplier robustness
- Validation and software compliance exposure
- Field performance data and complaint trends
- Talent capability of the acquired organization

- Target Baseline Assessments
- Integration roadmap execution
- Parallel remediation + operational stabilization
- Audit readiness and sustainable system deployment

Providing leadership with:

- Realistic remediation scope
- Integration complexity assessment
- Risk-based integration strategy

Integration risk is business risk. We quantify it early and support resolution.

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COMMON MEC ROLES

MEC Resources are often required to support the following activities:

- Target Baseline Assessment
- Program/Project Management
- Project Planning (Project Plan)
- Remediation (DHF, Risk, Validation, etc.)
- Interim Target Assessments
- Acquisition Documentation
- Closure Target Assessment

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CASE STUDIES

OVERVIEW

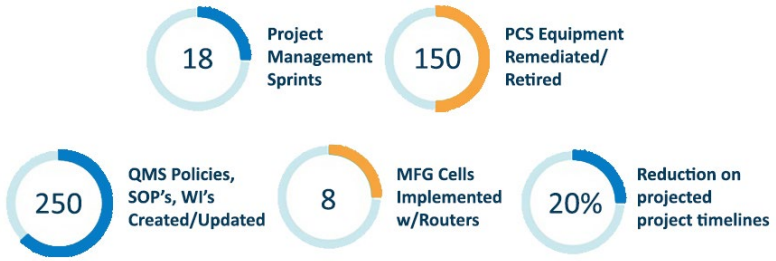
PROJECT TYPE Acquisition QMS Integration

CHALLENGE Acquisition consisted of a new business type for client which did not fit into current QMS and relevant internal expertise did not exist.

Required to meet compressed timelines through aggressive planning and flawless execution, due to projected accelerated growth of acquired business.

SCOPE QMS Creation, Remediation and Integration of 2 separate Business Systems (BU1 and BU2).

RESULTS



OVERVIEW

PROJECT TYPE Acquisition QMS Integration

CHALLENGE Integrate Quality Management System (QMS) while preserving compliance with drug led combination regulatory requirements. Acquisition consisted of combination drug/device Target by a Medical Device exclusive company.

SCOPE Integration of QMS, Distribution, Economic Operators, Regulatory and Quality IT systems.

RESULTS

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QUESTIONS

We asked participants for specific questions they'd like addressed during the webinar:

1. Do acquisitions always lead to integration?

2. Can you integrate QMS's from different sub-industries? Such as device and pharma, tissue, biologics, etc.

THANK YOU!

For further information or support contact:

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www.medicalengineeringconsultants.com