The VIP Method:
Transforming Business Performance through Quality

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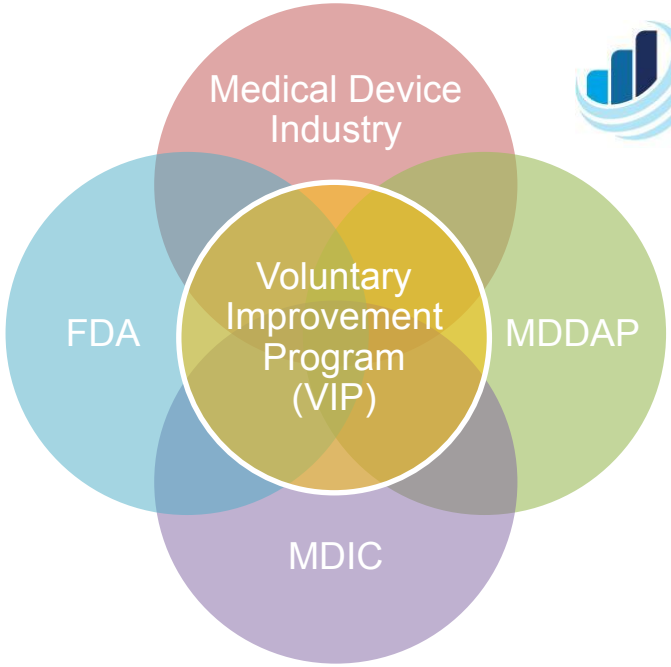
WHAT ARE WE TALKING ABOUT?



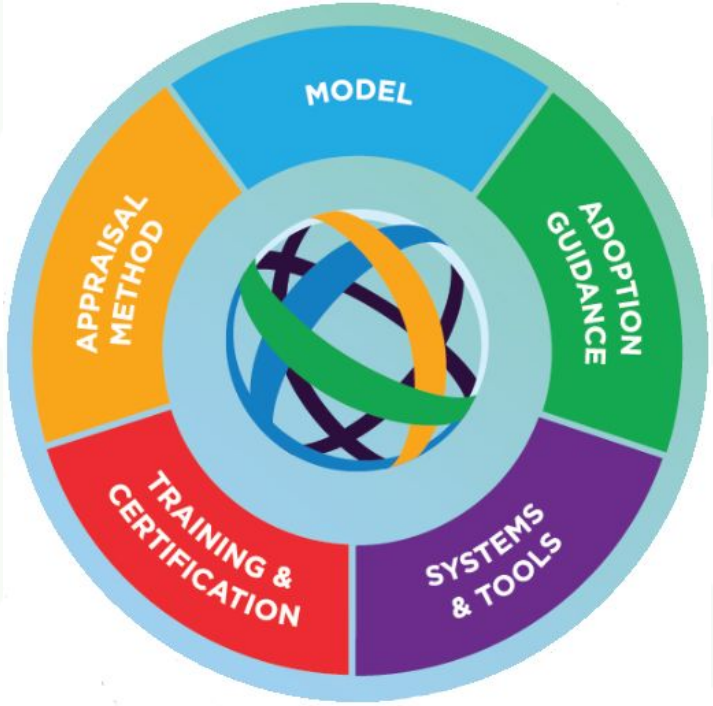
VOLUNTARY IMPROVEMENT PROGRAM

A collaborative initiative

Regulatory Compliance

Advancing device quality and safety

To achieve better patient outcomes



Leveraging the Medical Device Discovery Appraisal Program (MDDAP), a tailored version of the CMMI framework

Commitment to continuous improvement and data sharing gives FDA confidence to offer regulatory opportunities to help accelerate improvements

Encouraging a culture of quality across the organization.

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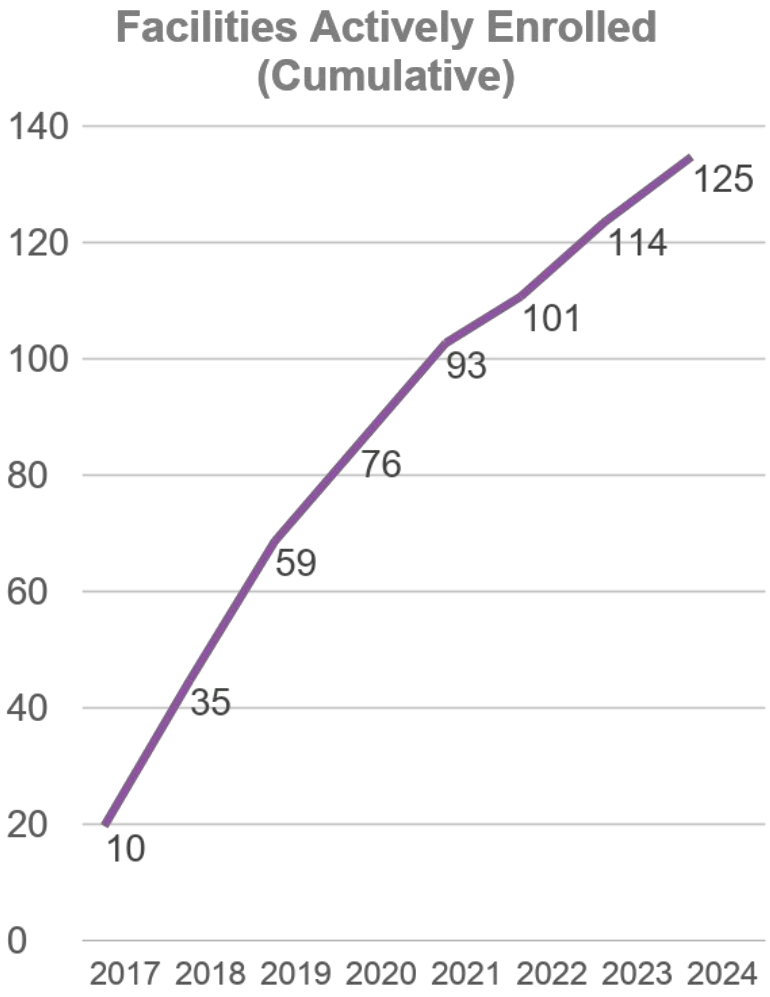
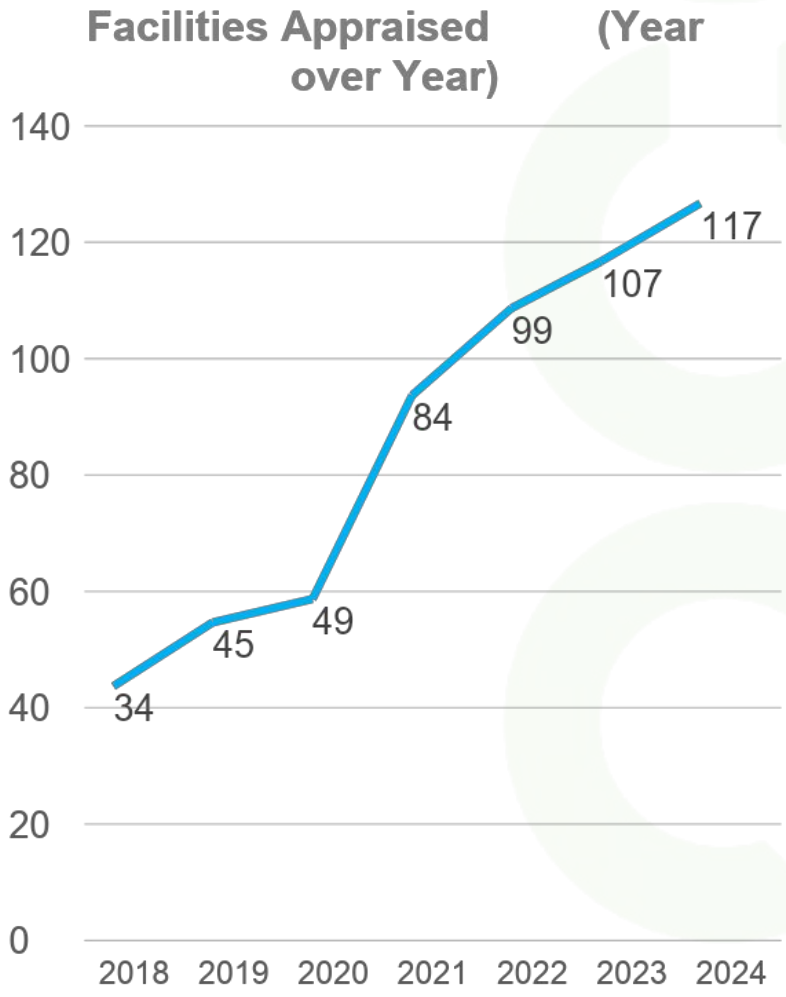
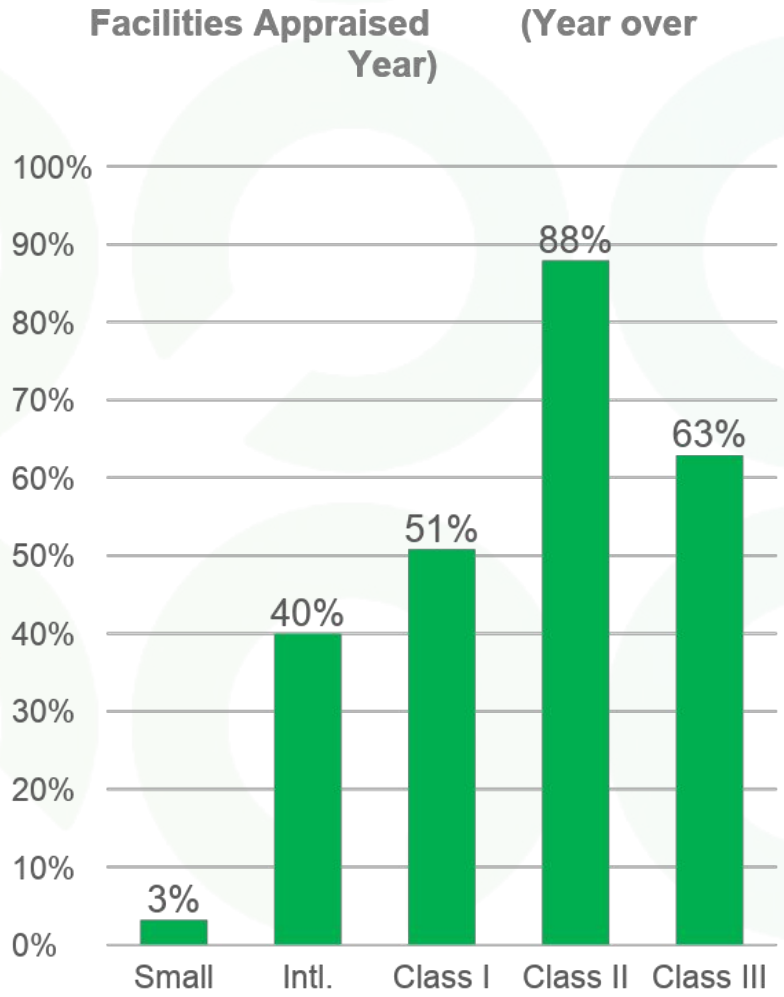
Program Adoption – Annual Growth







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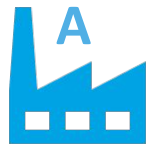
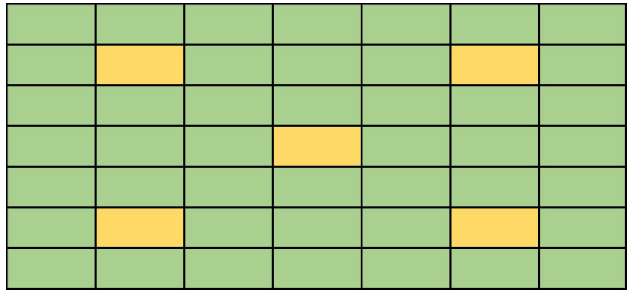
How does this work? A Case Study





ORGANIZATION APPLIES → MDDAP PROCESSES → FDA ACCEPTS APPLICATION

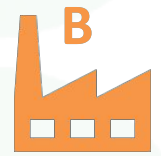
5 days from application to enrollment

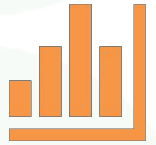
PMO, appraisal team, and organization determine appraisal scoping, scheduling, and plan

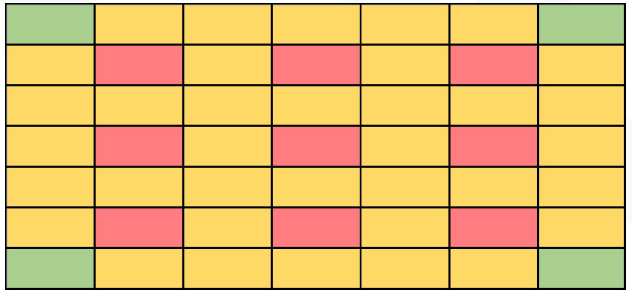
Within 60 days of enrollment

Routine inspection waived → APPRAISAL EXECUTED AND RESULTS PROVIDED TO ORGANIZATION

Within 90 days of enrollment







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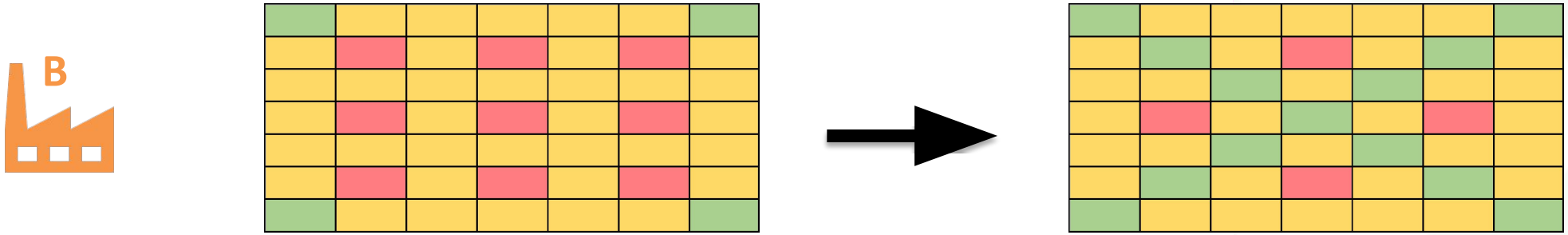

- 62% increase in daily production
- 70% decrease in staff turnover
- 90% reduction in time to ID root cause
- 95% reduction in complaints per million
- Motivated for the right reasons
- FDA partnership evolution
- Accelerated culture change

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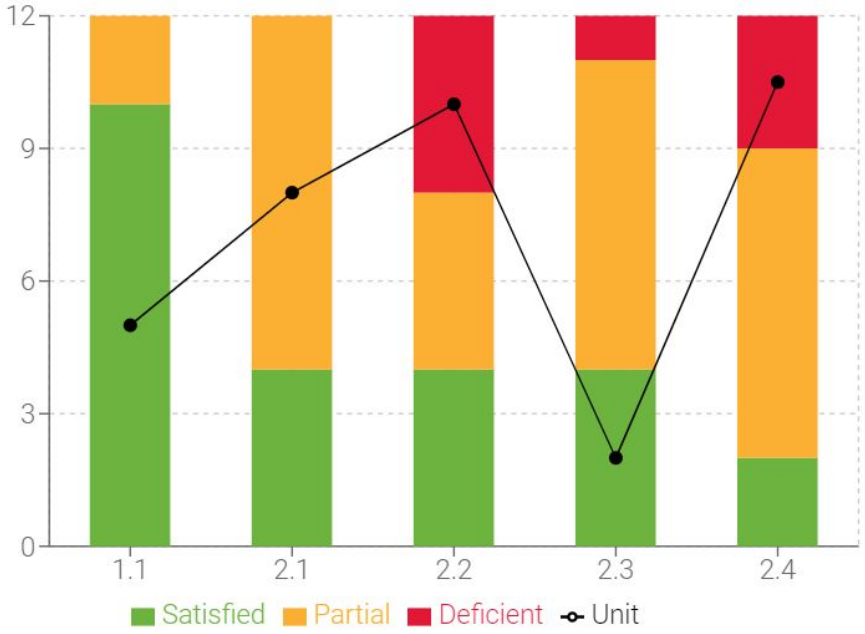
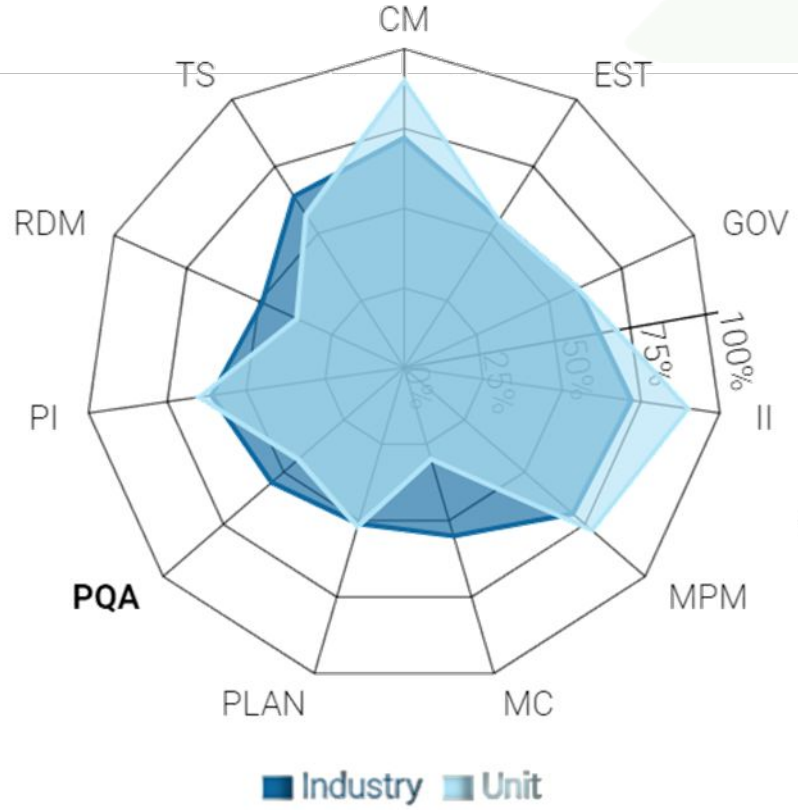
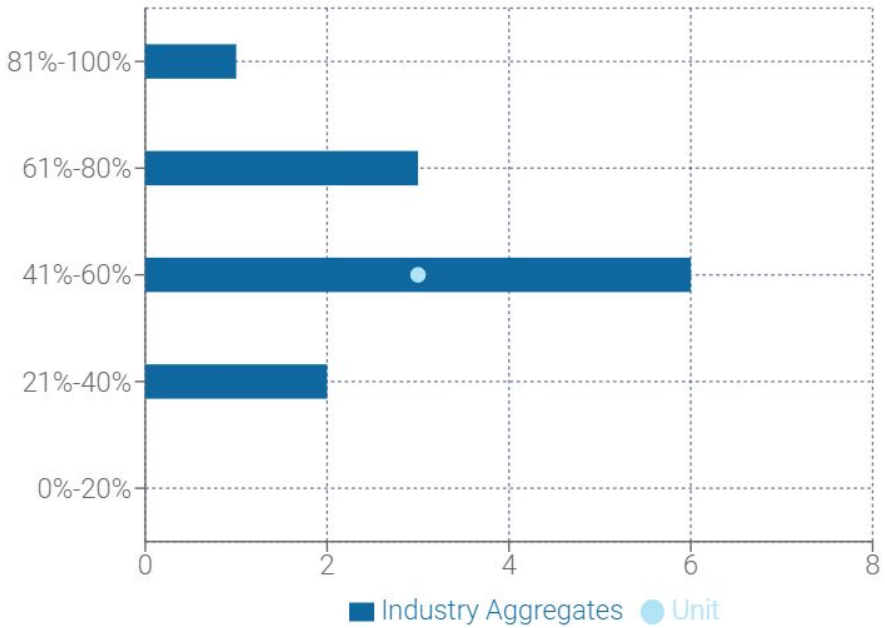
VIP Portal – Industry Trends and Comparisons







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NOT AUDIT BY ANOTHER NAME – HOW VIP IS DIFFERENT

VIP Does…

- Focus on capabilities and activities that add value to the organization
- Collect information by talking to individual contributors to understand how work is actually performed
- Drive discussions for how to improve performance in a focused way that makes sense to the business

Participants report 75%-85% less time and resource investment than an audit or inspection

VIP Does NOT…

- Does not check for compliance to CFR as that is a requirement to enroll in VIP
- Does not review SOPs with those who typically manage audits in a “front room” / “back room” manner
- Does not expect all identified opportunities to be addressed like a corrective action list

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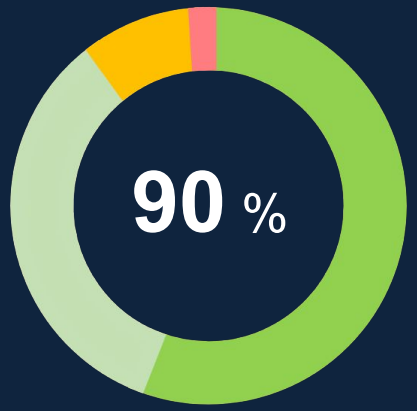
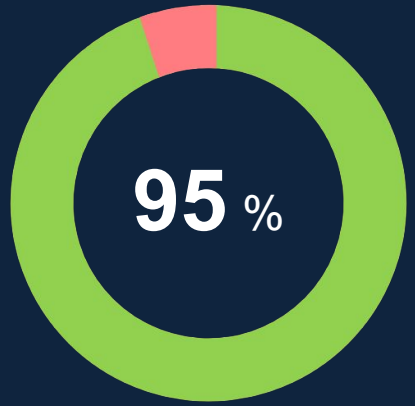
Program Effectiveness – Survey Results

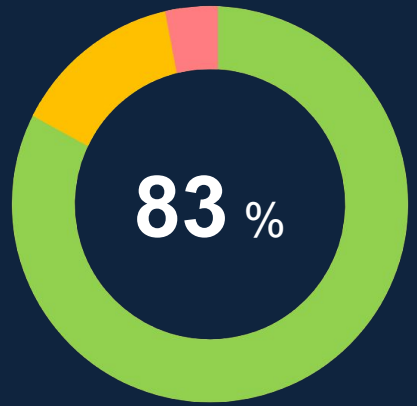
(2024, 362 responses)



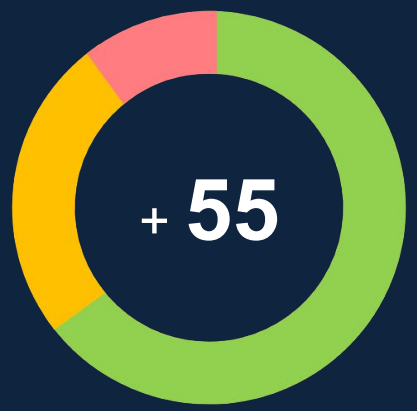
Had an excellent or above average experience with the appraisal activities



Believe the appraisal identified opportunities to improve product quality



Believe the appraisal provided broader value add to the organization



Net Promoter Score

Range:
-100 to 100

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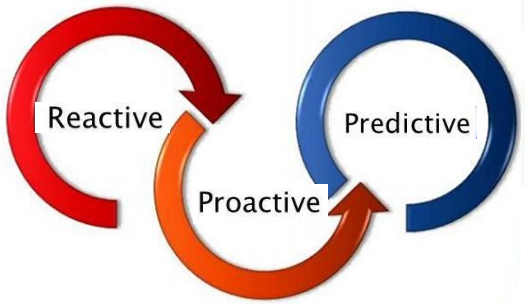
Program Effectiveness – Survey Themes in Product Quality

- **Aligned objectives** as a company
- **More access and sharing** between departments, getting the right people together
- **Standardized reporting** metrics, better understanding of measurement systems, tracking mechanisms supporting accountability



- **Increased rigor and predictability** in new product development and training
- **Better risk mitigation** of nonconforming products, process control, and supply chain
- **Agility** in decision making

- Pursuit of **systemic changes with lasting benefits** rather than just addressing problem at hand
- Shift **from tactical to strategic** thinking
- Recognition that **every person contributes** to quality

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“The MDDAP program has enabled BSC to establish new relationships with peer companies for sharing of best practices, while also strengthening our relationship with FDA. And significantly, it has given our participating sites access to the impactful regulatory benefits that this program offers– which in turn benefits our patients and customers around the world.”

Conor Dolan
VP Global Quality Systems & Supplier Quality
Boston Scientific

Regulatory Opportunities

Manufacturers who demonstrate a commitment to continuous improvement in the program may benefit from the following VIP-specific regulatory opportunities:

Inspections: Program engagement informs a risk-based approach to FDA inspection planning and resource allocation for routine surveillance, pre-approval and post-market inspections.

Change Notices: Program data enables use of a modified submission format with reduced timeframes (resources permitting) for Premarket Approval Application (PMA) and Humanitarian Device Exemption (HDE) 30-Day Change Notices.

Site Changes: Program data enables use of a modified submission format with reduced timeframes (resources permitting) for PMA and HDE Manufacturing Site Change Supplements.

Manufacturing Modules: Program data enables use of a modified submission format for PMA or HDE Manufacturing Modules.

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PROGRAM EFFECTIVENESS – REPORTED VALUE IN PROGRAM

27%

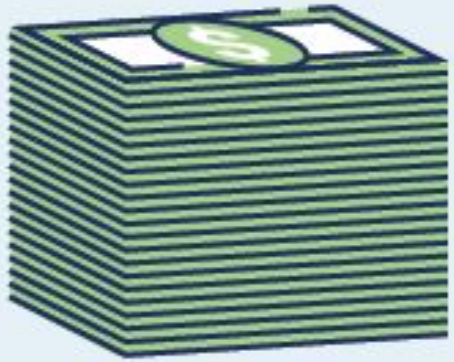
decrease in time taken to close complaints

880+

additional high-risk patients received life-saving treatment

$15M+

in product sales reported from operational improvements in streamlined change notice process



4x

increase in manufacturing capacity, resulting in increased revenue

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Questions?

Stop by Booth #26!

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ISACA.org/VIP

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