Applying Quality System Improvements to the Device Field Action Process

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Call to Action

- As part of our compliance remediation journey, we looked at improvement opportunities for our entire Quality System over the life cycle of the products.
- This talk will share our improvements and learnings for our Field Action Process. To drive improvements to our Field Action process, we focused on the following:

Timeliness of
Issue Awareness to
Field Action Decision and
Notification to Regulators

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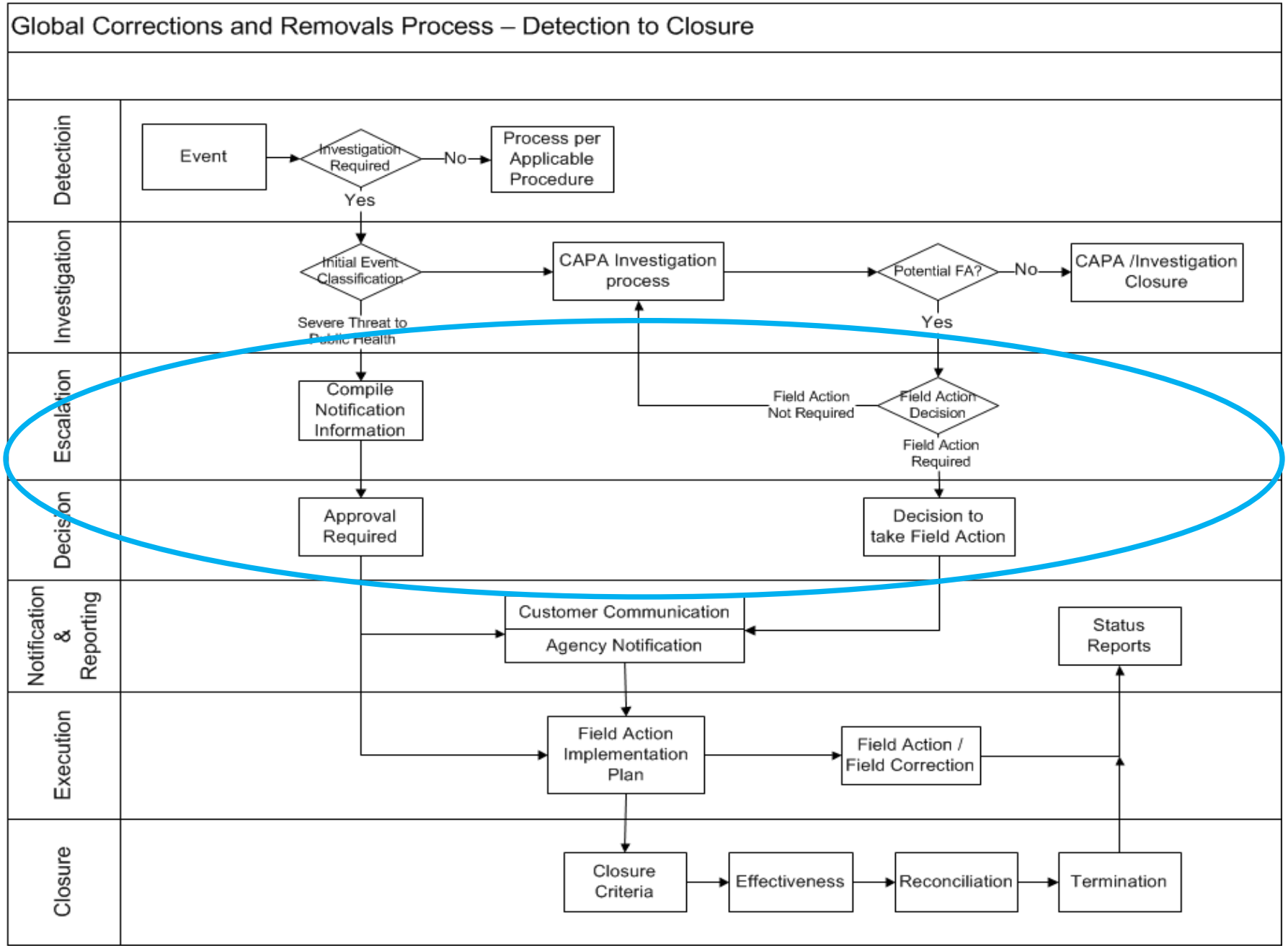
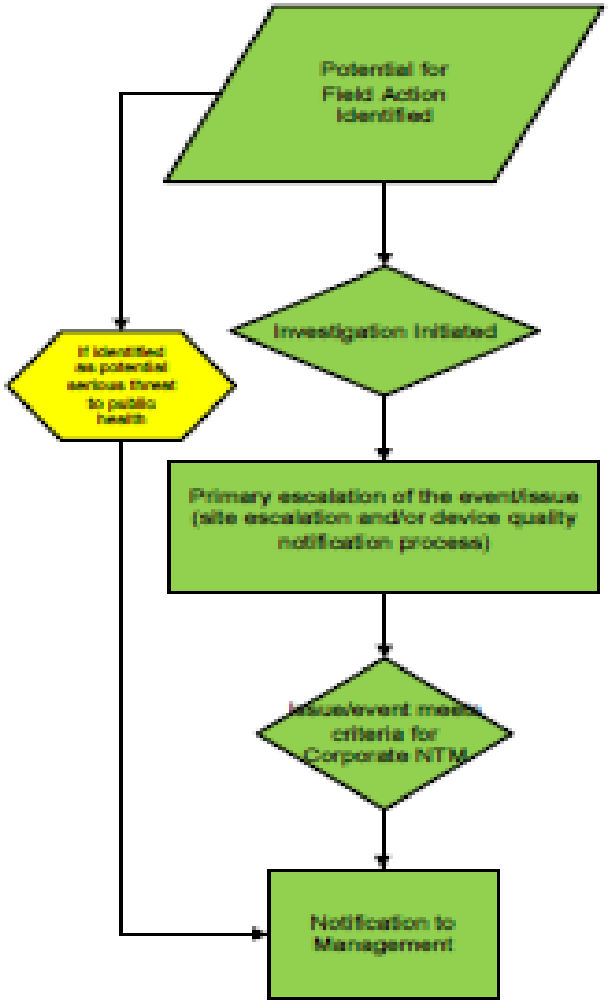
Medical Device Corrections and Removal Process



What is Notification to Management?

- A cross-functional, risk-based review and decision-making process for issues that may warrant regulatory notification, field action, and/or recall.
- The NtM process requires
  - timely notification of events that could potentially have an adverse impact on the safety, quality, and/or regulatory compliance of Hospira on-market products
  - proper notification, documentation, and communication of all decisions made regarding regulatory notification, field action, and/or recall



Evolution of our Escalation and Decision Making Process

Prior to 2012
Issue Elevation

2012
Notification to Management (NtM)

- Fundamental changes include:
  - Revamped template for information required to be shared at NtM meetings
  - Tighter timeliness requirements around notification, dissemination, and follow up action
  - Cross-functional inclusion of Operations as core member and legal as an extended member on the NtM team
  - Clearly specified level of Management required at meetings and delegation rules

2012 Improvements

- Major change to program including name change
- Updated purpose and scope
- Updated roles and responsibilities and clarified responsibilities of core and extended members

2013
Enhancements to NtM

- Clarification of responsibilities and required attendees
- **Inclusion of health hazard analysis, field action strategy, field action reportability, scope and draft of field action communication letter as an *input* to NtM**

2013 Improvements

- Major Revision to the Template to ensure inclusion of all required inputs
  - Template no longer optional
  - Separate template for Pharma and Device
  - Inclusion of NtM Checklist

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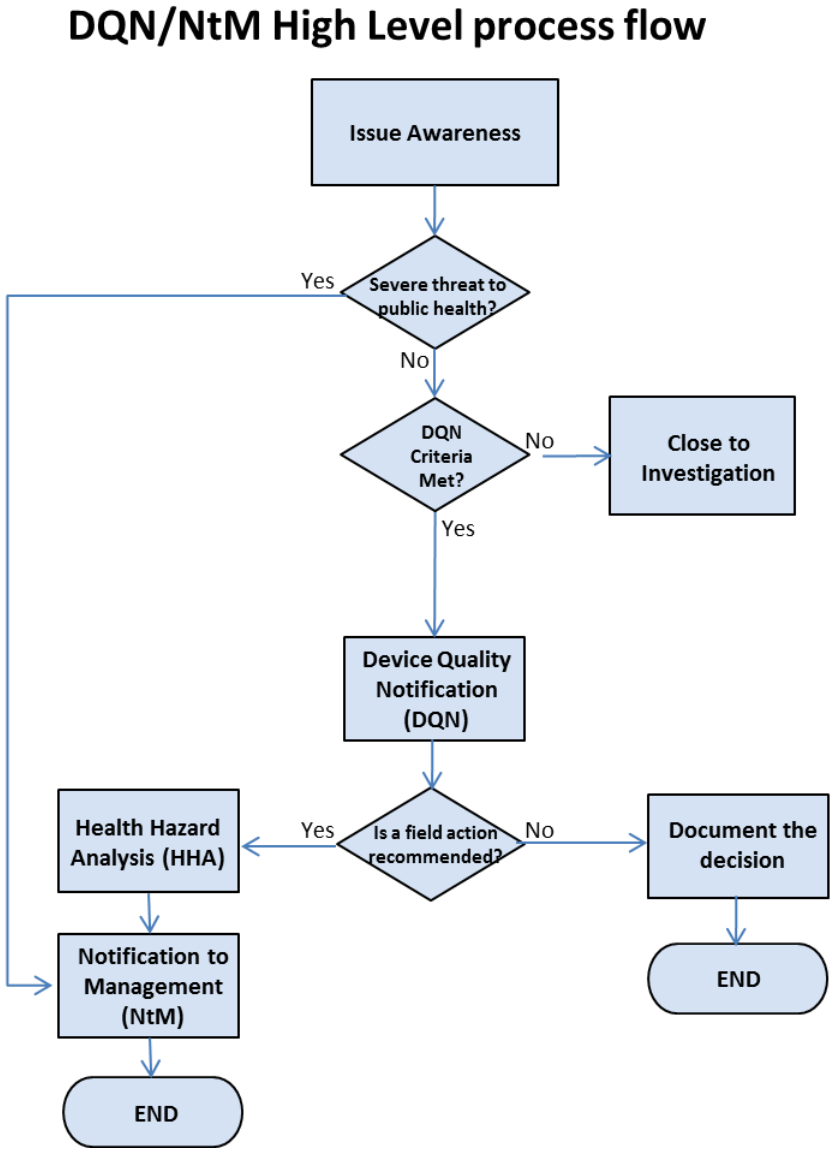
In 2013 the Device Quality Notification (DQN) process was introduced as a pre-cursor to the NtM process

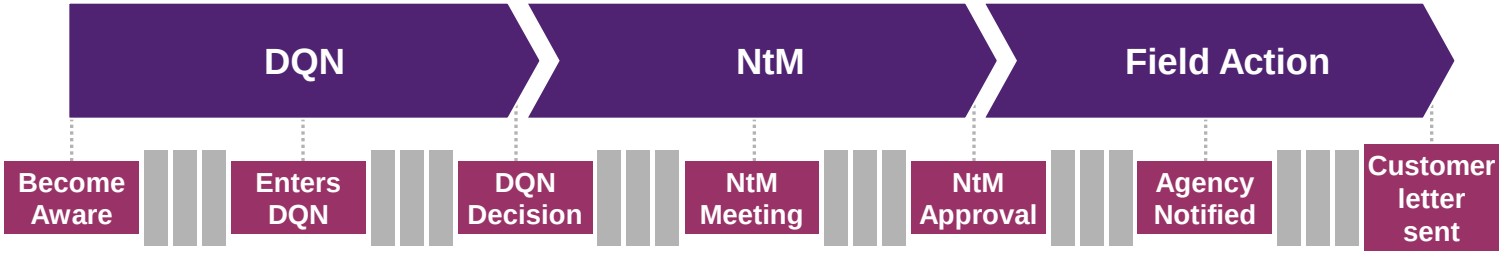


The DQN process allows for elevation of events early in the CAPA process to ensure timely response.

If during the CAPA process, any one of the following criteria is met, the event must be escalated to the DQN Board:

- Risk is
  - Found to be high
  - Found to be medium and the acceptability not supported by a Clinical Benefits Analysis
  - Risk is found to be increased when compared to the risk file
- Identified Material:
  - Nonconforming material in the field
  - Failure of material to meet regulatory requirements
  - Device not performing per intended use
  - Regulatory Mandate

The DQN and NtM processes allow for quick escalation, enabling rapid action as necessary.



Targets: 45 days | 30 days | 9 days | 2-3 days
Overall Target for Awareness to Decision is 90 days

Quality Oversight	• Weekly DQN Meetings • Monthly management meetings	• Weekly NtM Meetings • Monthly management meetings	• Monthly management meetings
Key Activities	• Initial risk assessment (RMFR/IRA) • Root cause investigation • Weekly review by DQN board	• Completion of IRA/HHA • Investigative steps requested by DQN board • Draft customer letter • Reportability determination • Field action strategy	• Additional steps requested at NtM meeting • Distribute NtM materials to regions/sites • Finalize customer letter

Continuous Improvement

In late 2013, we reviewed data to determine effectiveness of the actions taken to determine how to enact the next improvement.

In 2014, we are focusing on the following pinch points:

- Streamlining of Complaint Activities
- Improvement of Complaint Trend Analysis
- Streamlining of Use Error Handling
- Reduction Field Action Determination Time
- Reduction of DQN and NtM preparation time
- Improvement of Impact Assessments
- Standardization of Workflows
- Update of DQN & NtM procedures

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So where are we thus far…

- We are not there yet, but we have experienced great improvement including:
  - Approximately 68% reduction in average age of CAPA from awareness to NtM decision
  - Approximately 90% reduction in time from NtM approval to notification to regulators

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Summary

- The Device Quality Notification (DQN) process allows for elevation of events early in the CAPA process to ensure timely response.
- Development and review of the Field Action Strategy begins during the DQN decision process.
- Review of the Field Action Strategy and Reportability recommendation as well as review of the Customer Letter is a part of the Notification to Management (NtM) decision process.
- Involvement of senior level, cross functional management at the NtM meeting is essential to rapid decision making.

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