

Enhancing Malignant Hyperthermia Preparedness via Practical Training : An Outcome Review of Process Improvement Collaboration

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EAGLE
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Introduction

- Anesthesiologists pioneered the use of simulation in healthcare
- Simulation-trained HCPs
 - Recognize conditions and events faster
 - Manage medical emergencies better
- Malignant Hyperthermia (MH)
 - Rare and unpredictable hypermetabolic crisis
 - Outcomes related to time to treatment and administration of antidote (IV dantrolene)
 - Routine training has been demonstrated to improve preparedness
- Mandated by multiple accrediting organizations
- RYANODEX® (dantrolene sodium) drill vials available to support emergency preparedness
 - Eagle has provided drill vials to licensed HCPs and facilities free of charge for >7 years
 - Also available though a partnership with the Malignant Hyperthermia Association of the US (MHAUS)

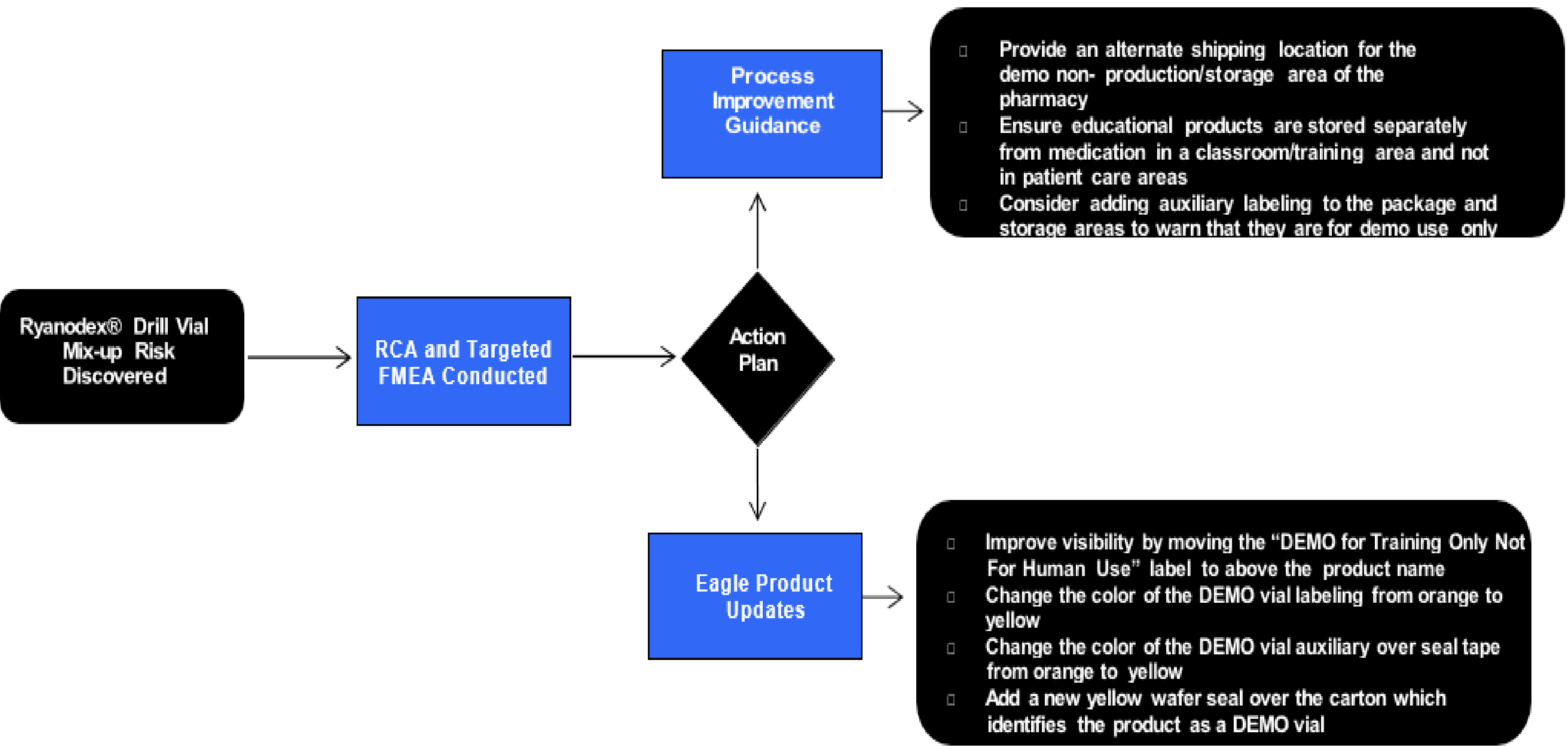


Methods

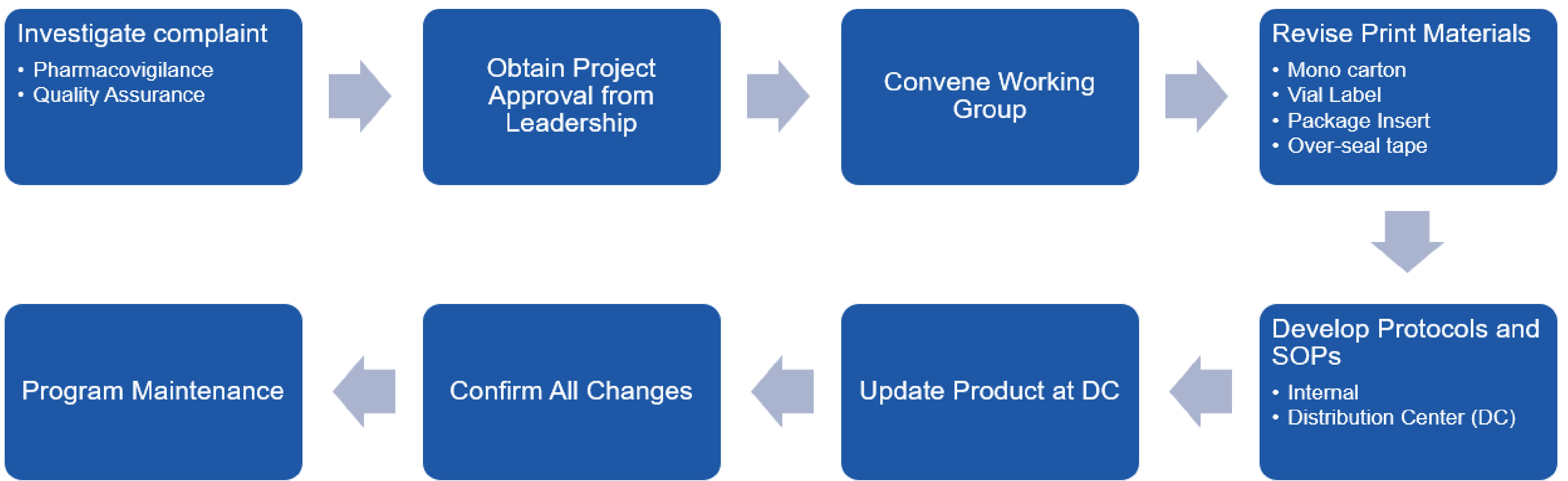
- Eagle was alerted of a medication error risk stemming from “Ryanodex Demo for Training” vials that were inadvertently stocked with commercial Ryanodex (dantrolene sodium) vials at a hospital.
- Eagle Pharmaceuticals assembled a working group engaging both internal and external stakeholders to put forth a collaborative risk mitigation plan.
- The working group completed a Root Cause Analysis (RCA) to address medication error risk and applied Failure Modes, Effects, and Causes (FMEA) principles to identify and mitigate future potential risks.
- These efforts made way for process improvements.



Risk Evaluation and Process Improvement Workflow



Eagle Response – RYANODEX Drill Vial Relabeling Project



Results

The multifaceted engagement identified the following process and product improvements.

1. An alternative storage area for demo and educational tools separate from commercial products storing area in pharmacies and patient care locations. Labelling the storage area distinctly to identify it as a training material only storage area.
2. A change to the visual appearance and labelling of the training tools to significantly distinguish it from the actual commercial product.
3. Instructing and training staff of the significance of storing and handling of simulation tools separate from the actual drug products.

The following changes are being implemented to the label of the drill vials as an improvement to the current processes.

1. Improve visibility of the Demo label by placing it right above the product name
2. Demo Vial labelling and Demo vial auxiliary over seal tape color has been changed to yellow which is significantly different from the orange color of the actual product vials.
3. An additional new yellow wafer seal will be placed over the drill vial carton to clearly identify it as a drill vial.



Ryanodex Drill Vial

Discontinued Ryanodex Drill Vial and Carton



Ryanodex Drill Vial and Carton *In Use*



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