



Industry Response to Mitigating Potential Medication Errors in Simulation

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Simulation-based Training and Emergency Preparedness

- 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 directly 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 through a partnership with the Malignant Hyperthermia Association of the US (MHAUS)

RYANODEX Drill Vial – Initial Presentation

- Commercial Product



- Drill Vial



- Differences

- No NDC number
- No expiration date
- No bar code
- “DEMO” added to lot #
- Auxiliary labelling
- Auxiliary over-seal tape

In June of 2023 ISMP informed Eagle of an intercepted or “near-miss” medication error

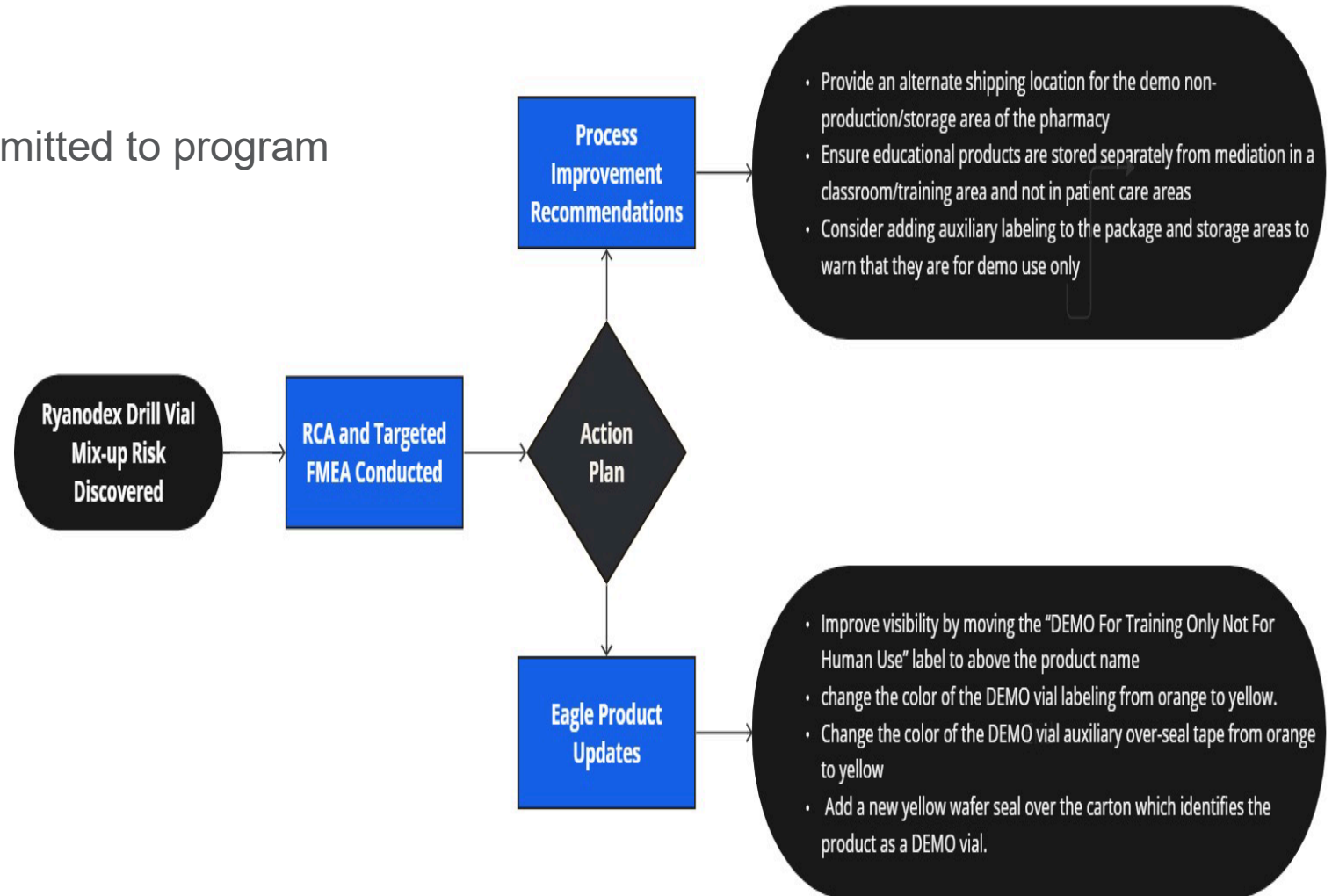
A hospital which stocks RYANODEX for the treatment of MH requested RYANODEX drill vials from Eagle

Upon receipt of the drill vials hospital supply staff shelved the drill vials with live product

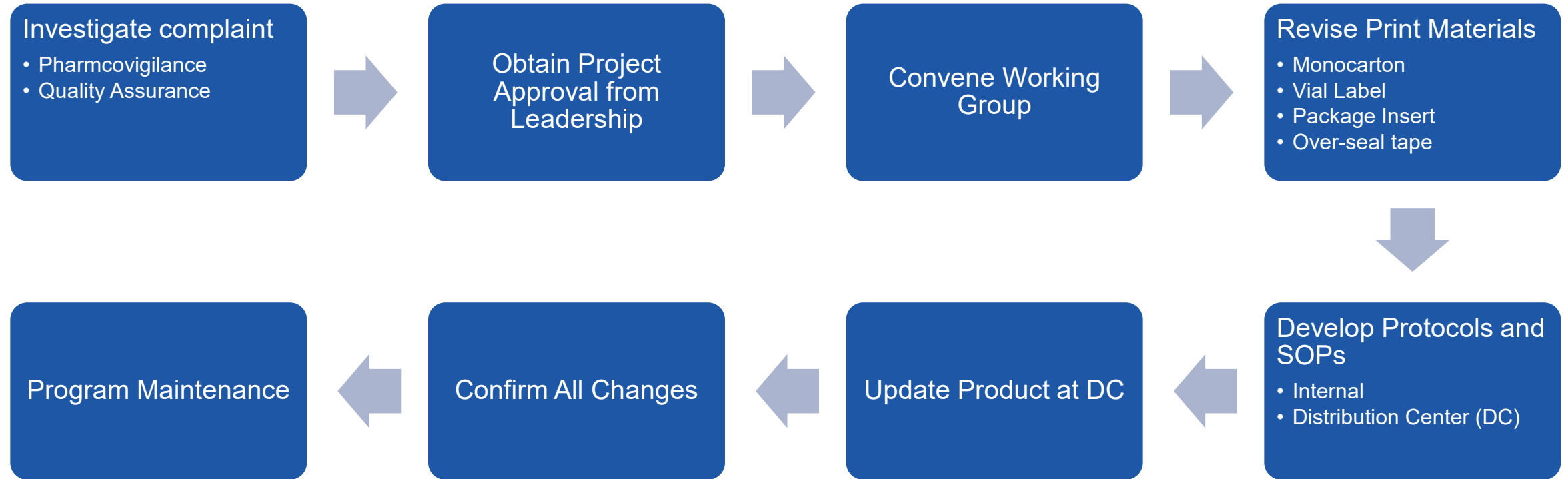
Storage error was identified before the product was used for patient care

Eagle Response – Identify Changes to Mitigate Risk

- Leadership remained committed to program
- Internal Working Group
 - Commercial
 - Legal
 - Medical Affairs
 - Quality Assurance
 - Regulatory Affairs
 - Supply Chain
- External Resources
 - ISMP
 - Eagle Consultants



Eagle Response – RYANODEX Drill Vial Relabeling Project



- Development performed under Good Manufacturing Practices (GMP)
- Normal timeline for a relabeling project 6 – 8 months
- This relabeling project was accomplished in 4 months

Revised Ryanodex Drill Vial and Carton



- Auxiliary labeling moved above product name
- Color changed on auxiliary labeling and auxiliary over-seal tape
- New yellow wafer seal

Conclusion

- Eagle leadership demonstrated continued commitment to emergency preparedness
- Collaborative efforts with internal and external stakeholders resulted in revised RYANODEX Drill Vial safety features and updated processes
- These changes are intended to mitigate the potential risk of medication errors