FORESITE 20-20

INTELLIGENT QUALITY CHECK PRIMER

Steven Hansen, Sai Phalke, Jose Osvaldo Alvarez, Brett Tweedie & Rachel Momanyi

09/23/2021

CardinalHealth

Essential to care™

Our Path Forward

WHY
we exist

We deliver products and solutions to **improve the lives of people every day.**

WHERE
we are going

We aspire to be **healthcare's most trusted partner** by building upon our scale and heritage in distribution, products and solutions, while driving growth in evolving areas of healthcare through customer insights, data and analytics, and focusing our resources on what matters most.

HOW
we will grow

VALUES
what we believe

- **Integrity**
- **Inclusive**
- **Innovative**
- **Accountable**
- **Mission driven**

BEHAVIORS
how we act

- **Invites curiosity**
- **Inspires commitment**
- **Builds partnerships**
- **Develops self and others**

What is a defect worth?

Dissatisfaction(Angry, Upset)

Reputation

Legal/Recall

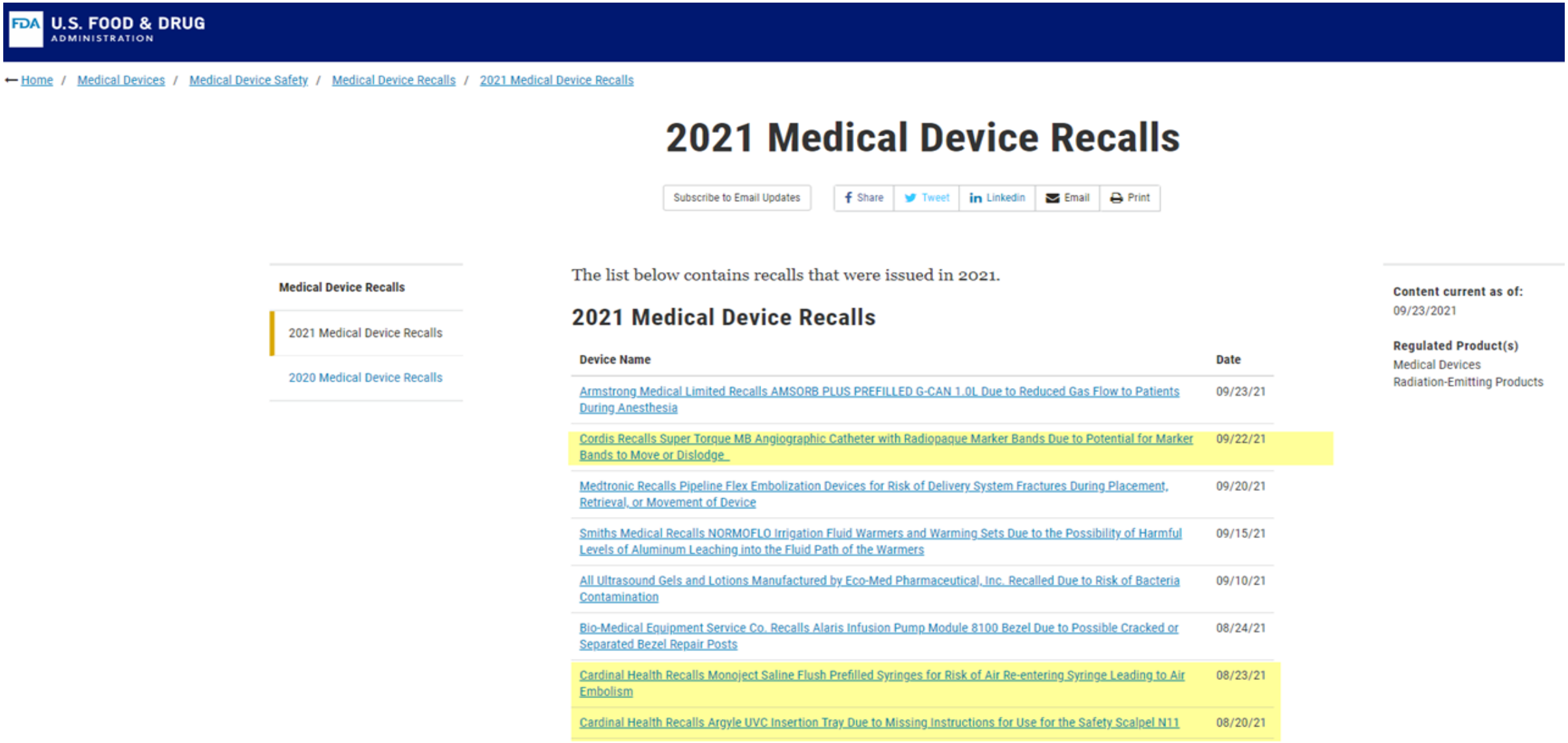
Potential for patient/user harm

Future business

$$$$$

CardinalHealth

Introduction



U.S. FOOD & DRUG ADMINISTRATION

← Home / Medical Devices / Medical Device Safety / Medical Device Recalls / 2021 Medical Device Recalls

2021 Medical Device Recalls

Subscribe to Email Updates | Share | Tweet | LinkedIn | Email | Print

Medical Device Recalls

- 2021 Medical Device Recalls
- 2020 Medical Device Recalls

The list below contains recalls that were issued in 2021.

2021 Medical Device Recalls

Device Name	Date
Armstrong Medical Limited Recalls AMSORB PLUS PREFILLED G-CAN 1.0L Due to Reduced Gas Flow to Patients During Anesthesia	09/23/21
Cordis Recalls Super Torque MB Angiographic Catheter with Radiopaque Marker Bands Due to Potential for Marker Bands to Move or Dislodge	09/22/21
Medtronic Recalls Pipeline Flex Embolization Devices for Risk of Delivery System Fractures During Placement, Retrieval, or Movement of Device	09/20/21
Smiths Medical Recalls NORMOFLO Irrigation Fluid Warmers and Warming Sets Due to the Possibility of Harmful Levels of Aluminum Leaching into the Fluid Path of the Warmers	09/15/21
All Ultrasound Gels and Lotions Manufactured by Eco-Med Pharmaceutical, Inc. Recalled Due to Risk of Bacteria Contamination	09/10/21
Bio-Medical Equipment Service Co. Recalls Alaris Infusion Pump Module 8100 Bezel Due to Possible Cracked or Separated Bezel Repair Posts	08/24/21
Cardinal Health Recalls Monoject Saline Flush Prefilled Syringes for Risk of Air Re-entering Syringe Leading to Air Embolism	08/23/21
Cardinal Health Recalls Argyle UVC Insertion Tray Due to Missing Instructions for Use for the Safety Scalpel N11	08/20/21

Content current as of:
09/23/2021

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

CardinalHealth

Introduction

Cardinal Health Recalls Monoject Saline Flush Prefilled Syringes for Risk of Air Re-entering Syringe Leading to Air Embolism

Medical Device Recalls

2021 Medical Device Recalls

2020 Medical Device Recalls

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Monoject Flush Prefilled Syringes (0.9% sodium chloride)
- Product Codes, All Lots:
  - **Product Code (SKU) - Product Description**:
    - 8881570121 - 12mL Syringe, 10mL Saline Fill
    - 8881570123 - 12mL Syringe, 3mL Saline Fill
    - 8881570125 - 12mL Syringe, 5mL Saline Fill
- Distribution Dates: July 1, 2019 to July 1, 2021

Content current as of:
08/23/2021

CardinalHealth

Introduction

Problem statement:
Addressing quality issues in manufacturing during or after the production is very time consuming, expensive and adds to restrain on backorders.

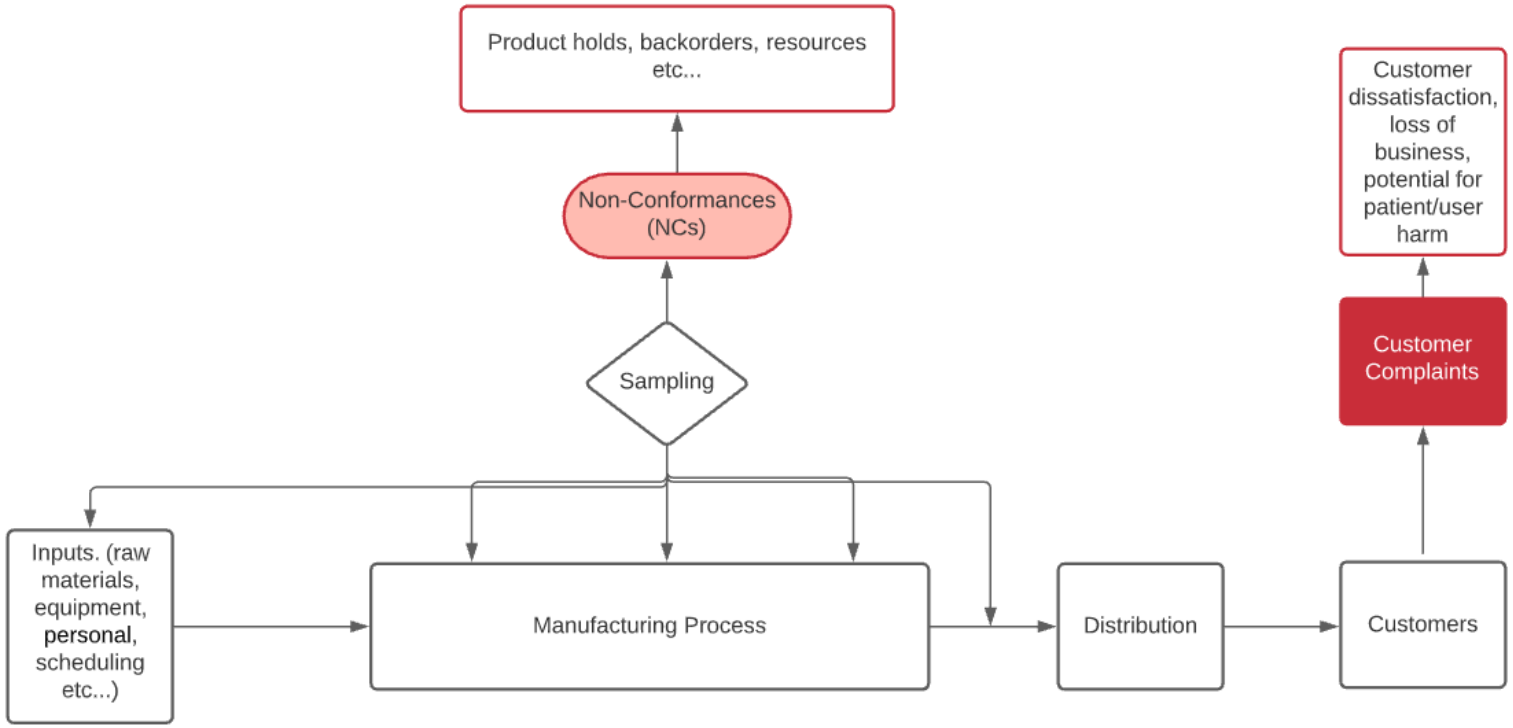
Current cost of awaiting Disposition for month of August 2021 at Crystal Lake Facility: **$ 441,517**
Average product disposition cost per year : **$ 1,103,762**
(excluding labor, overhead costs etc)

Risk Associated: Regulatory and Compliance Risks.

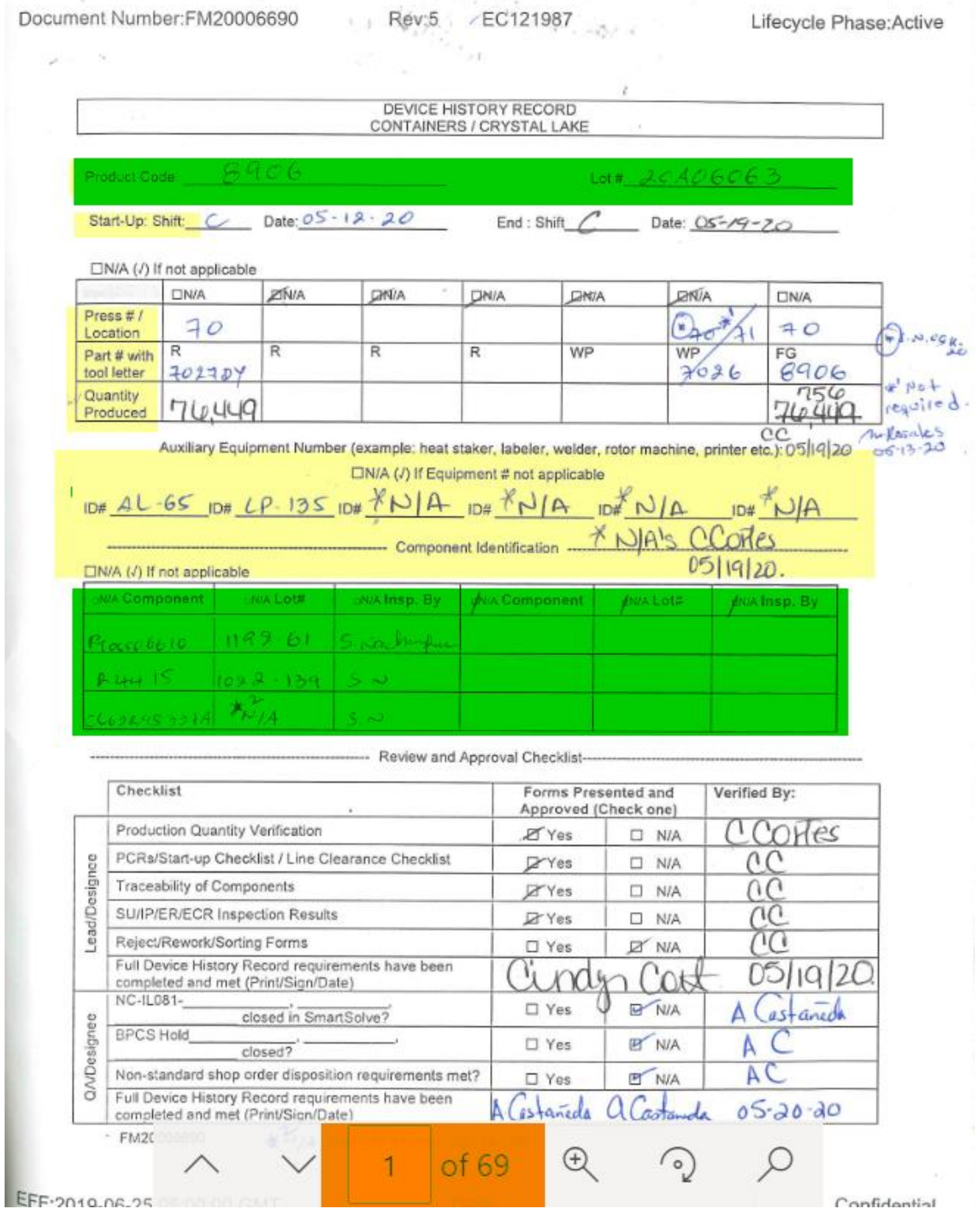
*Inherent friction between quality and manufacturing.

Solution :
Leverage LOT data, maintenance data and other manufacturing inputs to predict potential quality issues so they can be addressed before production.

Manufacturing Process Overview



Data Mining



Document Number:FM20006690 Rev:5 EC121987 Lifecycle Phase:Active

DEVICE HISTORY RECORD
CONTAINERS / CRYSTAL LAKE

Product Code: 8906 Lot #: 20406063

Start-Up: Shift: C Date: 05-12-20 End : Shift C Date: 05-19-20

☐N/A (√) If not applicable

	☐N/A	☑N/A	☑N/A	☑N/A	☑N/A	☑N/A	☐N/A
Press # / Location	70					70 / 71	70
Part # with tool letter	R 70270Y	R	R	R	WP	WP 7026	FG 8906
Quantity Produced	76,449						756 76,449

Auxiliary Equipment Number (example: heat staker, labeler, welder, rotor machine, printer etc.): CC 05/19/20

☐N/A (√) If Equipment # not applicable

ID# AL-65 ID# LP-135 ID# *N/A ID# *N/A ID# *N/A ID# *N/A

Component Identification *N/A's CCortes 05/19/20.

☐N/A (√) If not applicable

☐N/A Component	☐N/A Lot#	☐N/A Insp. By	☑N/A Component	☑N/A Lot#	☑N/A Insp. By
[illegible]	1199 61	[illegible]			
[illegible]	1022-139	[illegible]			
[illegible]	*N/A	[illegible]			

Review and Approval Checklist

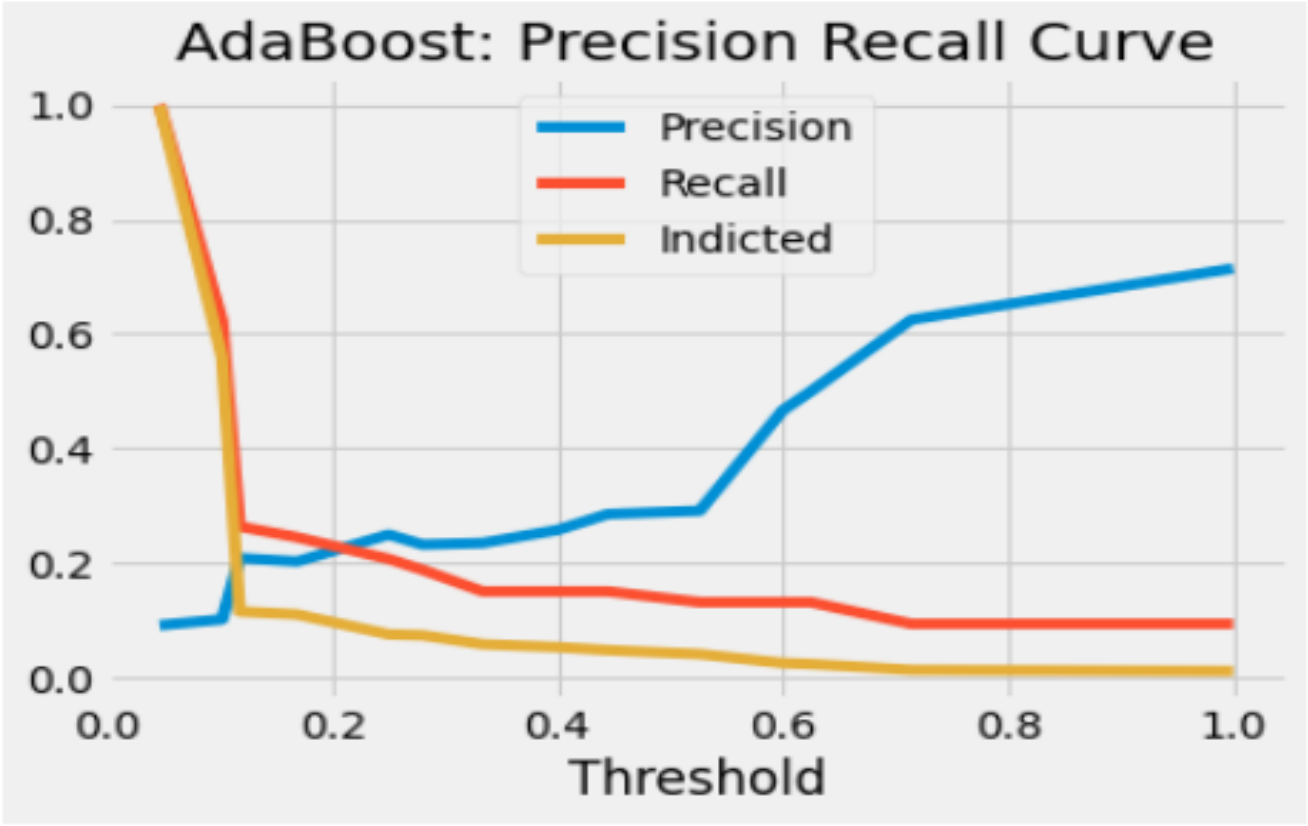
	Checklist	Forms Presented and Approved (Check one)		Verified By:
Lead/Designee	Production Quantity Verification	☑ Yes	☐ N/A	CCortes
	PCRs/Start-up Checklist / Line Clearance Checklist	☑ Yes	☐ N/A	CC
	Traceability of Components	☑ Yes	☐ N/A	CC
	SU/IP/ER/ECR Inspection Results	☑ Yes	☐ N/A	CC
	Reject/Rework/Sorting Forms	☐ Yes	☑ N/A	CC
	Full Device History Record requirements have been completed and met (Print/Sign/Date)	Cindy Cortes		05/19/20
QA/Designee	NC-IL081-____, ____, ____ closed in SmartSolve?	☐ Yes	☑ N/A	A Castaneda
	BPCS Hold____, ____, ____ closed?	☐ Yes	☑ N/A	A C
	Non-standard shop order disposition requirements met?	☐ Yes	☑ N/A	A C
	Full Device History Record requirements have been completed and met (Print/Sign/Date)	A Castañeda A Castaneda		05-20-20

FM20

1 of 69

EFF:2019-06-25 Confidential

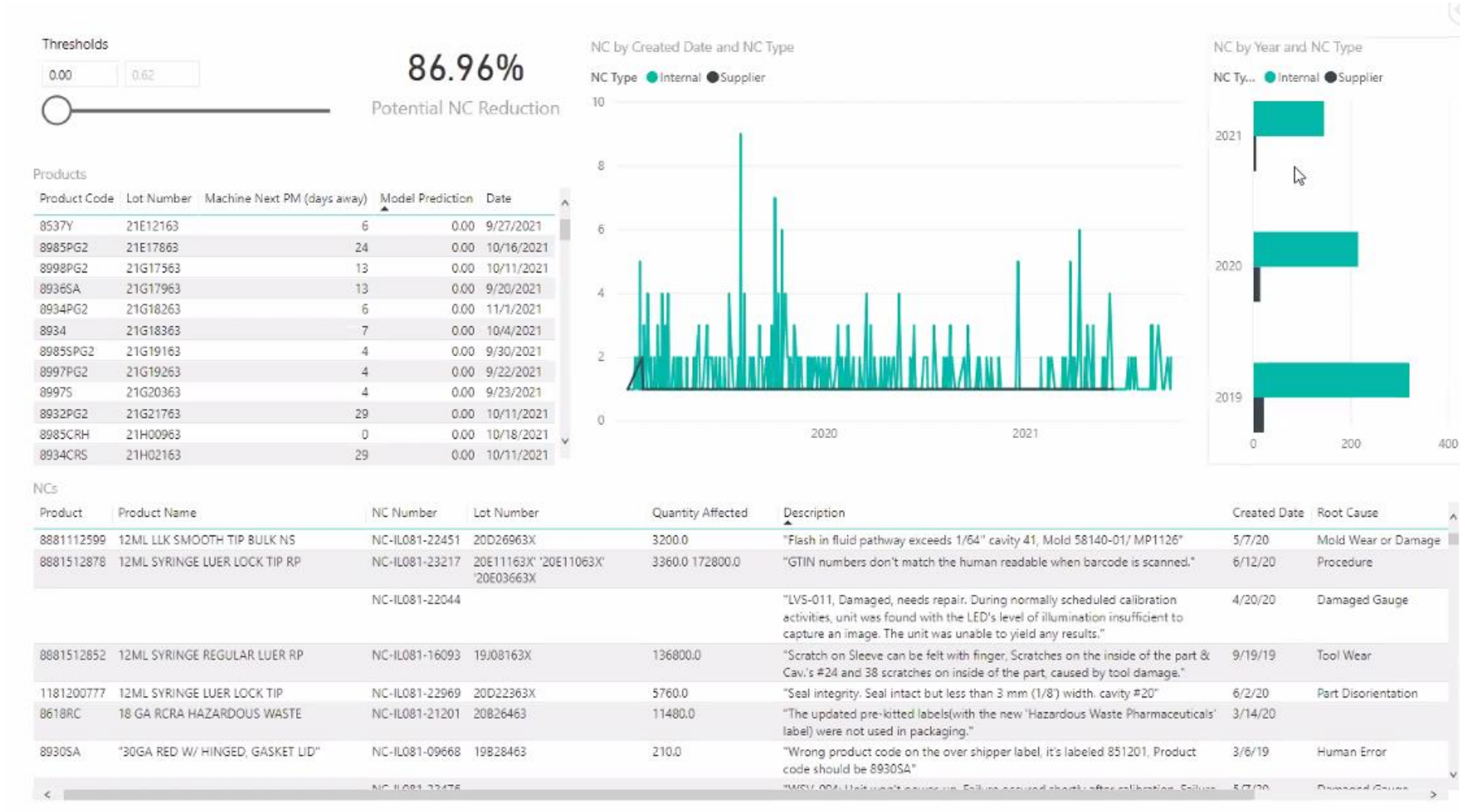
Data Model Overview




```
----- AdaBoost low estimaters, deep depth Model -----
percent of lots indicted = 1.211%
recall (NC reduction) = 9.43%
total number of predicted NCs = 7
True Positives = 5.0
precision = 62.5%
```

- 10% of training data had NCs
- Class imbalance
- Small dataset
- Focused on ensemble method

FORESITE 20-20



Impact

Process Efficiencies

- Earlier interventions on lots predicted to have a higher non-conformance rate
- Customized quality check process
- Resource efficiency
- Decreased production turnaround time.

Material Savings

- Reduce Average product cost per year by 10% ($ **110,376)** at Crystal Lake
- Additional Savings for labor and overhead cost
- Reduction of cost of awaiting Disposition monthly at Crystal Lake: **$ 44,151**

Growth Opportunities

- Model can scale to other sites and within Cardinal
- Enhanced the **partnership** between Manufacturing and Quality

CardinalHealth

Questions