Johnson&Johnson Innovative Medicine

Reducing Visual Defect Rates (%) in Concerta Tablets for Fuji Japan Inspection

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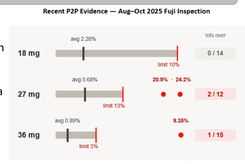
This DMAIC project focuses on reducing recurring visual-defect NCs in Concerta 18 mg, 27 mg, and 36 mg tablets manufactured at J&J Innovative Medicine Gurabo for Fuji-Japan inspection. Historical VOC/QRA data and recent investigation records show that printing and coating-related issues are the primary defect drivers. The project establishes a data-based foundation to improve process reliability, reduce COPQ, and strengthen customer satisfaction.

D DEFINE

Problem Statement

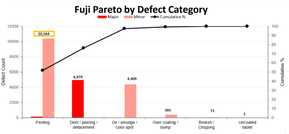
Concerta 18 mg, 27 mg, and 36 mg tablets manufactured at Gurabo continue to generate recurring visual-defect NCs at Fuji-Japan inspection

The issue has been tracked historically through QRA/FMECA and remains active in recent P2P data During Aug–Oct 2025, 3 of 41 lots exceeded Japan market acceptance limits, while average defect rates by strength remained within acceptance ranges.



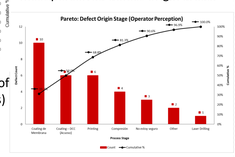
Recurring NCs continue to drive investigation, documentation, and cross-functional workload, contributing to Cost of Poor Quality.

VOC

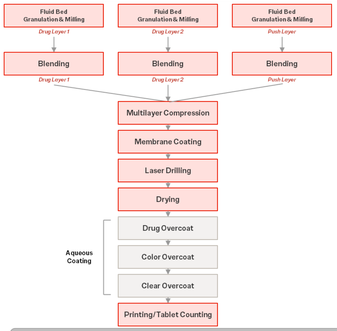


Historical Japan data, shows Fuji AQL inspection of 93 bulk lots (Oct 2021–May 2024; 20,415 defects) shows Printing (51.7%) and Dent/Peeling/Defacement (24.4%) account for 76.1% of all visual defects.

Gurabo's operators VOC responses identified coating and printing as the most perceived defect-origin areas.

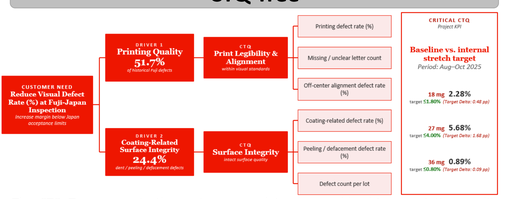


Process Flowchart



The manufacturing process includes granulation, blending, multilayer compression, coating, drying, and printing. Coating and printing are key focus areas because defects introduced in these steps are visible at final Fuji-Japan inspection.

CTQ Tree



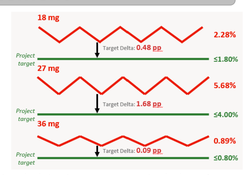
The CTQ Tree connects the customer need to measurable drivers: printing quality, coating integrity, and defect-rate reduction at Fuji-Japan inspection.

SIPOC

Goal Statement

By end of Q4 2026, reduce the average visual defect rate for Concerta tablets inspected at Fuji-Japan from baseline Aug–Oct 2025 levels to:

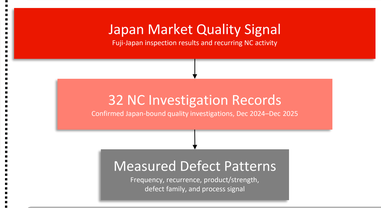
18 mg: 2.28% → ≤1.80% (0.48 pp reduction)
27 mg: 5.68% → ≤4.00% (1.68 pp reduction)
36 mg: 0.89% → ≤0.80% (0.09 pp reduction)



Targets are internal improvement targets intended to increase margin below Japan acceptance limits and reduce recurring NCs.

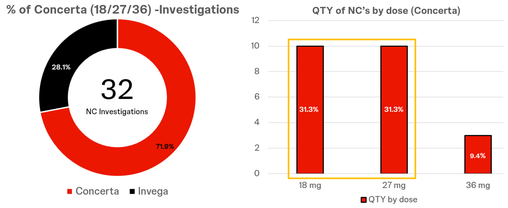
M MEASURE

Overview



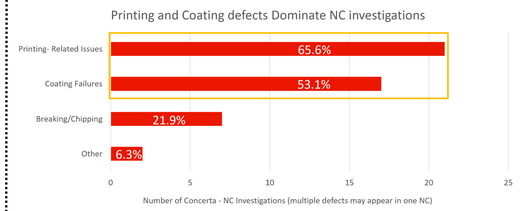
Measure establishes the baseline using Fuji-Japan inspection signals and 32 Japan-bound NC investigation records. The analysis quantifies defect frequency, recurrence, affected strengths, process signals, and COPQ.

Baseline & Scope



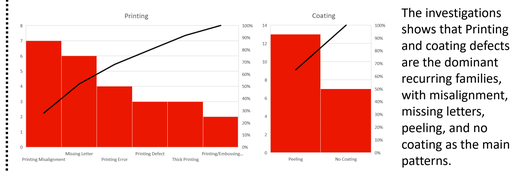
Concerta represented 71.9% of the 32 reviewed NCs. Among Concerta strengths, 18 mg and 27 mg showed the highest recurrence, with 10 investigations each.

Defect Frequency



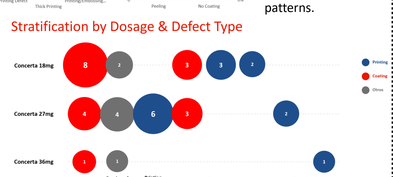
Printing-related issues and coating failures were the most frequent defect families, appearing in 65.6% and 53.1% of the 32 investigations, respectively.

Process Stability/Recurrence



The investigations shows that Printing and coating defects are the dominant recurring families, with misalignment, missing letters, peeling, and no coating as the main patterns.

Stratification shows that recurrence is not evenly distributed; 18 mg and 27 mg concentrate most of the repeated printing and coating patterns.



Recurrent lots suggest potential process stability concerns

Lot #	Product	# NCs	Defects
25BD5062	27mg	3	Coating, Printing, Breakage
25AD4874	27 mg	2	Coating, Printing, Breakage
25DD5413	18 mg	2	Coating
25HD5941	INV 3 mg	2	Printing

4 — 27mg Recurrent NCs

3 — Printing Issues

Several lots appear in multiple NC investigations, lot 25BD5062 (27 mg) recurs three times, signaling potential process-stability concerns. Recurrence concentrates in the 27 mg strength (4 recurrent NCs) and in printing-related issues (3 counts).

Financial Impact

$283K — TOTAL FINANCIAL IMPACT: Total Cost (Investigation Cost + Product Loss)

$33K — INVESTIGATION COST: Cost of investigator time spent on open investigations

$250K — PRODUCT LOSS: Cost associated with discarded tablets

2.4M — Tablets Discarded: Total tablets rejected or discarded

KEY DRIVERS
- *Investigations opened*
- *Average aging (working days)*
- *Discarded tablets*
- *Estimated Investigator Effort*

Investigation Cost	Product Loss
Working days x Avg. Hrs/Day x Hourly rate	Data available in each investigation report

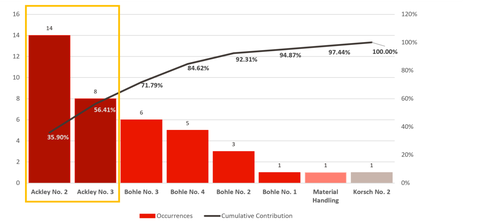
A ANALYZE

From NC Data to Root-Cause Focus

1. 32 NC Investigation Reports — All 32 NC Reports reviewed
2. Data Structuring — Workbook created
3. Work-Center Pareto — Where defects concentrate
4. Fishbone — Potential causes mapped
5. Root-Cause Pareto — Most frequent cause identified
6. 5 Whys Analysis — Most frequent causes analyzed

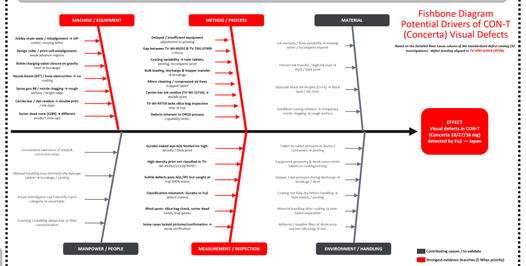
The 32 NC investigation records were structured into a workbook and analyzed using Pareto, Fishbone, and 5 Whys tools to identify where defects concentrate, which causes repeat, and why they recur.

Where Defects Concentrate (Work-Center Pareto)

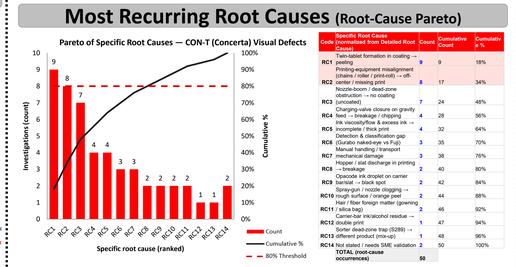


Ackley No. 2, Ackley No. 3, and Bohle No. 3 concentrate 71.8% of defect-origin occurrences, guiding the focus for deeper root-cause analysis.

Potential Causes



Most Recurring Root Causes (Root-Cause Pareto)



Specific Root Cause Code (normalized from Detailed Root Cause)		Count	Cumulative Count	Cumulative %
RC1	Twin-tablet formation in coating → peeling Printing-equipment misalignment (shains / roller (print-roll) → off-center	9	9	18%
RC2	center / missing print Coating-system / dead-zone obstruction → no coating (uncoated)	8	17	34%
RC3	Charging-valve closure on gravity feed → breakage / chipping	7	24	48%
RC4	Ink viscosity/flow & excess ink → incomplete / thick print	4	28	56%
RC5	Detection & classification gap (Gurabo naked-eye vs Fuji)	4	32	64%
RC6	Manual handling / transport	3	35	70%
RC7	mechanical damage Hopper / slat discharge in printing	3	38	76%
RC8	→ breakage Opacode ink droplet on carrier	2	40	80%
RC9	barstat → black spot Spraygun / nozzle clogging →	2	42	84%
RC10	rough surface / orange peel Hair / fiber foreign matter (gowning	2	44	88%
RC11	/ silica bag)	2	46	92%
RC12	Carrier-bar ink/alcohol residue → double print	1	47	94%
RC13	Sorter deselection trap (S2Bb) → different product (mix-up)	1	48	96%
RC14	Not stated / needs SME validation	2	50	100%
	TOTAL (root-cause occurrences)	50		

Major Offender #1: Coating/twin-tablet

WHY	QUESTION	ANSWER
PROBLEM	Why are CON-T tablets showing coating defects [peeling, no coating, twin tablets, dent]?	Some tablets stick together, trap, or separate during/after coating, creating coating defects before or during the transition to printing.
WHY 1	Why are tablets sticking together or separating after coating?	Twin tablets can form during membrane, DCC, or color coating when tablets contact each other before the coating layer is fully stable or dry.
WHY 2	Why can twin tablets remain attached or pass forward in the process?	Controls and sorting reduce occurrence but may not detect/remove every twin tablet, especially if subtle or it separates later in handling, discharge, or printing.
WHY 3	Why are some twin tablets / coating defects only detected later by Fuji?	Gurabo AQL, IPC, and release inspections can have lower sensitivity for subtle coating defects than Fuji's 100% visual / automatic inspection criteria.
WHY 4	Why does the process still allow rare coating defects even when controls are followed?	The coating process has inherent variability — tablet movement, tablet-to-tablet contact, coating wetness/drying, equipment geometry, and post-coating handling.
WHY 5	Why has this variability not been fully eliminated?	Current process capability and inspection strategy minimize these rare defects but don't fully prevent twin-tablet formation, late separation, or subtle defects reaching downstream inspection.

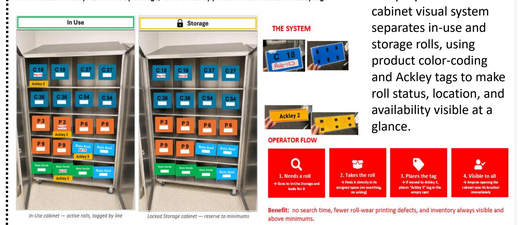
Major Offender #2: Printing setup → emboss error

WHY	QUESTION	ANSWER
PROBLEM	Why are CON-T tablets showing emboss-printing errors (off-center, missing letter, incomplete imprint, thick print, lack of printing)?	Because the printing system is not always achieving a consistent and repeatable imprint transfer onto the tablet surface.
WHY 1	Why is the imprint transfer not always consistent and repeatable?	The Ackley setup depends on several critical conditions: alignment, roller contact, print-roll height, ink transfer, chain condition, and correct roller selection.
WHY 2	Why do these critical setup conditions vary?	The setup has been highly manual / artisanal, lacking enough visual aids, standard reference points, and shift-to-shift controls to guide operators to the same conditions every time.
WHY 3	Why is the setup process vulnerable to variation across shifts?	Expert knowledge isn't fully converted into visual standard work, and the condition, availability, location, and correct use of chains, design rollers, and rubber rollers aren't controlled visually enough.
WHY 4	Why does weak visual control of these components increase printing-defect risk?	If chains, design rollers, or rubber rollers are worn, misaligned, unavailable, misidentified, or overheated, operators may search, improvise, delay replacement, or set up with variable equipment conditions.
WHY 5	Why has this continued to recur despite existing procedures?	The system relies too heavily on operator experience and manual verification, instead of an integrated visual setup system that standardizes work, controls component status, and ensures consistent execution across all three shifts.

I IMPROVE

Printing-Roll Visual Inventory

Two-cabinet visual system: In-Use / Storage, color-coded by product with the use of Ackley tags



The proposed two-cabinet visual system separates in-use and storage rolls, using product color-coding and Ackley tags to make roll status, location, and availability visible at a glance.

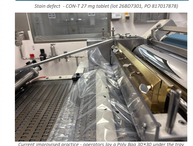
Benefit: no search time, fewer roll-wear printing defects, and inventory always visible and above minimums.

Ackley Setup Standard Work + Training

The Ackley printing changeover is highly manual and dependent on operator execution. Setup variability has been identified as a recurring contributor to printing defects, including off-center prints, missing prints, and embossing issues. Standard work and operator training have been implemented to align all shifts to a single documented method.

Ink Protector Guard

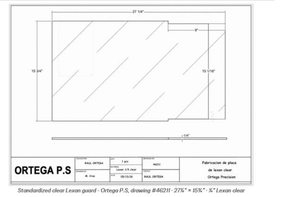
Stain defect - CON-T 27 mg tablet (lot 26B07301, RO B17037878)



Current improvised practice - operators lay a Poly Bag 30×30 under the tray

THE GAP

- Ink handling / change / removal carries a spill risk; spills on the carriers create stain-type defects on tablets.
- TV-WI-15716 (v29.0) does not standardize a preventive barrier before manipulating or removing ink / tray.
- The protective practice already exists informally — but is not controlled or standardized across shifts.



Standardized clear Lexan guard - Ortega P.S, drawing #46231 - 275." × 155." × .¼" Lexan clear

THE FIX - TV-WI-15716, TABLE #3

Place the Lexan guard under the tray before any ink handling. Add the instruction in two places:

Pg. 17 — Ink Quality (before removing used ink)

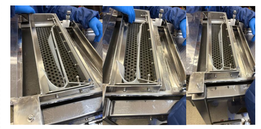
"Before removing the used ink, place the Lexan Guard/Protector under the ink tray to contain any spill and avoid interruptions to the process."

Pg. 18 — Printing Finalization (before removing tray)

"Before removing the ink tray for cleaning, place the Lexan Guard/Protector under the tray to prevent spills, reducing unplanned cleanings and interruptions during batch reconciliation."

Benefit:
Fewer unplanned cleanings & interruptions · fewer stain defects · standardization across shifts (material already on the floor).

Twin-Tablet Separator



THE PROBLEM

Twin tablets formed in coating arrive joined at the laser discharge. The sorter is meant to separate them, but it is not doing this reliably - joined pairs slip through and drive the twin-tablet / peeling defect (RC1).

THE PROTOTYPE

A custom insert that mounts on the Laser 1 & 2 sorters to force joined tablets apart before inspection. Prototype received at the plant; dimensional fit check on the sorter completed.

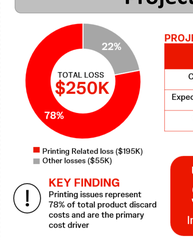
STATUS IN PROGRESS

Not yet challenged with real product — the current design did not fully convince on separation performance. Next: review with the equipment supplier (Ackley) to confirm whether the sorter itself needs a change, then run a product trial.

TRACKED IN THE MSAT FMECA

Benefit:
A reliable mechanical barrier against twin tablets reaching print / inspection - attacking the #1 root cause (RC1) at the laser sorter.

Projected Financial Benefit



PROJECTED SAVINGS SCENARIO

Scenario	Reduction in Printing Issues	Calculation based on $195K	Estimated Annual Savings
Conservative	15%	$195K x 15%	29K
Expected (Base Case)	25%	$195K x 25%	49K
Optimistic	40%	$195K x 40%	78K

KEY FINDING
Printing issues represent 78% of total product discard costs and are the primary cost driver

Up to **$78K** In annual savings

NON-FINANCIAL BENEFITS
- Reduced Investigations Workload related to Printing/Coating Issues
- Faster cycle time for deviation closure
- Increased process reliability and consistency
- Improved Operator confidence and standardization
- Enhanced Compliance Readiness

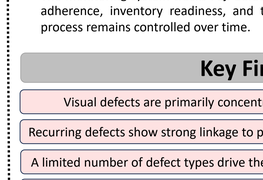
C CONTROL

Control Plan Matrix

Process Area	What to Control	Metric	Frequency	Owner	Reaction Plan
Fuji-Japan inspection	Overall visual defect rate by strength	18 / 27 / 36 mg defect rate %	Monthly / when data available	Quality / Process Owner	Review lot trend; open investigation if limit exceeded
NC recurrence	Concerta visual-defect NCs	# NCs per month / quarter	Monthly	QA / Manufacturing	Trigger NC review; update action tracker
Twin-tablet / peeling (RC1)	Twin-tablet separation at laser sorter (CM4 separator)	% joined pairs reaching inspection; RC1 NC count; separation-trial result	Per trial; monitored via NC	MSAT / Operations	Continue Ackley supplier review; escalate per FMECA MRG-014632
Printing rolls	Roll availability and condition	% rolls available / overdue replacement / missing-roll events	Weekly	Manufacturing / Area owner	Replace, escalate shortage, update inventory board
Ackley setup (RC2)	Standard setup execution	Setup adherence audit score	Per setup or weekly sample	Supervisor / SME	Coach operator, correct setup, update training if recurring
Printing protector	Lexan protector used during setup	% setup checks with protector used	Per setup	Operations	Stop / correct setup; document observation
Training	Operator capability & setup-competency refreshers	% trained / qualified; visual-exam pass rate (Summit)	Monthly + periodic refresher	Training / Supervisor	Re-train / re-examine; refresh Web Help guides

The Control Plan defines the key process controls, metrics, owners, frequency, and reaction plans required to sustain the proposed improvements and respond quickly to recurring visual-defect signals.

Monitoring KPI



Daily — Tier 1 shift Gemba board — operators log defects & flag anomalies in real time.

Weekly — Area tier review — defect trend vs. baseline + LPA / 5S audit findings.

Monthly — CI / Quality review — KPI vs. baseline, countermeasure adherence, FMECA (CM4) status.

ESCALATION / OCAP

If the defect rate breaches the control limit or a Pareto category spikes → contain affected lots, trigger root-cause analysis, and escalate to QA / MSAT.

The monitoring system tracks Fuji defect-rate trends, NC recurrence, setup adherence, inventory readiness, and training completion to ensure the process remains controlled over time.

Key Findings

- Visual defects are primarily concentrated in coating and printing stages.
- Recurring defects show strong linkage to process variability and handling conditions.
- A limited number of defect types drive the majority of quality issues (Pareto effect).
- Inconsistent inspection criteria contributes to variability in defect detection.
- Data gaps and lack of standardization hinder effective root cause identification.

Conclusion

Historical and recent data show that recurring visual defects in Concerta tablets are primarily driven by printing and coating-related issues. These defects create investigation workload, product loss, and Cost of Poor Quality. By focusing on the highest-priority process drivers and implementing targeted countermeasures, the project creates an opportunity to reduce defect recurrence, improve process reliability, and strengthen quality performance for Fuji-Japan inspection.

Acknowledgements

The team gratefully acknowledges Prof. Carlos Gonzalez for his guidance throughout the IE 4995 Capstone Design Course, and Johnson & Johnson Innovative Medicine Gurabo for sponsoring this project and providing access to data, process knowledge, and manufacturing expertise. Special thanks to our project sponsors, Luz Guzman and Jonathan Perez, as well as the OROS Manufacturing supervisors, Ackley setup SMEs, and operators who shared their frontline knowledge. We also thank Universidad Politécnica de Puerto Rico for its academic support.

Reducing visual defects is not just a quality fix. It protects the Japan market, lowers Cost of Poor Quality, and strengthens process reliability.