Innovation & Advancing GMP

"APPLYING AI/ML TO DEVIATION TREND ANALYSIS"

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THE CHALLENGE

Deviation Trending — A Manual, Labour Intensive Subjective Process

High Volume

A large volume of deviations with rich free-text descriptions — too many to manually review for hidden patterns.

Category Dependency

Traditional trending relies on pre-defined categories selected by authors — subtle cross-category themes are missed.

Reviewer Variability

Different reviewers may identify different trends from the same data, introducing subjectivity into the process.

WHAT IF WE COULD ANALYSE THE LANGUAGE IN DEVIATION DESCRIPTIONS (NOT THE CATEGORIES) TO IMPROVE EVALUATION WHERE SIMILAR EVENTS ARE CLUSTERING?

THE ORIGIN

Innovation from Within Quality

This project didn't start in IT or Data Science. It started with a Quality professional recognising that the language used in deviation records held untapped insight — and partnering with a Data Engineer to unlock it.

1. **Identify the Opportunity**

   A Quality Professional recognised that free-text descriptions contain richer trend signals than pre-defined categories alone employed in traditional trending.

2. **Cross-Functional Partnership**

   Quality expertise paired with Data Engineering skills to design an ML pipeline purpose-built for deviation data.

3. **Prototype & Validate**

   Built a working tool and validated outputs with area experts to confirm clusters reflected real-world trends.

4. **Expand the Use Case**

   Same engine repurposed for inspection preparation — one investment, multiple returns.

HOW IT WORKS

The ML Pipeline — Fully Automated, End to End

Deviation Records

Free-text: Titles and descriptions

→

Text Embedding

Turns text into a format the system can understand

→

k-Means Clustering

Groups semantically similar deviations

→

t-SNE Projection

2D visual map of cluster proximity

→

LLM Labelling

Gives descriptions and names to each cluster

→

Power BI Dashboard

Interactive results ready for end-user review

Unsupervised

No labelled training data needed

Language-Based

Clusters by meaning, not keywords

Adaptive

Reflects trend shifts automatically

Scheduled

Models refresh automatically

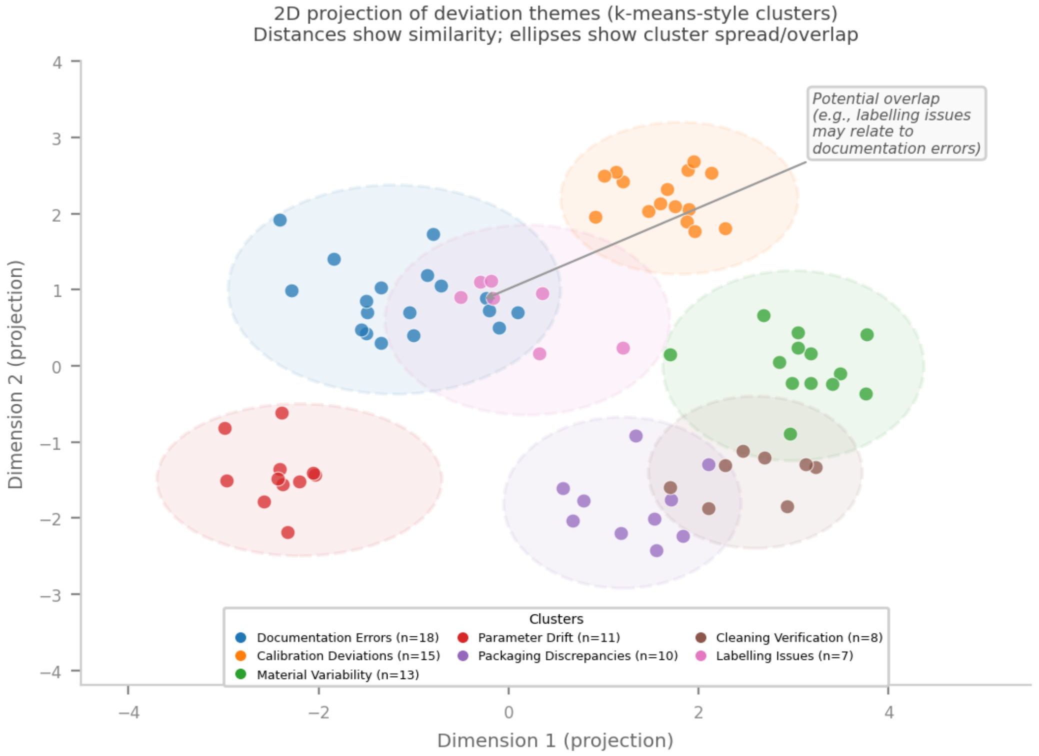
Cluster Map — Deviation Trend Detection

Each dot is a deviation positioned by semantic similarity. Clusters are ranked by density. Related clusters overlap — e.g., labelling issues and documentation errors share boundary points.

Illustrative demo only (not company data); themes use generic deviation categories common across the industry; dots/counts are synthetically generated placeholders (not from any internal/company systems or records).

Cluster Rankings, AI Labels & Descriptions

Rank	AI Label	AI Description	Size
1	**Documentation & Record Errors**	This cluster includes trends such as incomplete batch records, missing signatures, transcription errors, and logbook discrepancies across multiple production areas.	18
2	**Calibration Deviations**	This cluster includes trends such as out-of-tolerance instrument readings, missed calibration schedules, and drift detected during routine verification checks.	15
3	**Material Variability**	This cluster includes trends such as incoming raw material specification deviations, supplier lot inconsistencies, and excipient attribute variation affecting process performance.	13
4	**Process Parameter Drift**	This cluster includes trends such as gradual shifts in mixing speed, temperature, or pressure parameters outside validated ranges during extended campaigns.	11
5	**Packaging Discrepancies**	This cluster includes trends such as incorrect carton counts, seal integrity failures, and blister pack defects detected during in-process or final inspection.	10
6	**Cleaning Verification Gaps**	This cluster includes trends such as residue above acceptance criteria, swab sample failures, and hold-time exceedances between cleaning and next use.	8
7	**Labelling Issues**	This cluster includes trends such as mismatched lot numbers on labels, incorrect expiry dates, and label reconciliation discrepancies at the end of packaging runs.	7



Note: Cluster overlap (visible in the scatter plot) indicates semantically related deviation categories that may share root causes or contributing factors.

USER EXPERIENCE

Zero Technical Effort for End Users

Data Extraction → Text Embedding → Clustering → Labelling → Visualisation

Workflow 100% Automated

Models are pre-computed and refreshed on schedule. End users open a Power BI dashboard — no configuration, no ML knowledge required. The User role is to apply expertise and professional judgement to assess whether clusters represent meaningful trends requiring action

🏆 Top Clusters

Ranked clusters with AI labels and interactive visual representation

🏭 Clusters by Area

Same map colour-coded by operational area

📈 Formation Timeline

Cumulative view showing patterns vs. emerging clusters

🔍 Drill-Through

Click into any cluster to read deviation details for SME assessment

One Engine — Multiple Applications

Operational Excellence

Cluster deviations to detect systemic trends and prioritise improvement initiatives across operational areas.

- ✓ Deviation trending across all areas
- ✓ Human error analysis per team
- ✓ Configurable time periods (quarterly, rolling)

SAME ENGINE

Proactive Oversight

Review historical deviations for signals to support informed quality oversight and demonstrate proactive site awareness.

- ✓ Highlight recurring themes
- ✓ Inform areas of routine quality focus
- ✓ Demonstrate data-driven site awareness
- ✓ Strengthen clarity of CAPA effectiveness

Agnostic Functionality — applicable to any text-rich dataset

Complaints | **CAPAs** | **Change Controls**

IMPACT

Benefits to Operations

Speed

Automated pipeline can replace days of manual trending — models refresh on a scheduled basis

Depth

Analyses meaning of free-text descriptions — revealing cross-cutting themes that categories miss

Consistency

Every reviewer sees the same algorithmically-derived clusters, removing subjective variability

Inspection Confidence

Data-driven evidence of site awareness and proactive management that supports inspection readiness

Decision-Support, Not Decision-Making

The tool surfaces signals — the SME makes the final call. This maintains human oversight while dramatically increasing the speed of trend analysis.

Reflections on Innovating Within Quality

1. **Quality SMEs are Innovators**

   The most impactful innovation came from deep domain knowledge. Technology was the enabler — Quality expertise was the driver.

2. **Start with the Problem, Not the Tech**

   We didn't start with 'let's use AI.' We started with 'our trending process has limitations' — then found the right tools.

3. **Build Once, Apply Many Times**

   One pipeline serves OpEx trending, human error analysis, QC models, and inspection preparation.

4. **Keep the Human in the Loop**

   AI outputs are signals, not conclusions. This maintains stakeholder ownership of the data and conclusions.

INNOVATION DOESN'T ALWAYS COME FROM OUTSIDE.

SOMETIMES IT STARTS WITH A QUALITY PROFESSIONAL ASKING

"WHAT IF WE COULD DO THIS BETTER?"

Mary Coyne, Quality Advisor

& Cian Linehan, Data Engineer

Thank you

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A MEDICINE COMPANY