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The use of artificial intelligence in the veterinary pharmaceutical industry

Drawbacks and challenges in the current scenario

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THE USE OF ARTIFICIAL INTELLIGENCE IN THE VETERINARY PHARMACEUTICAL INDUSTRY

Artificial Intelligence (AI) has transformed various operations in the veterinary pharmaceutical industry – from research and manufacturing to distribution and pharmacovigilance.

Topics which will be covered in this presentation includes the application of AI in the following areas:

-Good Manufacturing Practice (GMP)
-Veterinary medical writing
-Distribution and supply planning
-Pharmacovigilance

Examples distinguish proposed applications, experiences and simulated data.

No company-specific datasets are disclosed. Predictive modelling, generative AI and conventional analytics serve different purposes.

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Good Manufacturing Practice (GMP)

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Predictive analytics in GMP operations.

Practical benefits, risks and implementation opportunities in veterinary GMP operations.



Dashboards describe observed results.

Predictive models estimate possible outcomes.

Focus: Stability • Environmental Monitoring • QC • QA • Manufacturing.

! Key principle: AI supports GMP decisions; it does not replace authorised personnel.

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Current analytics and additional modelling

Power BI already includes predictive and AI-assisted features

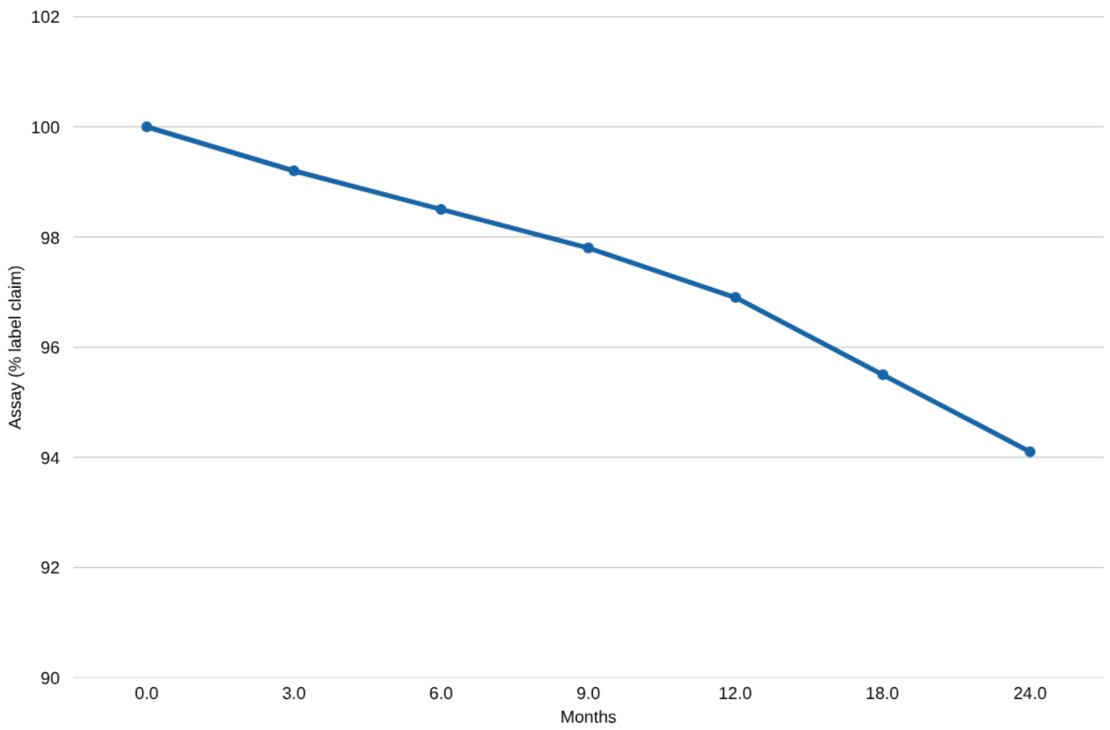
CURRENT DASHBOARDS/STATISTICS	ADDITIONAL PREDICTIVE MODELS
➢ Historical assay, impurity and CFU charts	➢ May identify multivariate patterns
➢ Averages, standard deviations and limits	➢ Estimates future outcomes with uncertainty
➢ Dashboards by batch, location and date	➢ Flags unusual combinations of results
➢ Rule-based alerts and conventional forecasting	➢ Support investigation and prioritisation

Important: Forecasting and anomaly detection can also be done with conventional statistics; not every predictive feature is AI.

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Example 1: Stability data trending

Illustrative product assay data — not actual results.



OBSERVED TREND

Shows observed decline and comparison with specification.

POTENTIAL AI BENEFIT

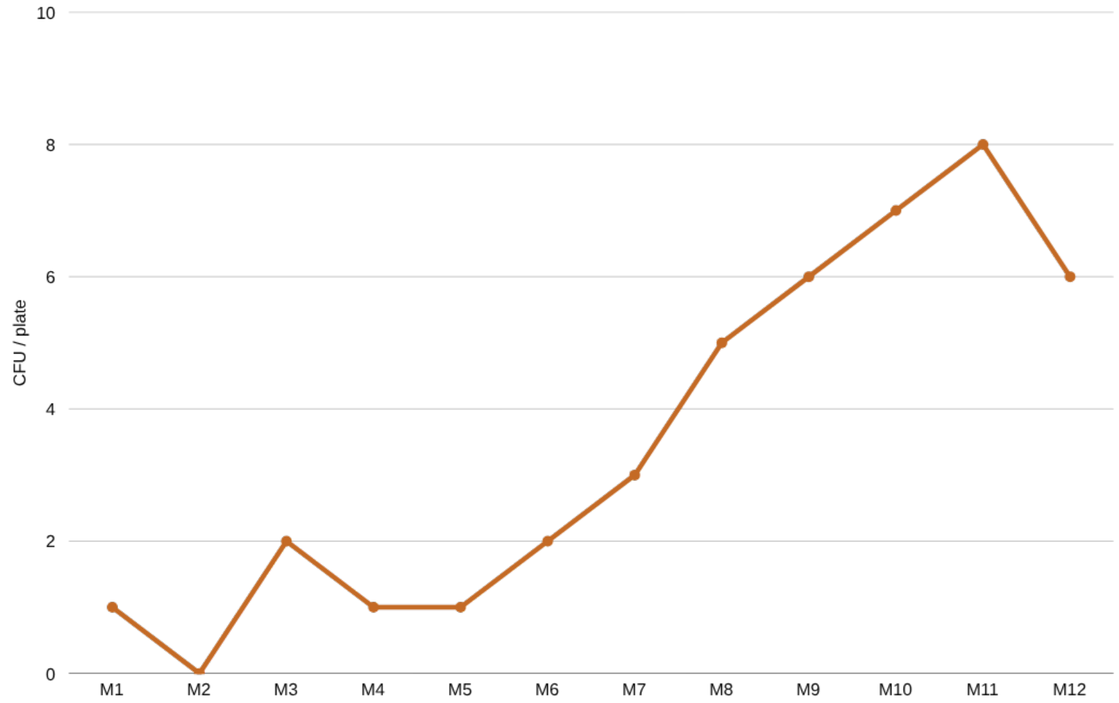
A tested model may estimate future decline with uncertainty and prompts review.

AI predictions cannot independently justify shelf-life extension or replace validated stability assessment.

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Example 2: Environmental monitoring

Illustrative Grade C location — investigate adverse trends before action limits are reached.



OBSERVED TREND

Shows historical results for review under the site's environmental monitoring procedure.

POTENTIAL AI BENEFIT

May flag patterns earlier and explore associations with room, shift or conditions.

An AI alert is a signal for microbiology review — not proof of contamination or a substitute for EM procedures.

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Benefits and negative impacts of AI

Balanced view for GMP-regulated pharmaceutical operations.

POTENTIAL BENEFITS	POTENTIAL RISKS
✓ Faster and increased capacity for review of large datasets	X Fabricated text from generative AI
✓ Earlier detection of unusual trends	X False alarms or missed real problems
✓ Better investigation support	X Biased or incomplete training data
✓ Reduced repetitive document work	X Confidentiality and cybersecurity risks
✓ Improved process understanding	X Weak auditability or model drift
✓ More consistent risk prioritization	X Over reliance and compliance gaps

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How to control the risks

Use AI as a controlled decision-support tool — never an autonomous GMP approver.

1	**Define intended use**	Document the exact task, inputs and acceptable outputs.
2	**Validate proportionately**	Test against representative historical data and known cases.
3	**Protect GMP data**	Apply access controls, audit trails and approved data handling.
4	**Keep human oversight**	QC, QA, Microbiology and QP retain final responsibility.
5	**Monitor performance**	Review errors, false alerts, drifts and change to the model.

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Illustrative implementation roadmap

Start with existing Power BI datasets and demonstrate measurable value.

01

Now

Review Power BI features

Confirm existing forecasts, alerts and data quality

02

0 – 3 months

Pilot stability and EM analytics

Compare statistical alerts with historical cases.

03

3 – 6 months

Test AI where it adds value

Assess prediction accuracy and false-positive rates.

04

6 – 12 months

Consider controlled GMP integration

Risk assessment validation, change control and oversight.

Recommended first pilots: stability degradation trending and EM adverse-trend detection.

Veterinary Medical Writing

AI-assisted magazine articles from published case reports

- Use AI to extract information, prepare an outline, draft text and improve language for the target readership.

- Use an organisation-approved environment and authorised, appropriately de-identified material. Use veterinarian-verified diagnostic interpretations.

Potential benefits

- Less drafting and formatting time.
- Assess total time, including preparation, checking, correction and approval.

AI-assisted magazine articles from published case reports

Drawbacks

- Unsupported content even with a well-designed prompt (Hallucinations).
- Neutral tone and lack of strong opinion.
- In practice the time required in uploading information to AI agent and review of the final AI generated document may take nearly the same amount of time as manual undertaking.

Notes

- Check AI training use, retention, access and confidentiality terms before uploading. A training opt-out alone is insufficient.
- The result can vary with using the same prompt, may depend on the profile of the person asking the questions, the AI model (paid and free versions).

A reusable prompt for a veterinary magazine article

- Using only the supplied, authorized case material, prepare an outline for a veterinary magazine article aimed at practicing veterinarians.
- Link each clinical statement to its source location. Preserve doses, units, dates and uncertainty. Do not invent findings, outcomes, quotations or references.
- List missing information as author queries. Wait for approval before drafting.
- After drafting: produce a claim-by-claim table showing each source and any unsupported statements.

Note

- The veterinarian should independently check the sources and the table. A prompt cannot guarantee accuracy.

Human review before publication

- AI can support extraction, outlining, drafting and language editing. Human authors remain responsible for the final article.
- The clinical author checks each claim, numerical value, unit, interpretation and reference against the original report.
- Authors verify attribution and permissions. The editor checks compliance with the outlet's requirements.
- Disclose AI assistance under the target outlet's policy. AI tools cannot take authorship responsibility.
- Resolve author queries and record human approval before release. Retain source material, prompts, drafts and approvals as an editorial record.

Distribution and supply planning

Topics for discussion

The use of AI in the following areas is discussed:

- Demand forecasting
- Procurement
- Design and document-review tools

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Demand forecasting and the integration of AI for streamlining

1. What is forecasting?

Deciding today how much to buy, for demand that has not happened yet.

Look at what sold → **Spot the pattern** → **Project it forward** → **Decide what to buy** → **Check what happened**

What makes a month unusual is usually not in the data

The season	An outbreak	A competitor	A tender	A supplier delay

We can see what is sold. We cannot see why.

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Demand forecasting and the integration of AI for streamlining

2. Manual process versus AI application

Items for comparison	Manual processing	AI-assisted workflow
Products covered	Top 20 to 30	~ 300 - 400
Time per cycle	Two to three days	Minutes reported*
Method	Person-dependent	Standarised workflow
Error measured	Not routinely measured	Measured monthly
Unusual months	Manual review	Configured alerts

*Reported figures are not independently validated; timings may exclude preparation and review.

Demand forecasting and the integration of AI for streamlining

3. AI training and testing process by the Data scientist

Everything the forecast knows comes from this step.

Step 1 - the monthly data feed

```
CONNECT   ERP  ->  monthly sales view
FETCH     customer orders, 66 months ...   462,219 lines
FETCH     stock on hand, month-end .....   491,197 rows
FILTER    keep real customer orders ....   231,034 lines
FILTER    remove internal transfers ....      -916 lines
FILTER    remove discontinued products .    -9,783 lines
FILTER    remove part-collected month ..    -3,823 lines
CHECK     missing values / negatives ...         0  OK
BUILD     one row per product, month ..    12,342 rows
READY     277 products x 65 months  ->  model
```

Step 2 - what the model reads

product	month	sold	last_mth	avg_3mth	category
PROD-0147	2026-01	1,259	522	628	Large animal
PROD-0147	2026-02	1,051	1,259	768	Large animal
PROD-0147	2026-03	1,326	1,051	944	Large animal
PROD-0147	2026-04	1,041	1,326	1,212	Large animal
PROD-0147	2026-05	722	1,041	1,139	Large animal

product codes replaced for this slide

Inputs: orders, sales, product age, availability, lead times and known demand drivers.

If not: we over-buy, sudden jumps stay unexplained, delivery time is guessed.

The model never questions what is given.

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Demand forecasting and the integration of AI for streamlining

4. One product : an unexpected demand spike

Product A, an injectable for large-animal practices.



about 700 a normal month	**7,072** January	**about 1,400** the AI expected

Worked

- Eleven months forecast well enough to order on
- Did the same for 276 other products

Did not

- January: ten times normal, not seen coming
- Then it over-ordered the month after

Eleven months on its own. The twelfth is why a buyer still signs off.

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Demand forecasting and the main challenges with the AI application

Full automation is extremely difficult in practice and still requires human oversight for final decisions.



Unexplained Sales Spikes

- Models struggle when demand suddenly surges.
- Root cause is not always explained by the data (e.g., an unexpected promotion or market panic).

Cannot rely on AI to generate purchase orders automatically, human review is essential to avoid overstocking or stockouts.



Limitations of AI Agents

- Mostly operate on predefined logic.
- Unable to adapt with rapid shifts in real-world market conditions and require manual adjustments.

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Demand forecasting and the main challenges with the AI application

Full automation is extremely difficult in practice and still requires human oversight for final decisions.



Overreacting to Small Fluctuations (Bullwhip Effect)

- AI models assume long-term demand growth with a slight increase in sales

Placement of excessive orders → Drives holding and inventory expiry costs



Unpredictable Lead Times

- AI models typically assume fixed shipping schedules.
- Customs delays and logistics disruptions cause fluctuating lead times → Stockouts

Procurement and the main challenges with the AI application

Purchasing (Material Requirement Planning)

AI-driven dashboards primarily rely on historical trends to forecast demand.

- May assess a product's performance over an entire year without considering its actual lifecycle.
  - *A product launched two months ago may be evaluated against 12 months of data, resulting in inaccurate sales trends and average monthly demand calculations.*

Human intervention is essential and ensure purchasing decisions reflect actual market requirements.

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Procurement and the main challenges with the AI application

Incorrect Judgements

AI may incorrectly classify products based on sales and stock availability.

Examples:

- Out-of-stock SKUs
  - *Products with no stock may be classified as having declining demand, despite continued market demand.*

- Quarantined SKUs:
  - *Products held in quarantine due to regulatory restrictions may be identified as slow-moving or declining in demand, even though sales are temporarily restricted rather than demand being absent.*

Procurement and the main challenges with the AI application

Idealistic Planning Assumptions

AI-based planning often relies on historical lead times and assumes a reasonable level of supplier and logistics reliability.

- Real-world supply chains are highly dynamic, with frequent supplier delays, logistical disruptions, and unexpected changes in delivery schedules.
    - Significant fluctuations in supplier lead times, resulting in stock shortages.
    - Unpredictable situations require proactive human intervention, supplier engagement, and continuous adjustments to purchasing plans, which AI may not adequately account for.

Design and document-review tools

Digital marketing

- Canva AI features can assist with ideas, draft copy and visuals.
- Human review is required to check accuracy, brand fit, rights and suitability.

Document review

- Tools such as GlobalVision, Verify and TVT support document comparison or proofreading. Capabilities depend on the product and configuration.

- Automated checks do not establish regulatory compliance. Qualified reviewers approve the final material. However, the high annual cost for license is a challenge for SMEs.

VETERINARY PHARMACOVIGILANCE

VETERINARY PHARMACOVIGILANCE

- Limited application of AI in veterinary pharmacovigilance.
  - Use of AI tools for translation of the reported cases from foreign language to English.
  - Internal tools for uploading guidelines and VeDDRA listing.
    - Supports selecting best matching VeDDRA terms and decisions based on published guidelines.
  - Microsoft co-pilot AI assistant for:
    - signal assessment
    - Generation of reporting incidences based on sales data per batch.

REASONS FOR THE LIMITED APPLICATIONS

- Absence of published guidance from the EMA.
- Lack of availability of information ensuring regulatory compliance
- Limited knowledge for the validation of AI tools for pharmacovigilance activities
- Costs associated with the AI tools
- Compatibility issues of the AI tools with data warehouse
- Calculation or estimation of potential errors

- Work-load has increased significantly following the implementation of Regulation (EU) 2019/6.
- Availability of published guidelines, validated AI tools with reasonable cost will support SMEs with limited resources to maintain compliance.

Sincere appreciation and heartfelt thanks to all colleagues who have shared their knowledge and experience!

(names are not disclosed due to confidentiality).