SPOOKFISH
INNOVATIONS

Machine Learning

.. AND ITS IMPACT TO THE PHARMA INDUSTRY

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Outline

01 Neurons and Neural Networks — Connect Dots

02 Machine Learning in Pharma — A Step Deeper

03 Intelligence Now — What Next?

Audience Poll 1

CHOOSE THE STATEMENT THAT YOU FEEL MOST CLOSELY DEFINES MACHINE LEARNING TODAY

1. Teaching a computer to think like a human
2. A computer learning “from experience”
3. Ability of a computer to adapt/solve without human intervention
4. Algorithms written by humans to train a computer
5. A computer’s intelligent “conscience”

Audience Poll 1: Answer

1. ~~Teaching a computer to think like a human~~
2. ~~A computer learning “from experience”~~
3. Ability of a computer to adapt/solve without human intervention
4. ~~Algorithms written by humans to train a computer~~
5. ~~A computer’s intelligent “conscience”~~

Audience Poll 1: Comments

HUMAN SCOPE

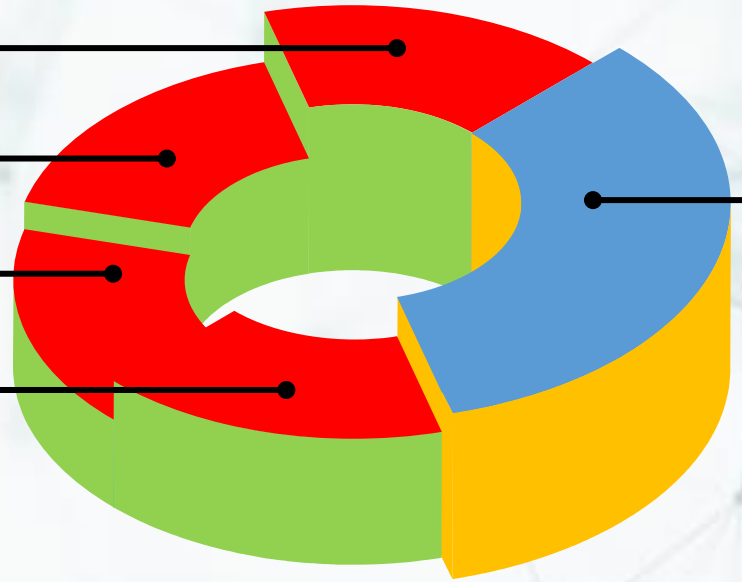
MACHINE SCOPE

DEFINE THE PROBLEM

PROVIDE RELEVANT DATA

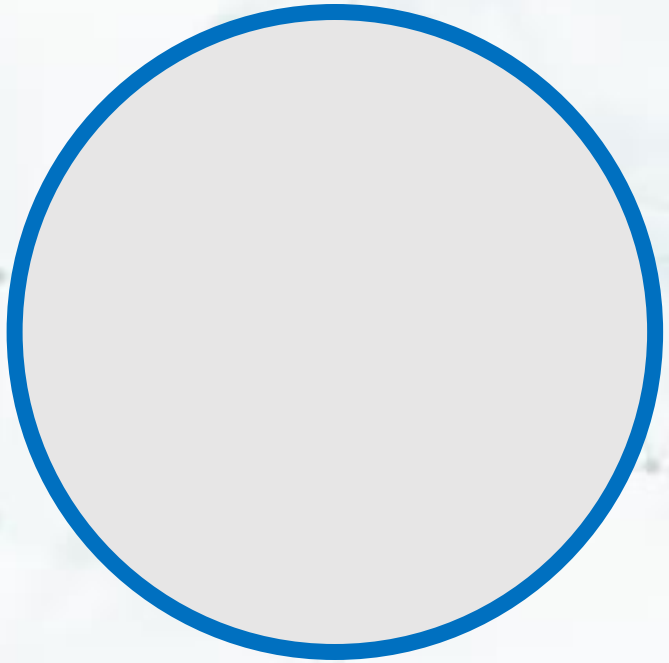
PROVIDE HINTS (DATA LABELS)

DESIGN THE MACHINE



LEARN AND INFER

The Neuron



The “atom” of any neural network.

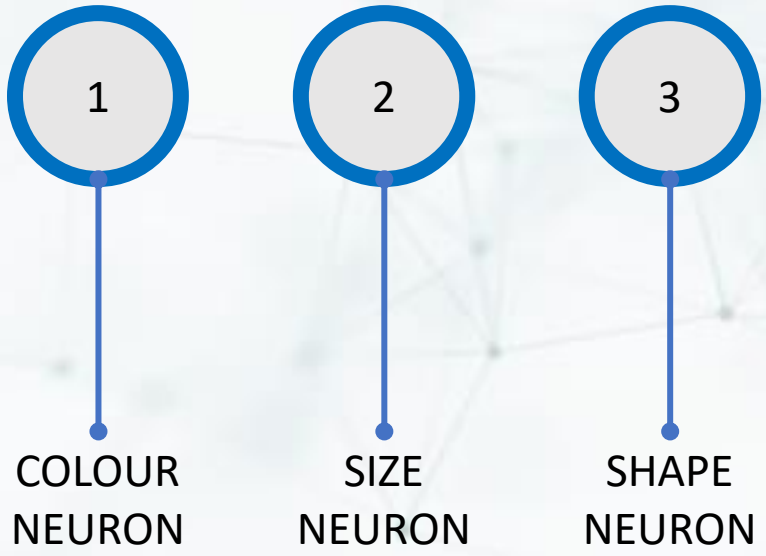
Learns a very simple “pattern”.

Responds with a binary answer – “yes” or “no”.

A neuron may be taught to go ON when it **sees a pattern it has learned**.

When it sees any other pattern, it stays OFF.

Neurons for Tablet Inspection



Consider 3 neurons

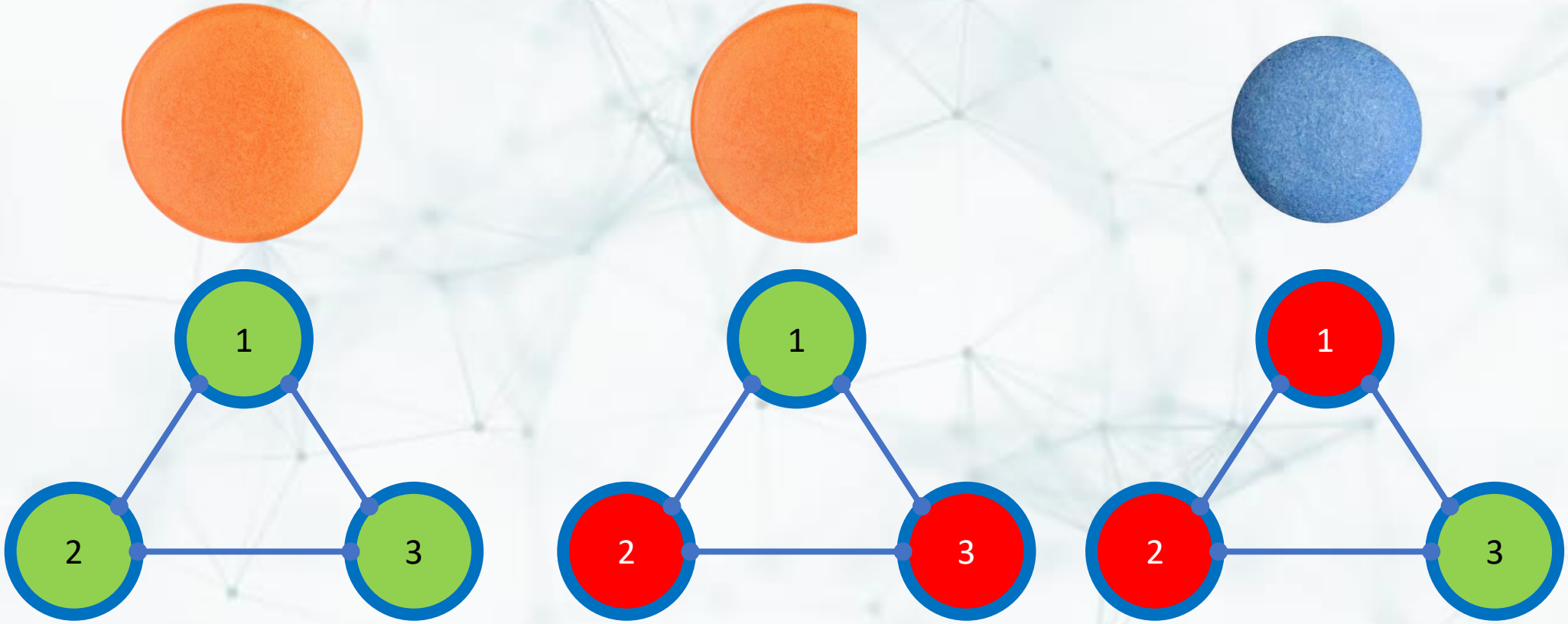
- Neuron 1: **The colour ORANGE**
- Neuron 2: **The diameter 10 mm**
- Neuron 3: **The shape ROUND**

Each neuron has been trained to perform a simple task.

Neuron stays ON for defined criteria.

Neuron stays OFF for other criteria.

A Simple Neural Network

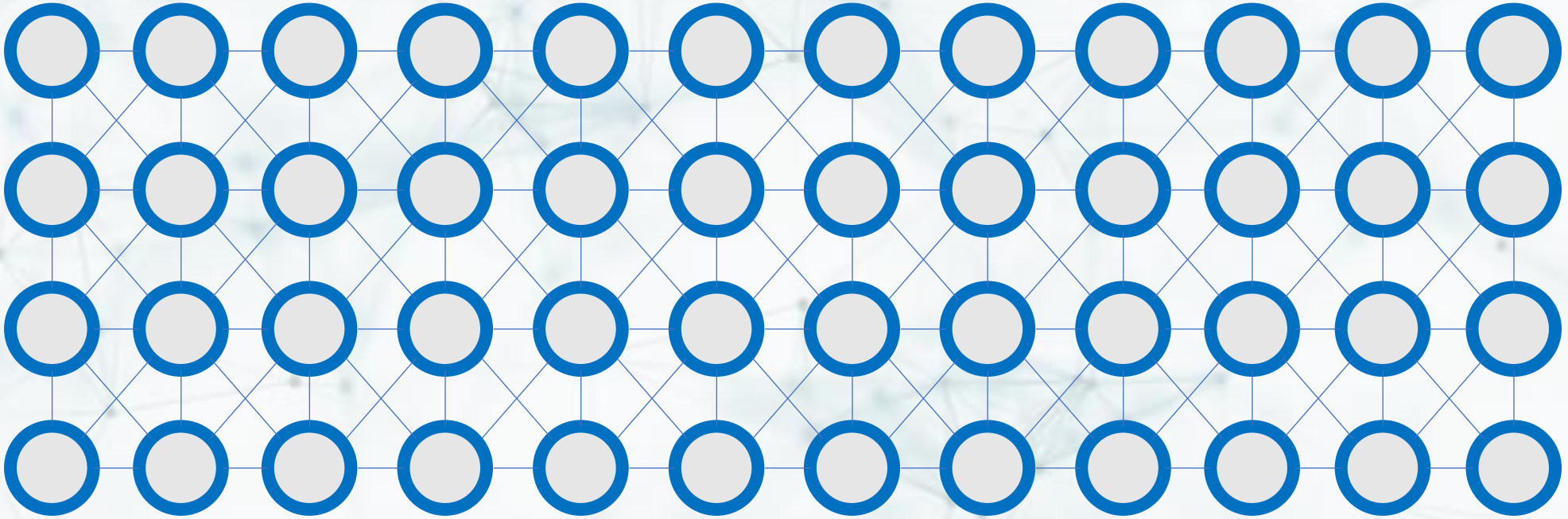


COLOUR	ON
SIZE	ON
SHAPE	ON

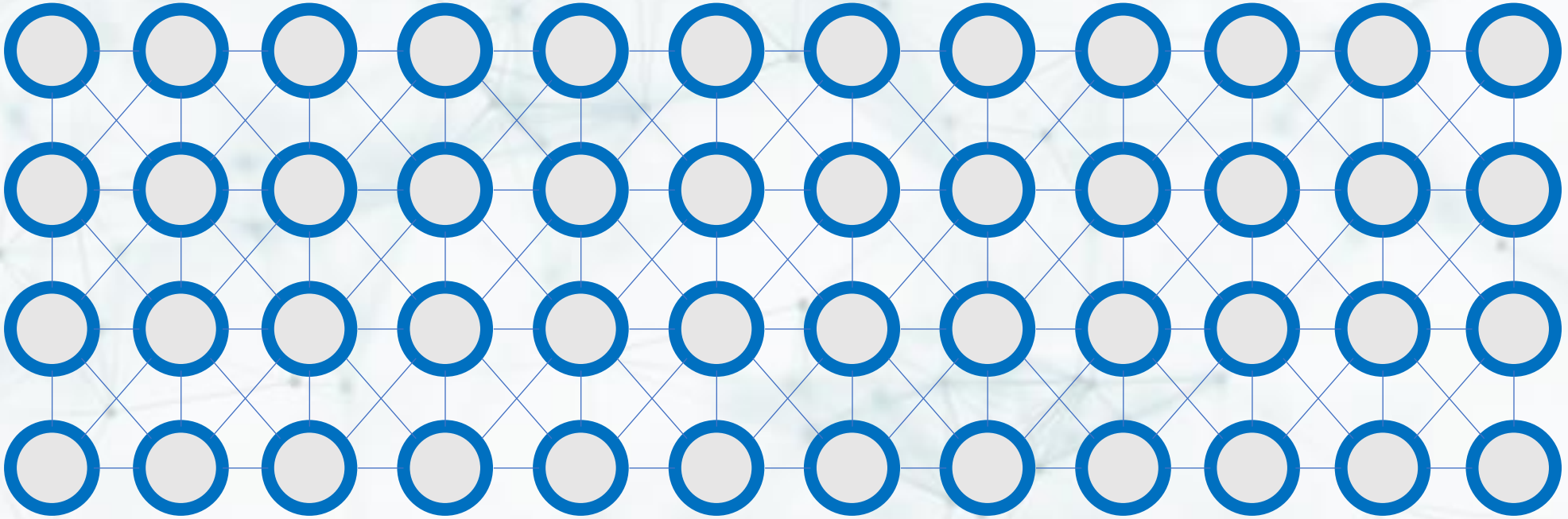
COLOUR	ON
SIZE	OFF
SHAPE	OFF

COLOUR	OFF
SIZE	OFF
SHAPE	ON

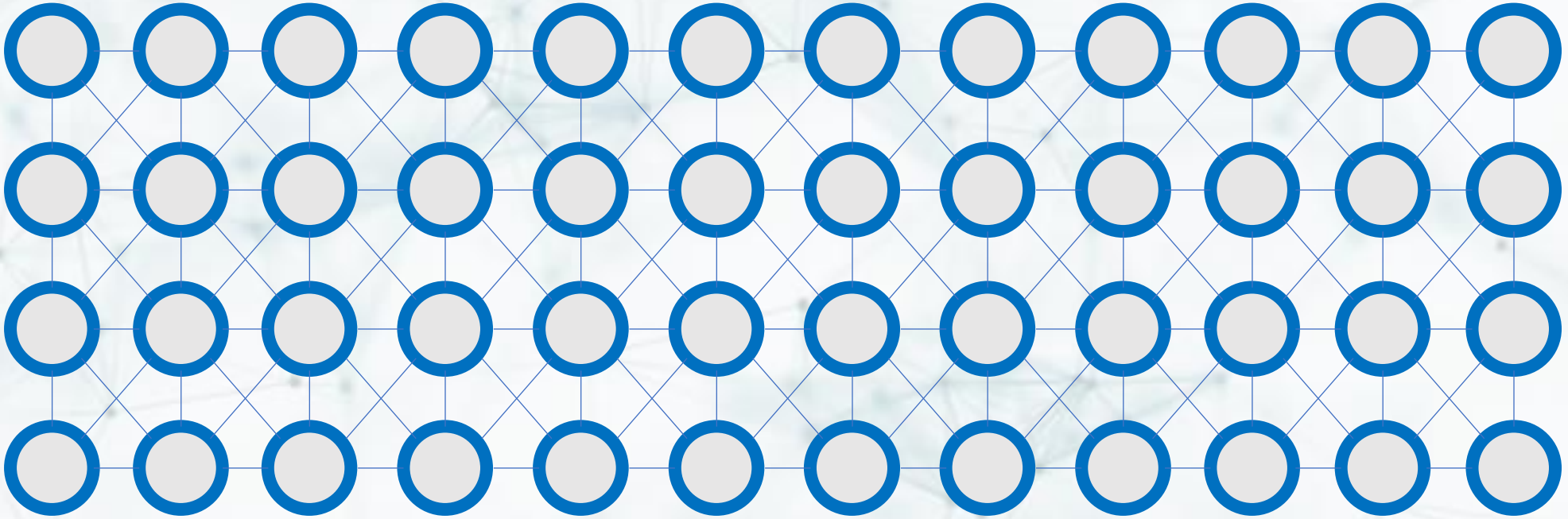
Example: Semantic understanding



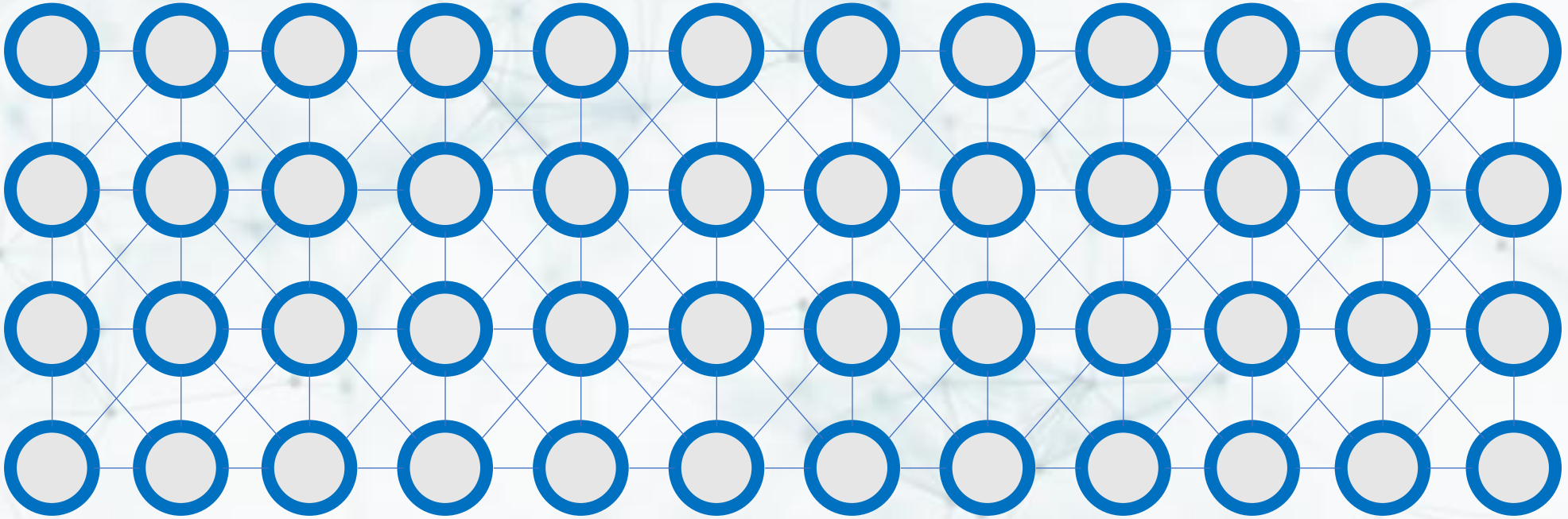
Example: Semantic understanding



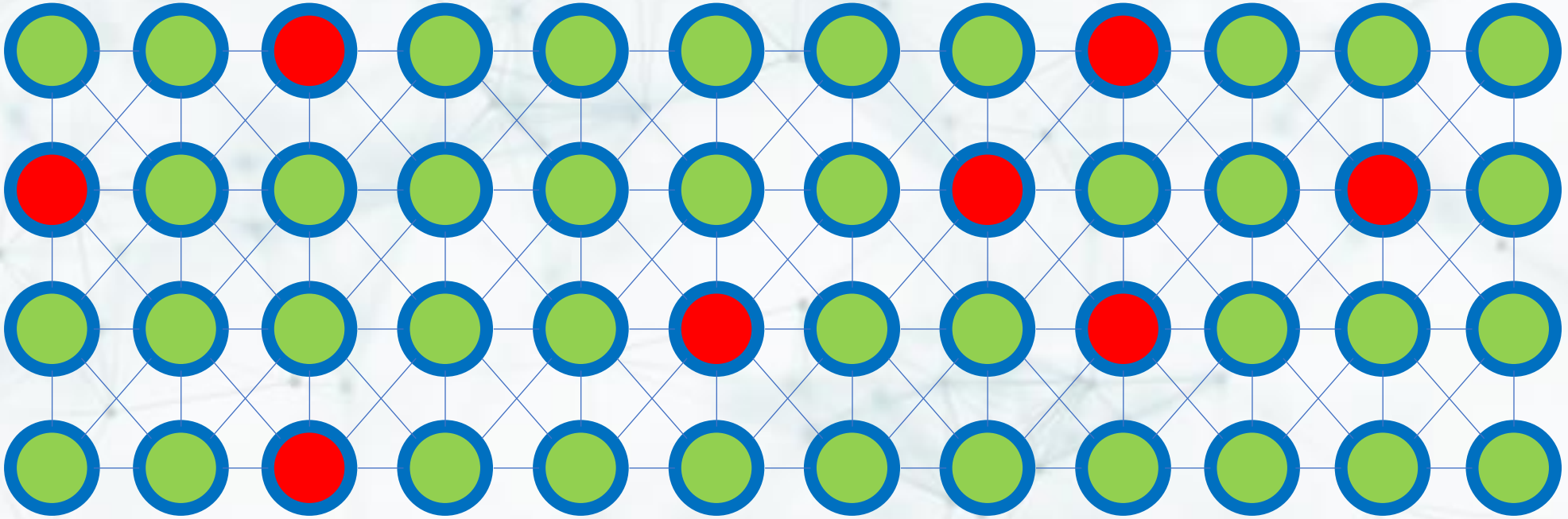
Example: Semantic understanding



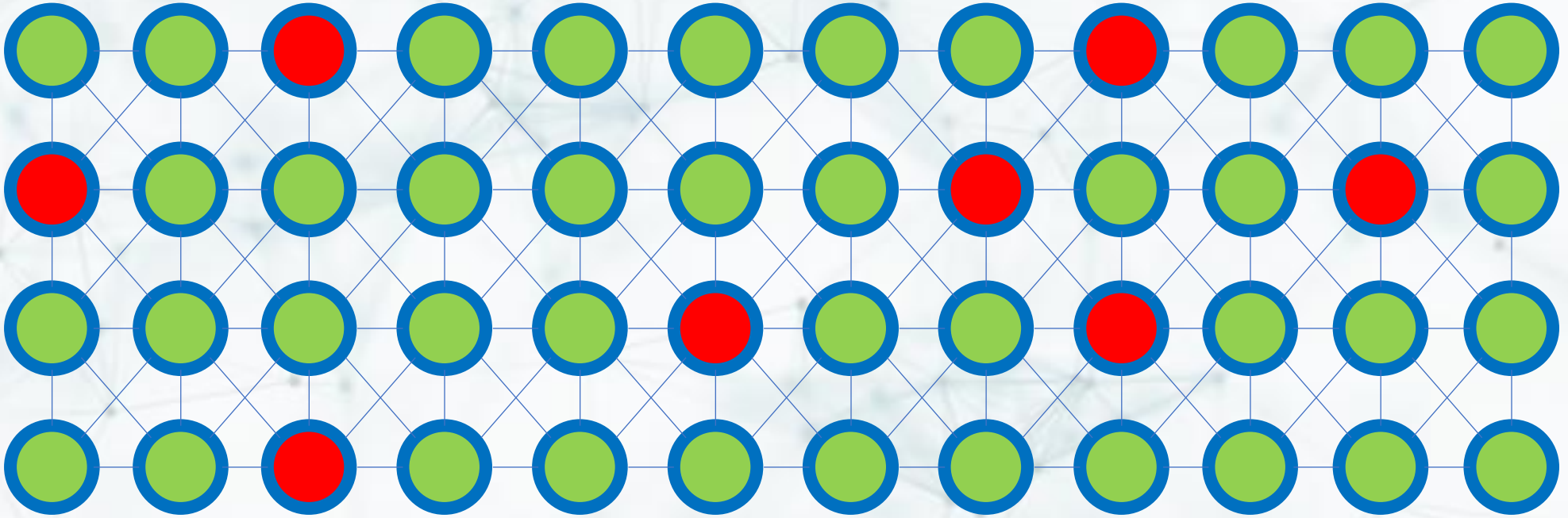
Example: Semantic understanding



Example: Semantic understanding



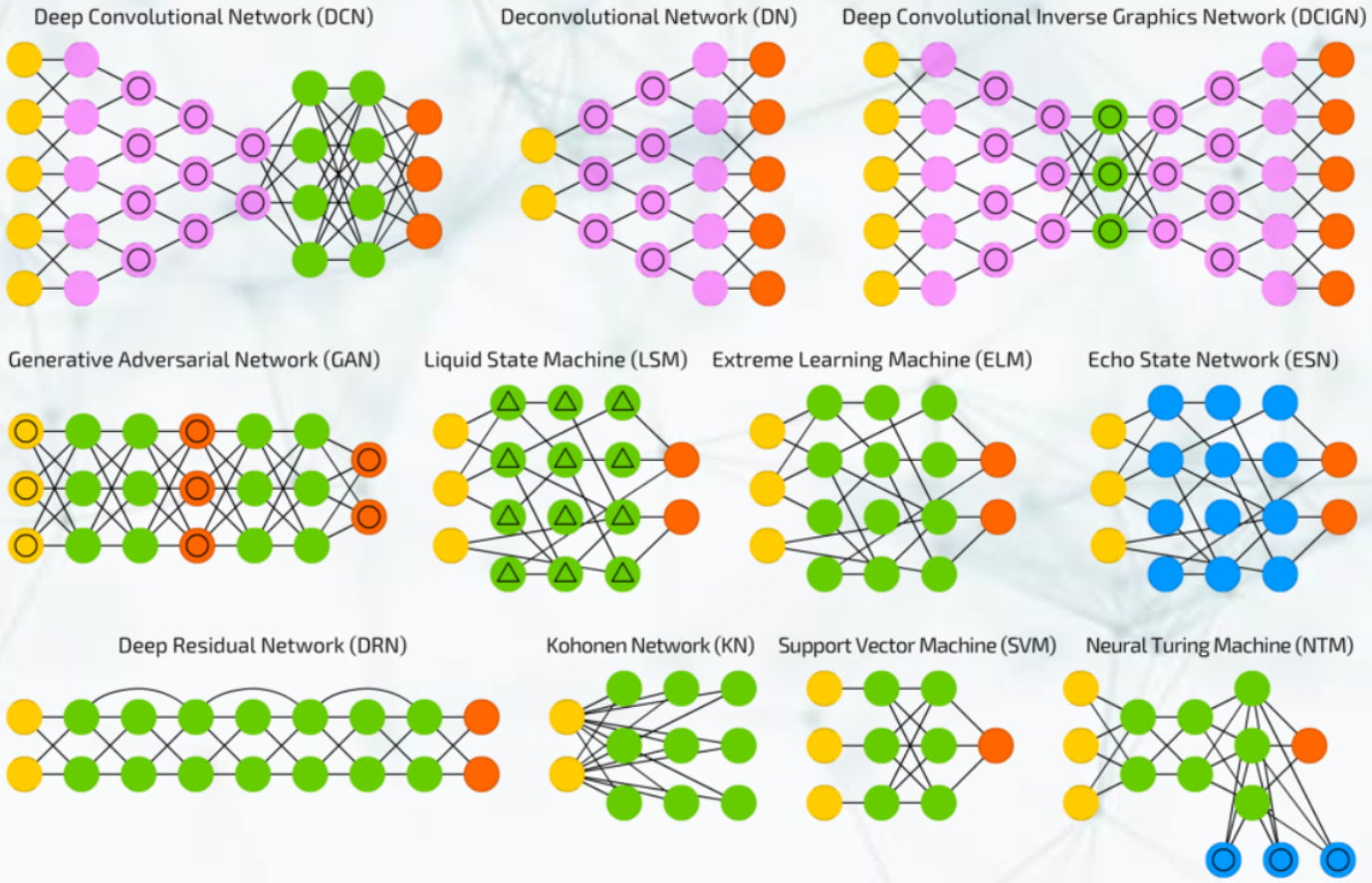
Example: Semantic understanding



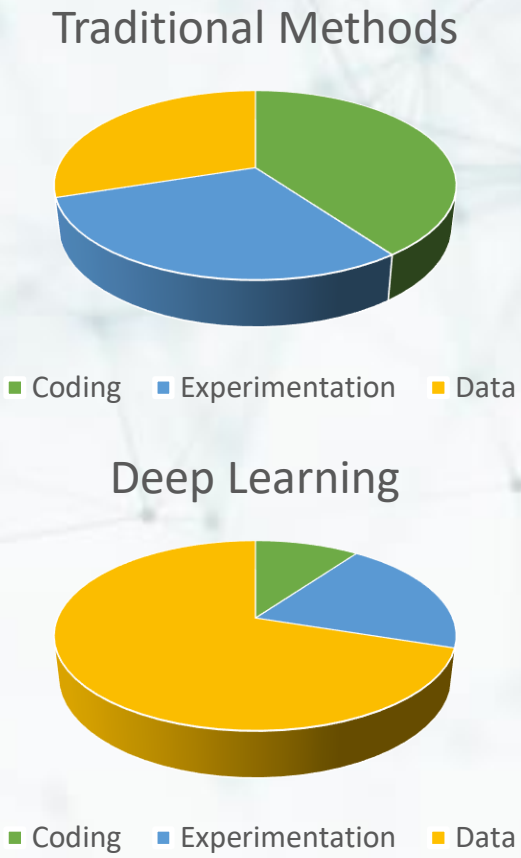
INFERENCE:

SUBJECT, POSSIBLY FEMALE, STANDING IN FRONT OF STAINLESS STEEL DOORS, STANDING ON TOP OF METAL PANELS WITH VENTS, WITH A GOWN POSSIBLY FOR ENTERING A PRIMARY PACKAGING AREA. GOWNING CONSISTS OF OVERALLS, SHOE COVERS WITH STRAPS, CAP, GOGGLES, MASK, GLOVES.

More Examples



Trend towards Deep Learning



Traditional learning methods depend on humans to define the neurons.

Deep Learning automatically defines appropriate neurons based on data.

Shift in focus, from designing the machine to **providing better data** to the machine.

Audience Poll 2

ON A SCALE OF 1 TO 4 PLEASE RATE THE IMPORTANCE OF MACHINE LEARNING IN GMP, FOR THE PHARMA INDUSTRY.

4 = ESSENTIAL

3 = IMPORTANT, BUT NOT ESSENTIAL

2 = MAY BE APPLICABLE

1 = NOT APPLICABLE AT ALL

You Don’t Always Get What You Want!

Intelligent Machines & GMP

Machines don’t always get it right. They are highly dependent on the data fed to train them.

UNDERSTAND the trade-off between false rejection rates and true rejection rates.

ASSESS the risk together with the machine supplier.

ASK about the machine learning procedures used. Has enough data been fed? Has it been carefully segregated?

ALLOW for updates to the learned models regularly.

Intelligent Machines & GMP

- FDA has cited a study named “Proposed Regulatory Framework for Modification to Model – Based as a Medical Device” in its recent effort to regulate AI and ML software.
- The policy allows in-process, adaptive learning to take place, wherein the models are continuously improved.
- An “Algorithm Change Protocol” (ACP) has also been proposed in order to allow for regular updates.
- This is very relevant to the pharma industry.

Tablet Inspection

Step 01

PRODUCT DETECTION

Step 02

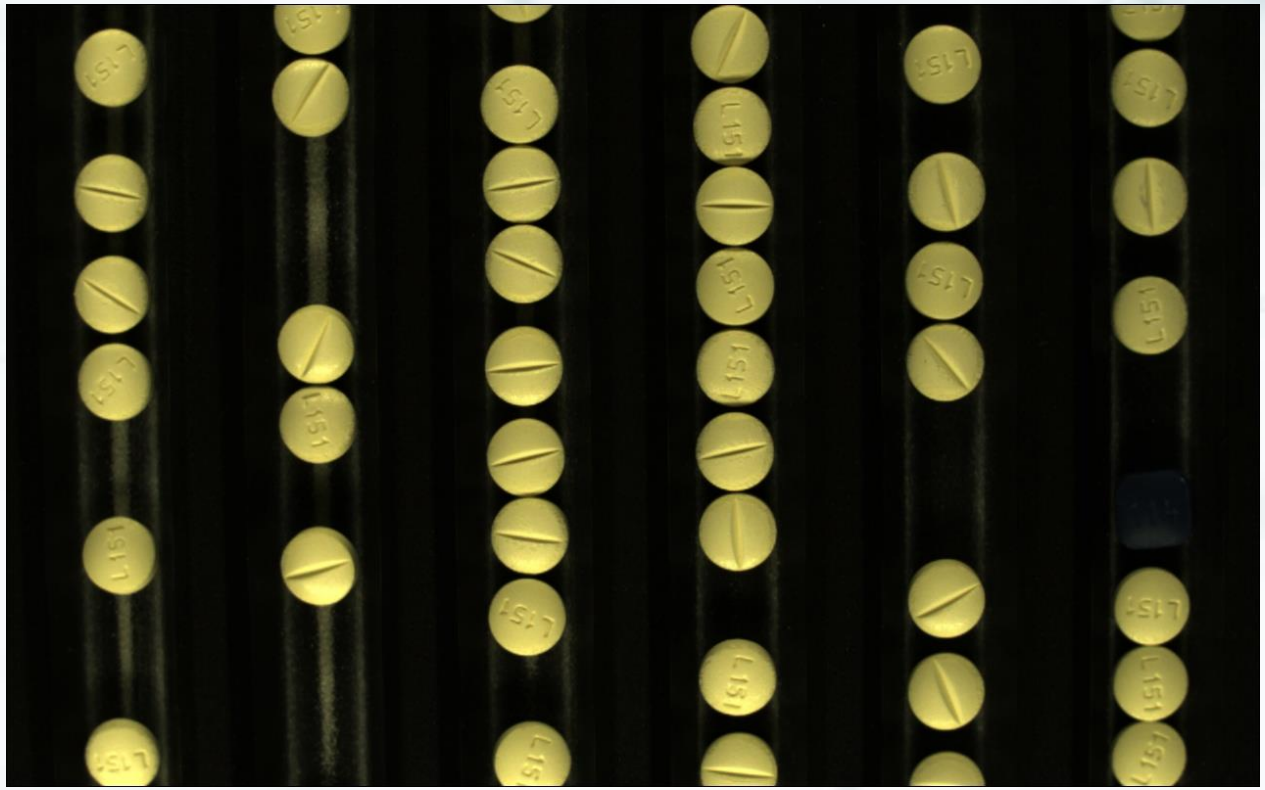
ONLINE PRODUCT LEARNING

Step 03

ONLINE INFERENCE

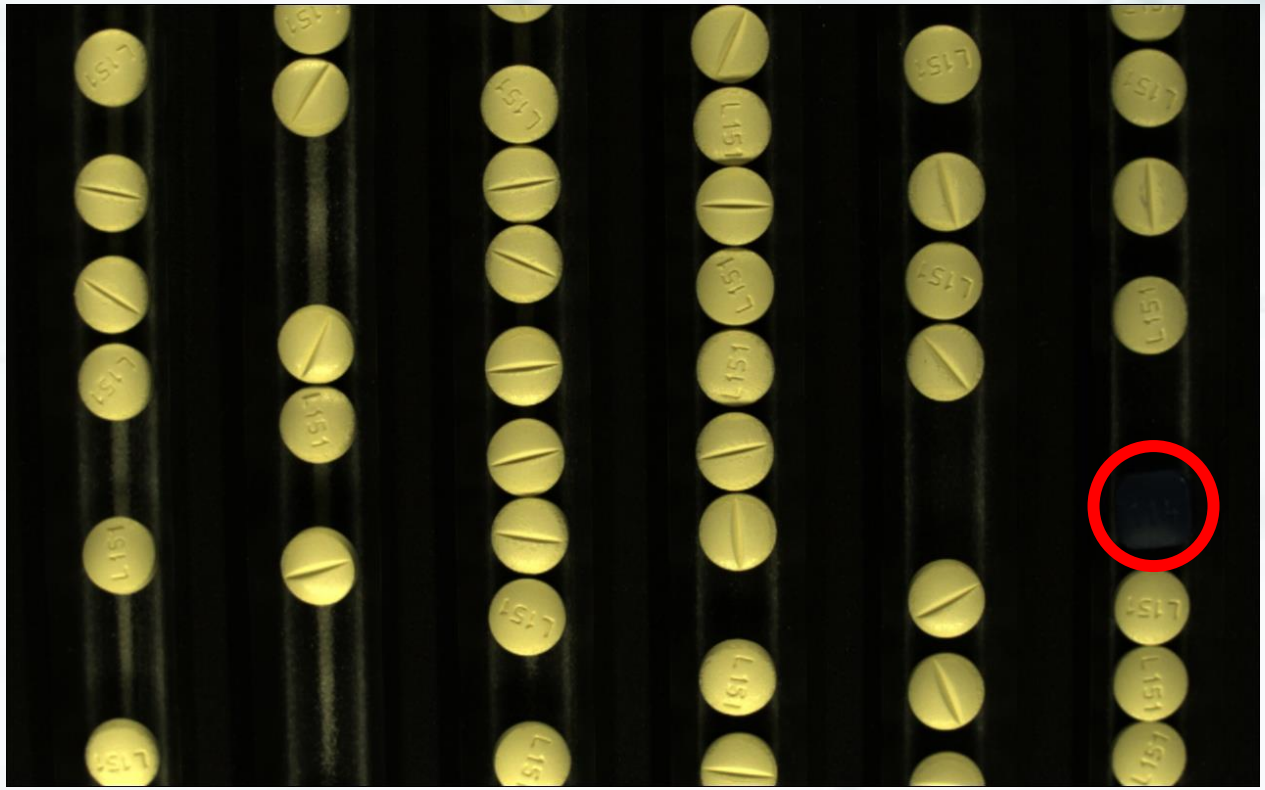
Tablet Inspection: Product Detection

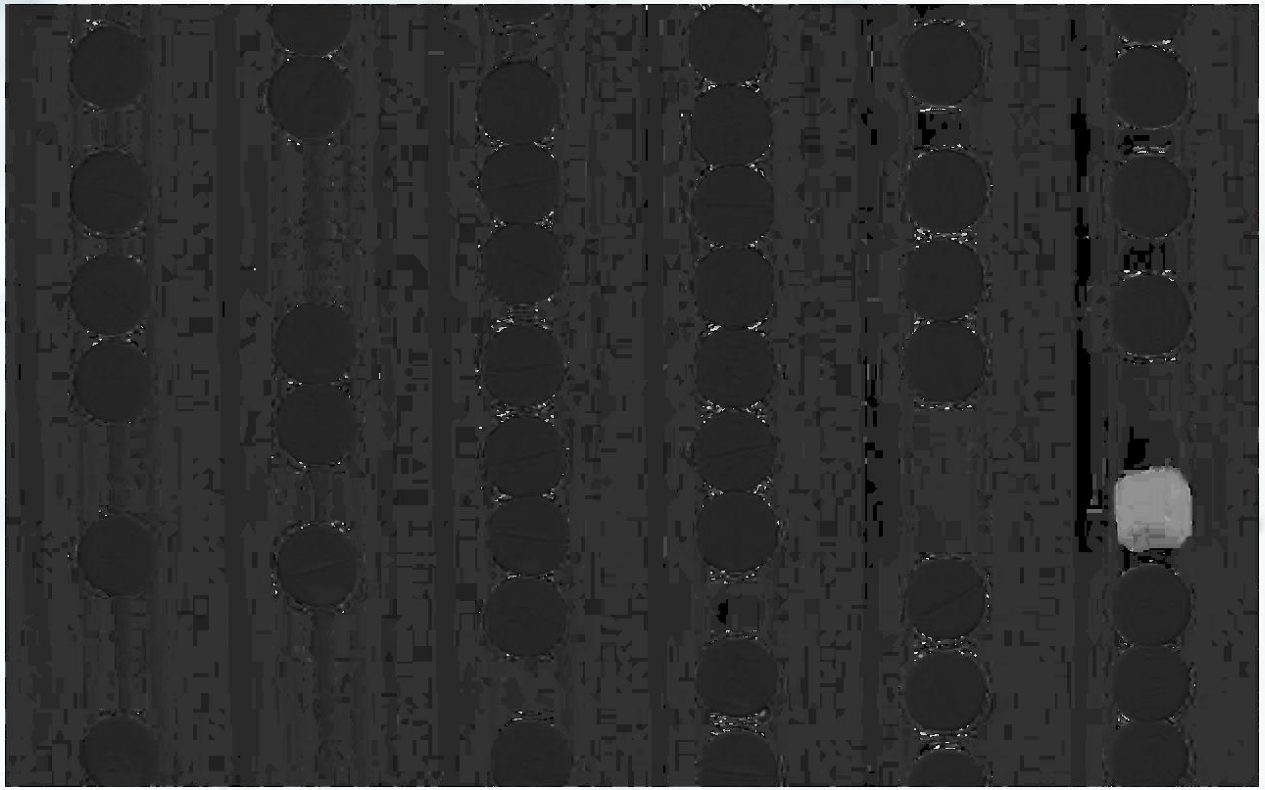
DETECT THE DEFECTIVE TABLET IN THE IMAGE!



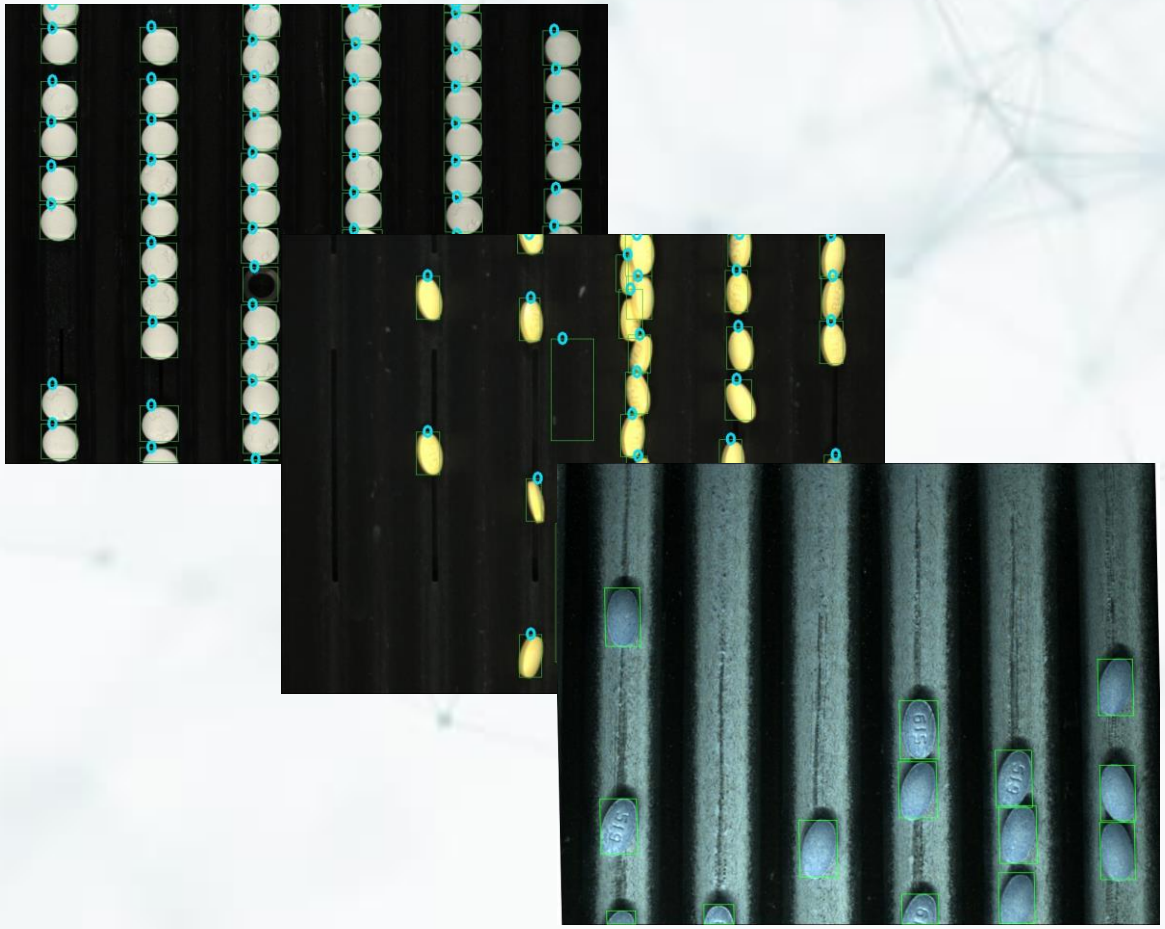
Tablet Inspection: Product Detection

DETECT THE DEFECTIVE TABLET IN THE IMAGE! DARK BLUE ROGUE!



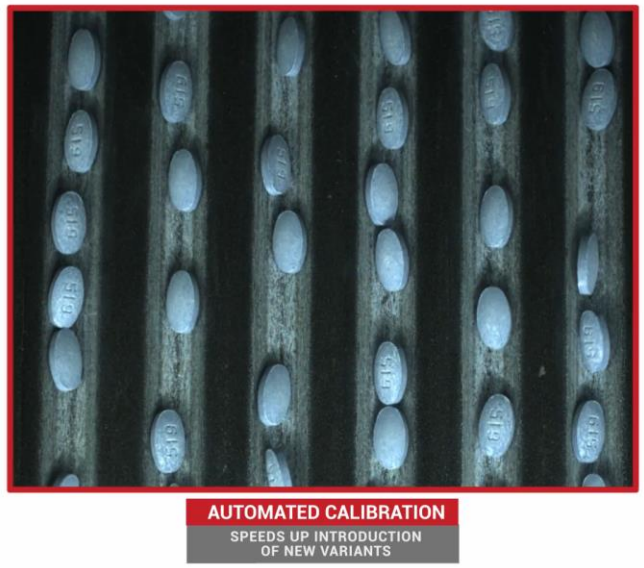


Tablet Inspection: Product Detection



- Over 2 million hand-annotated images used for training a DETECTION model using machine learning OFFLINE.
- Each tablet is carefully outlined and fed into the model.
- Deep Learning used – highest importance to data quality.
- Post-processing steps used to refine detections.

Tablet Inspection: Product Learning



- AIM: Automatically learn the specifications of a product ONLINE just before a batch is run for inspection.
- PROCEDURE: Run 500 products under the camera, and the machine learns specifications without manual labelling.

Tablet Inspection: Online Inference

- After a combination of OFFLINE learning for detection and ONLINE learning for product specifications, the machine is now ready for ONLINE inspection.
- *YOUR MACHINE IS NOW INTELLIGENT! PAPPU PASS HO GAYA!!*

Other Examples

ptc

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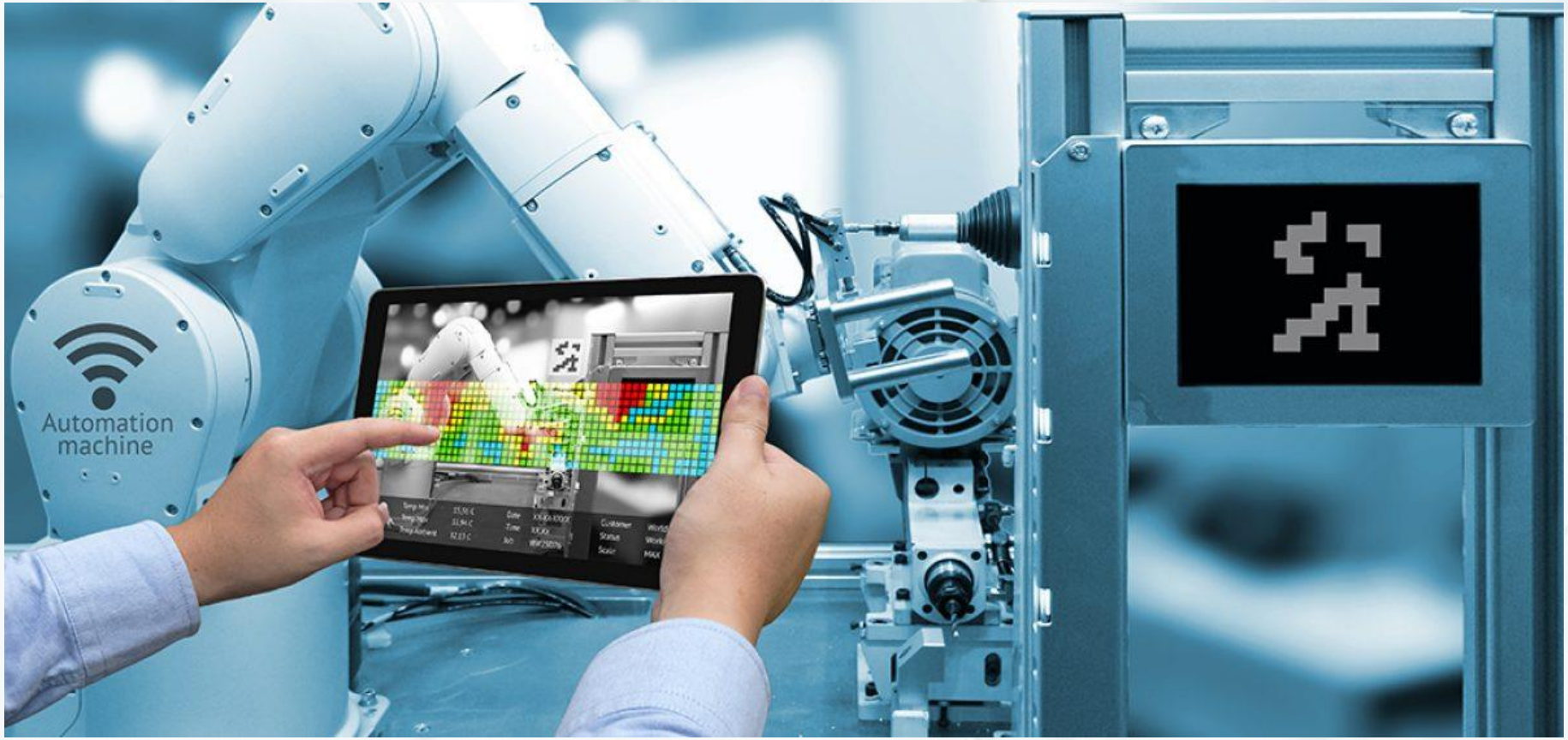
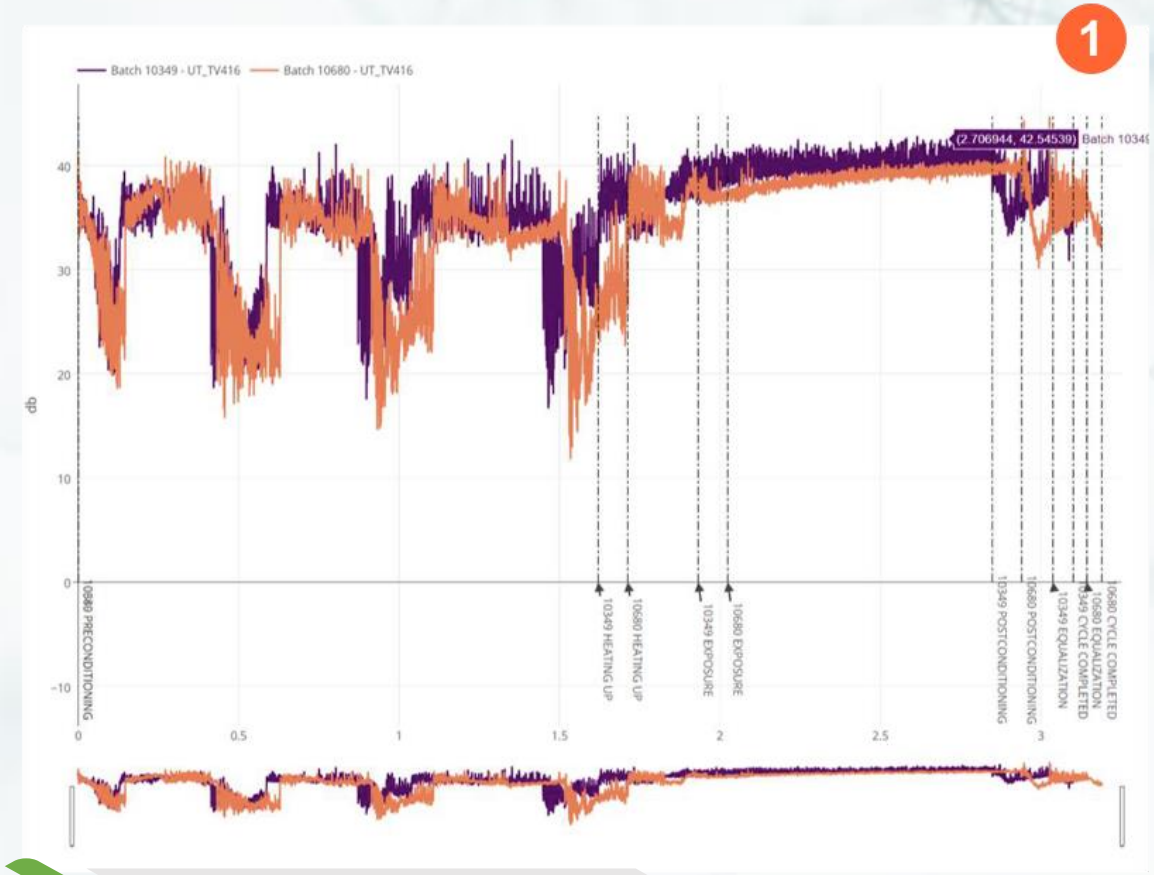
INTERACTIVE TRAINING WHERE THE MACHINE VERIFIES THE SOP

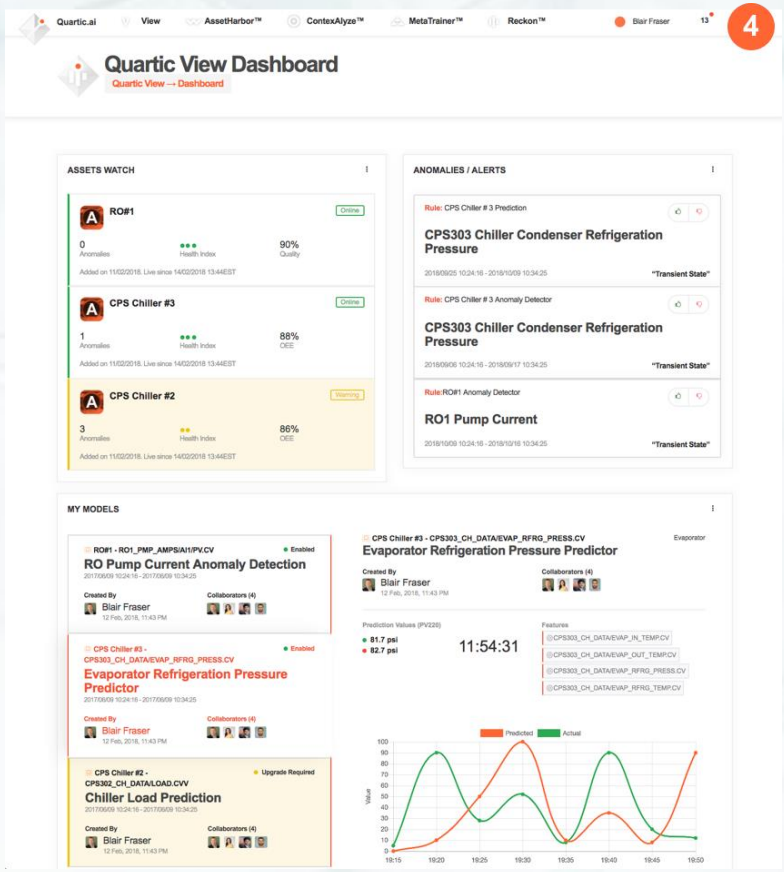


Other Examples

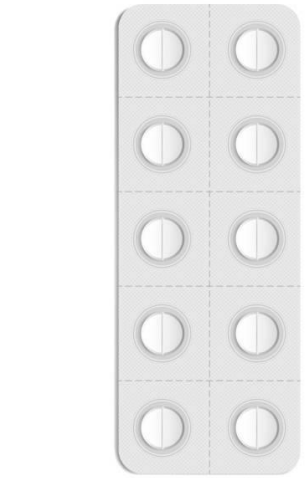
Quartic.ai

DATA-DRIVEN AUTOMATIC DEVIATION PREDICTION & RISK ASSESSMENT



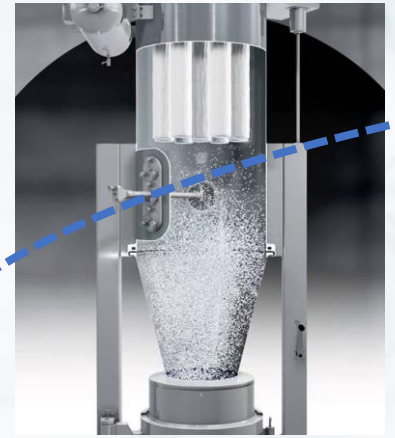


Lots of Data, Little Use

EXCIPIENTS	BLENDING	GRANULATION	COMPRESSION	PACKAGING
				
DATA	DATA	DATA	DATA	DATA

Close The Loop!

EXCIPIENTS

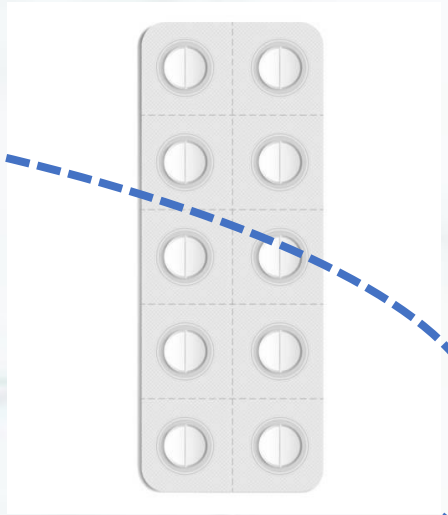


BLENDING

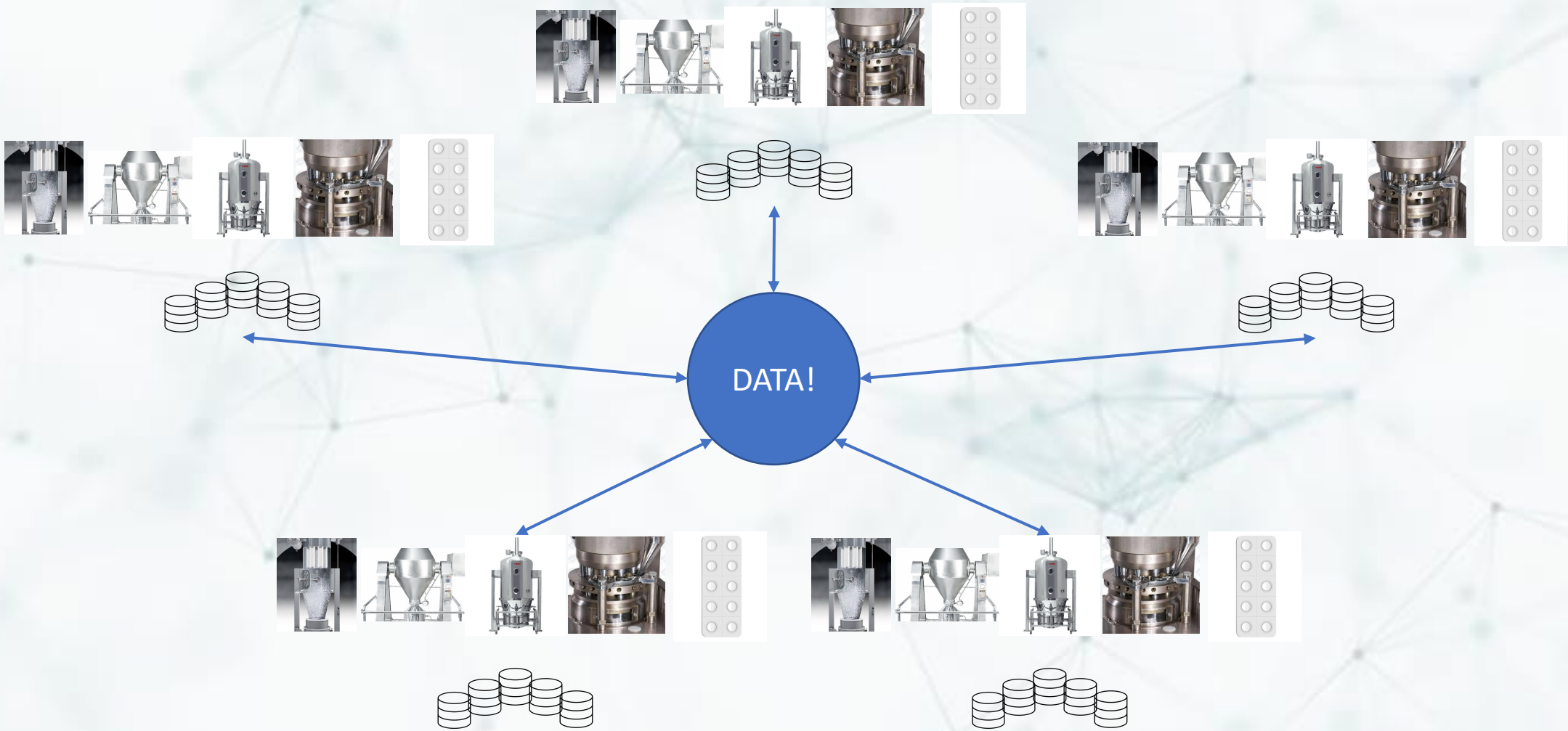
GRANULATION

COMPRESSION

PACKAGING



Share, Learn, Distribute, Repeat!



Data Integrity & Privacy

Once a machine is trained with data from any of several sources, the learned “model” abstracts the incoming data.

The data itself **cannot be reverse-engineered** or reproduced from the learned model.

Sharing data across facilities to improve learned models is a no-brainer.

Audience Poll 3 (in conclusion)

Are we ready for suppliers to share abstracted data across companies for better learning in the interest of consumer health/safety?

1. YES
2. NO
3. I NEED TO THINK ABOUT IT
4. LET THE REGULATORS DECIDE!

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