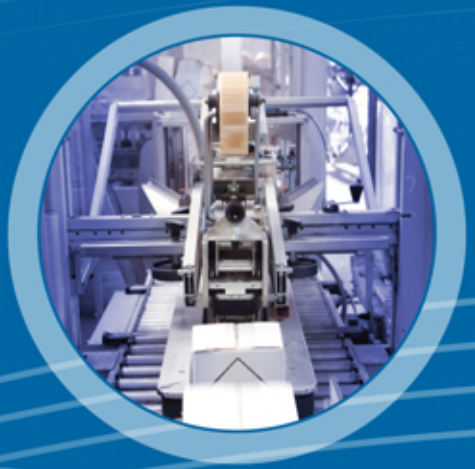
Connecting People, Science and Regulation®

# A Case for Quality Intelligence in Automated Inspection:

## Moving Beyond the Confines of Pass/Fail



# Introduction

This is **not** a conventional talk on:

- New vision algorithms
- Cameras
- Stats-based processes
- Regulatory mandates
- Human visual inspection paradigms

# Introduction

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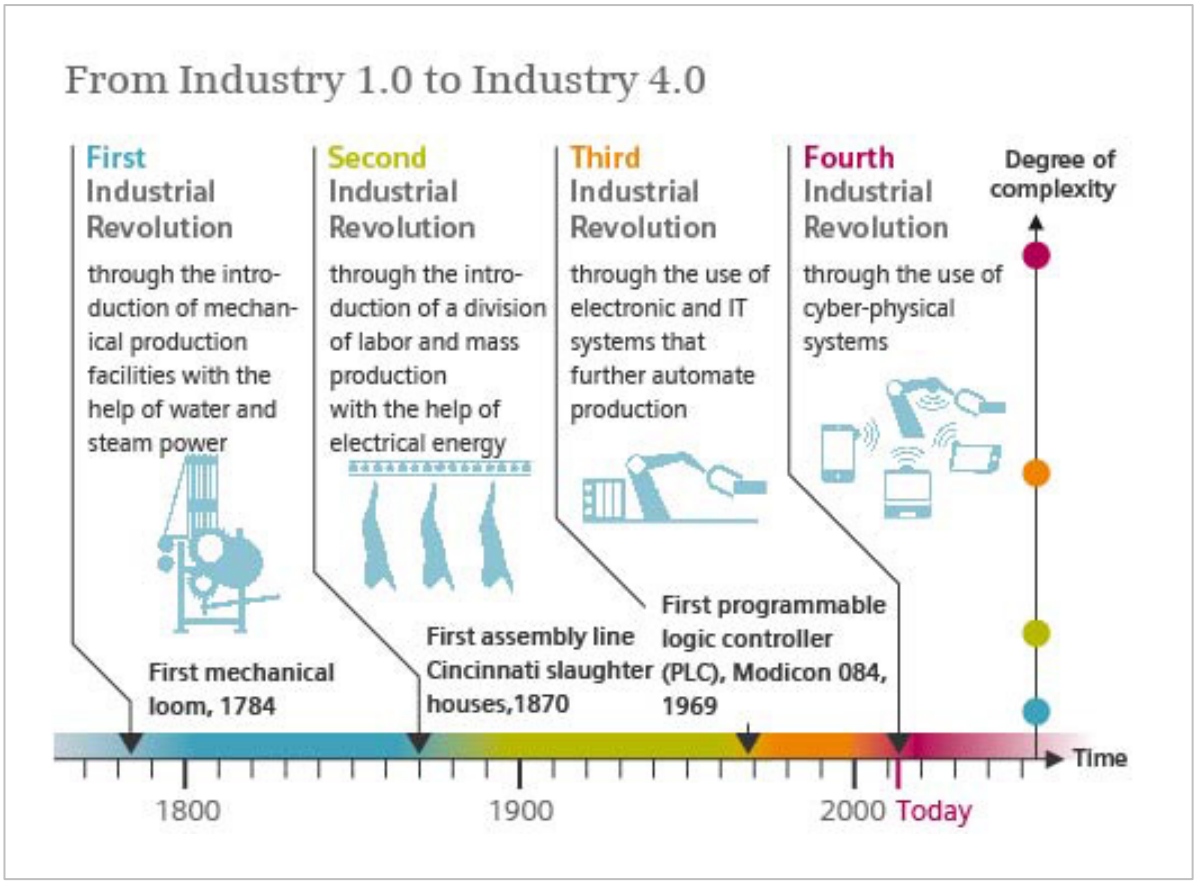


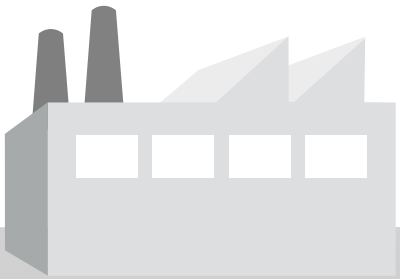

Source: DFKI (2011)

# Introduction

This talk is on leveraging inspection technologies and practices currently being applied in other verticals to help in biotech inspection

- The end goal of the process is inspecting quality into the products
- Consumer Internet tools applied to manufacturing, with some concrete examples of how this might look for parenteral inspection


Consumer Internet tools



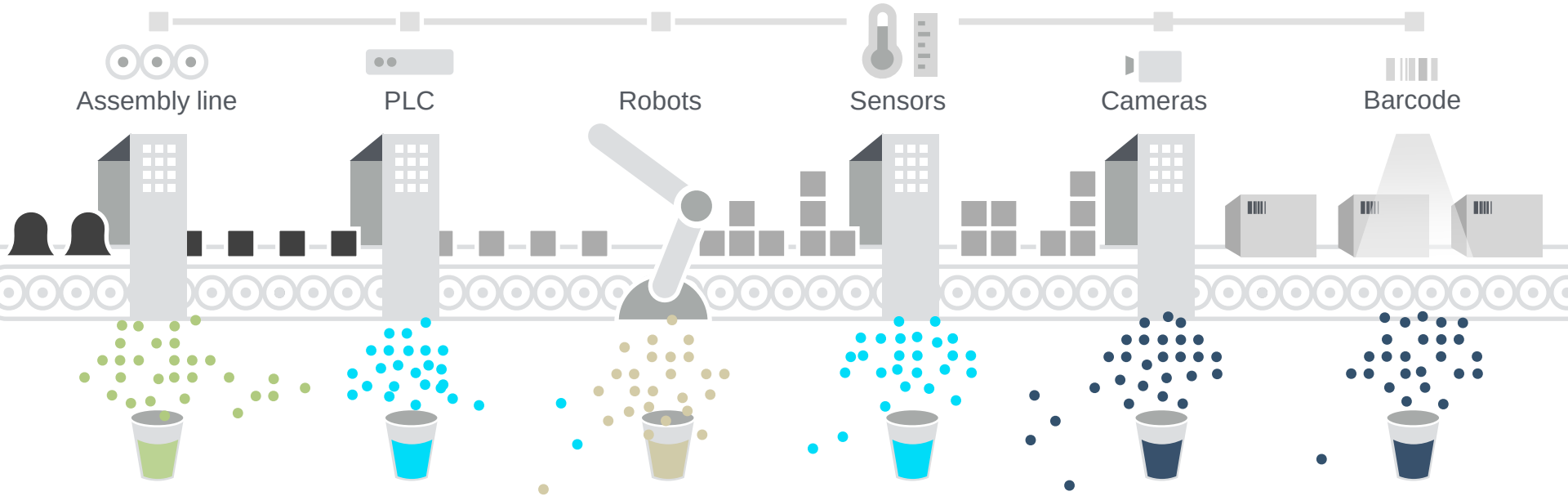
Visual Inspection / manufacturing

# Data is collected — and then discarded

Incredible mechanical engineering

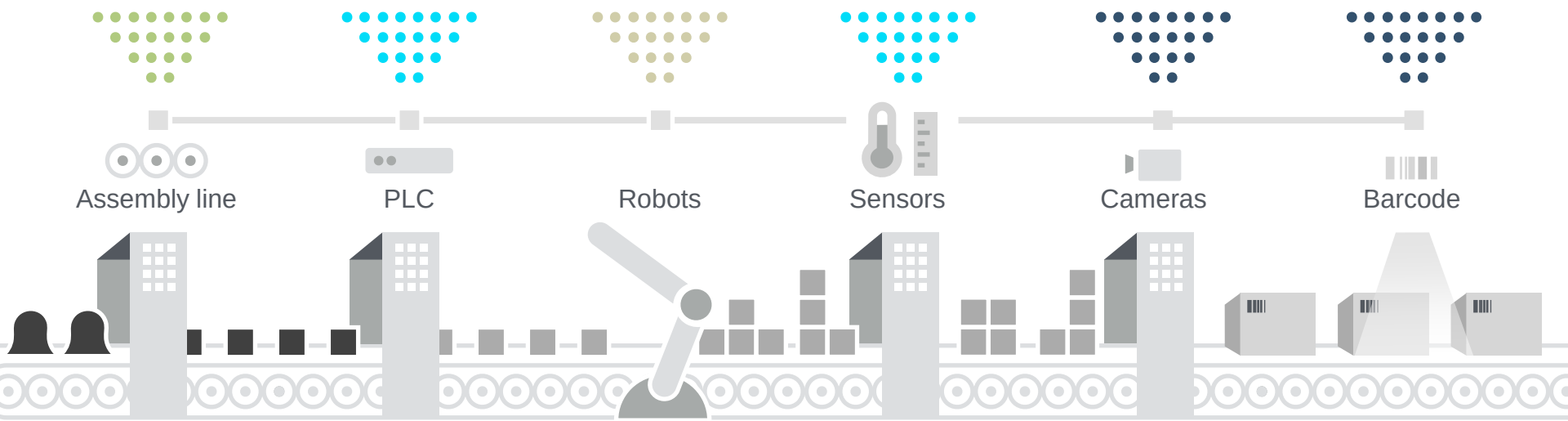
World class robotics

Vision algorithms and up-front tuning




… then we throw all the data in the trash

# Collected generated data provides valuable insight




What does this get you

- Defensive recordkeeping
- Vision algorithm tuning
- Predictive analytics

# Why do we throw it away?

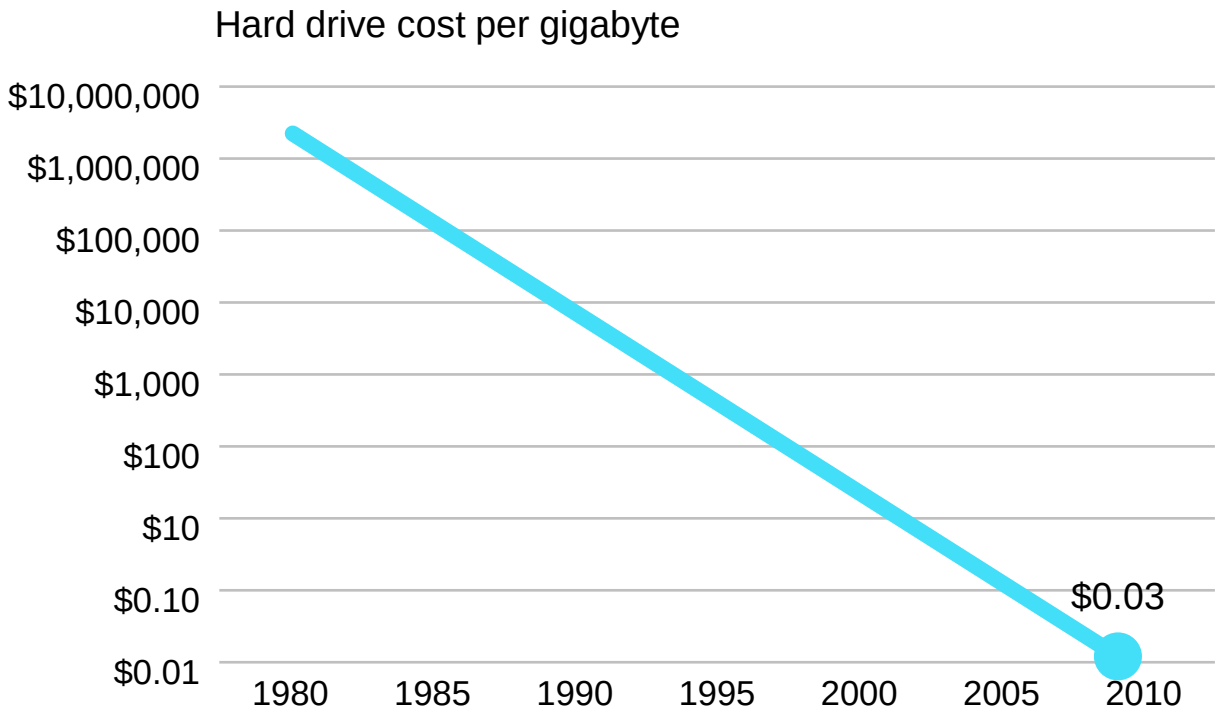
XL The data is too large!

??? The software infrastructure doesn't exist!

$$$ It's just too costly and effort-intensive!

# Storage costs are no longer prohibitive

The data is too large!



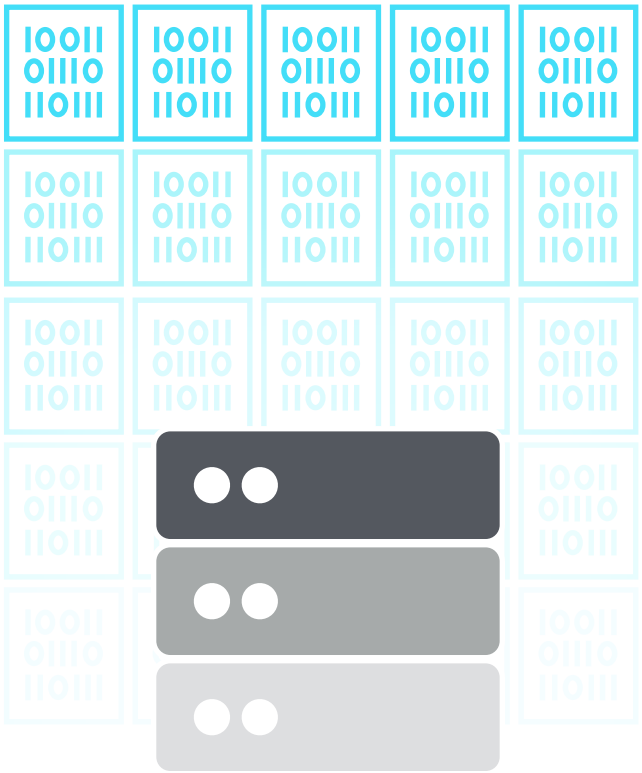
# Software tools exists for large data management

??? The software infrastructure doesn't exist!

There's a chasm between consumer Internet and vision inspection technologies

- Google deals with 10s of exabytes of data (1 exabyte = 1M terabytes)

The same tools apply and can be leveraged

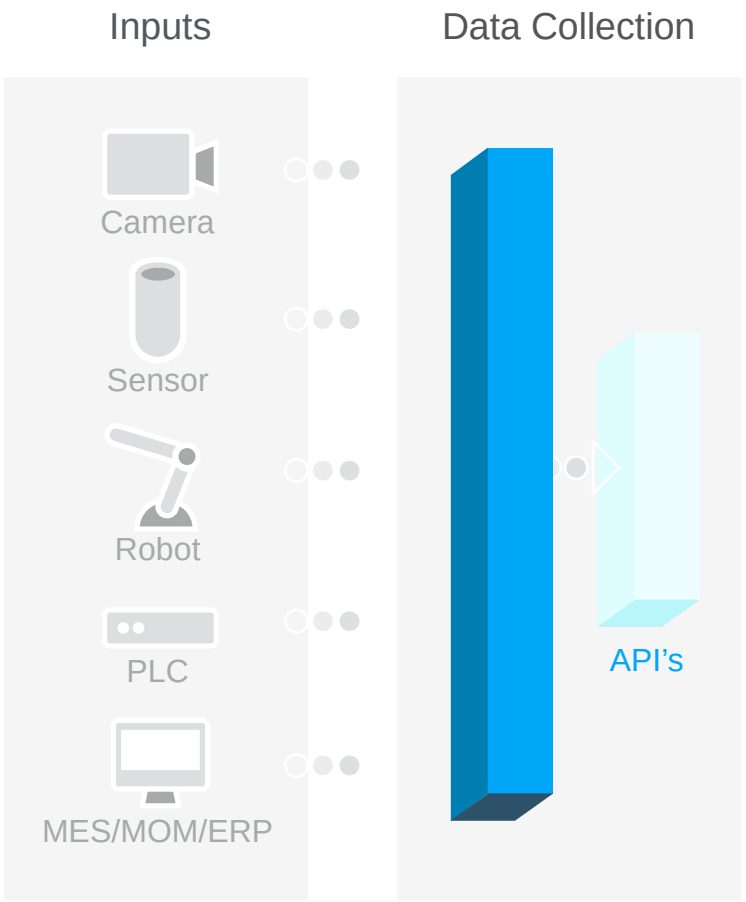


# Standards & Services help with implementation


It's just too costly and effort-intensive!

Standards are reducing integration work

Managed services make upkeep reasonable



# Big Data mentality

## Save everything!

(And if you can’t, then save nearly everything)

# Big Data mentality

For visual inspection this would encompass not just images and videos of the product, but also sensor data

- Spin rates
- Lighting Intensity
- Temperature
- Humidity
- Hopper table speed
- Timing sequences
- Etc.

# Defensive record keeping and retrospective analysis

Recalls are sometimes associated with mishaps relating to something you are already looking for. They are often associated with new issues that we didn't even know were issues before

- Lamellae
- Unexpected lapse in CCI

Regulatory considerations: Now and Future

Having a log of this data allows rapid root cause analysis, isolation of the problem and future prevention

# Vision algorithm tuning

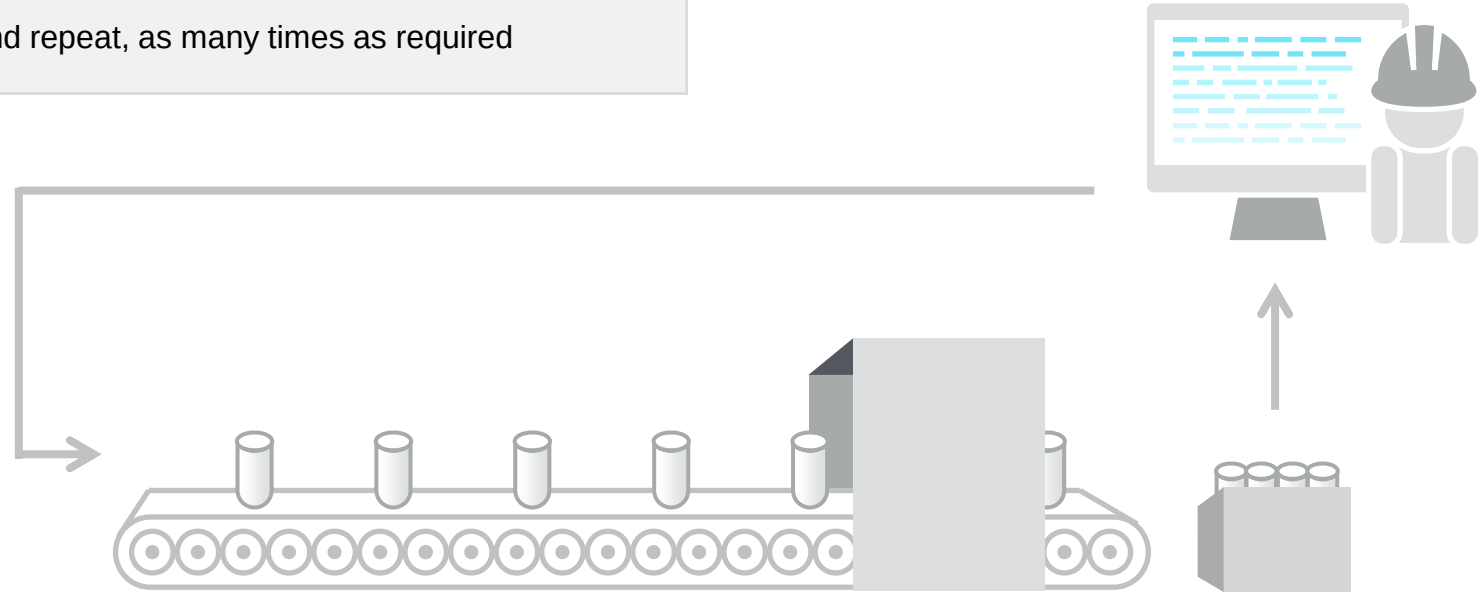
## Tuning vision algorithms

- Biotech inspection is solving hard problems
  - Particles: Detect/size/count/characterize
  - Cosmetic defects (crimp inspection, glass surfaces)
  - Dimensional characterization

Large characterization population allows for tuning that will allow higher efficacy with reduced scrap

# Inspection qualification: traditional paradigm

- Obtain a set of defect vials
- Run them through with vision algorithms
- Tweak things on the algorithm side
- Run them through again
- Look for improvements, or if you broke anything
- Rinse and repeat, as many times as required



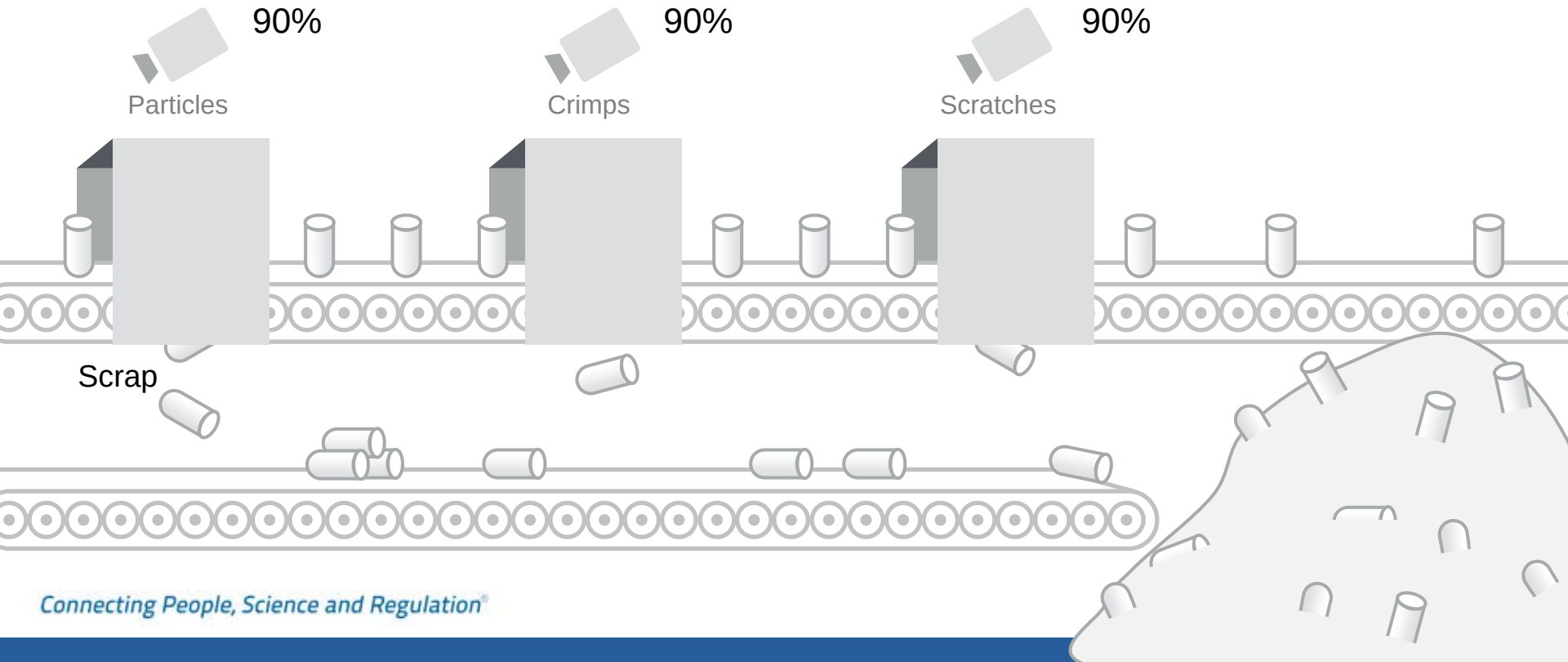
# Inspection qualification: Big Data approach

- Obtain a set of defect vials
- Run them through several times to get a statistically relevant population
- Take that data and, offline, tune all your algorithms
- The first time you implement the algorithms online, you have high confidence in your detection statistics

# This is critically important as we start inspecting for more and more things

The goal: Avoid needless scrap but ensure we inspect for critical attributes

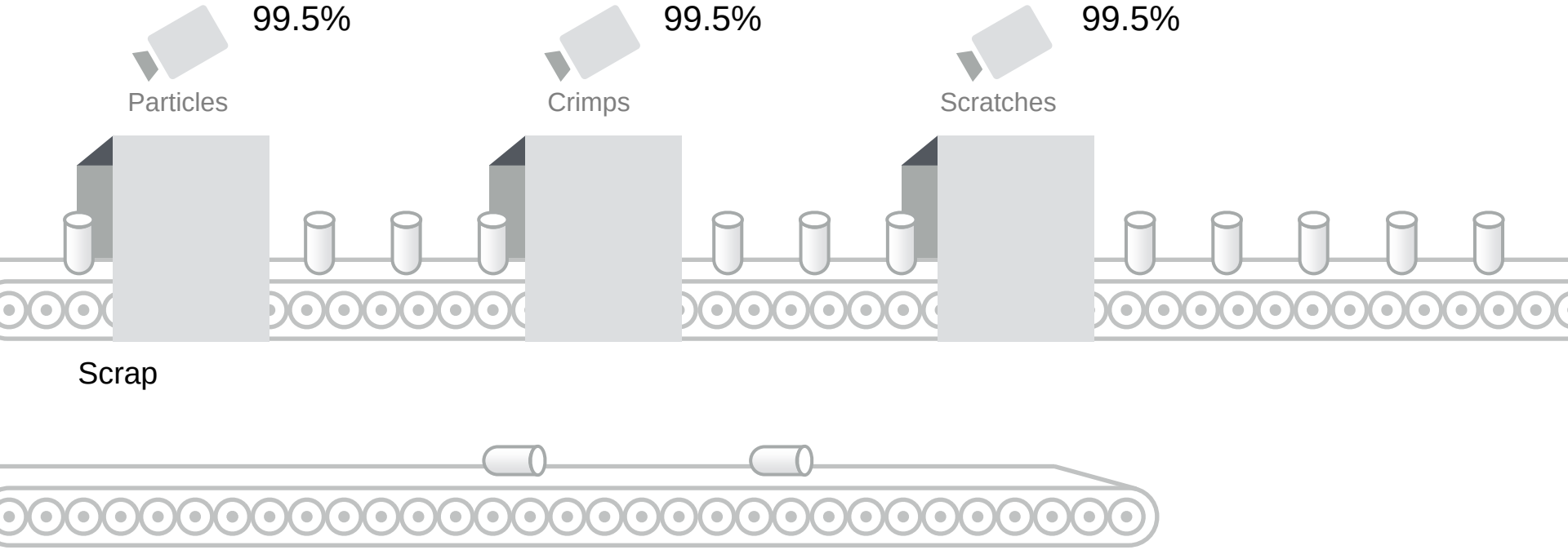
Combinatorics dictate that efficiencies in each inspection need to be extremely high or scrap skyrockets



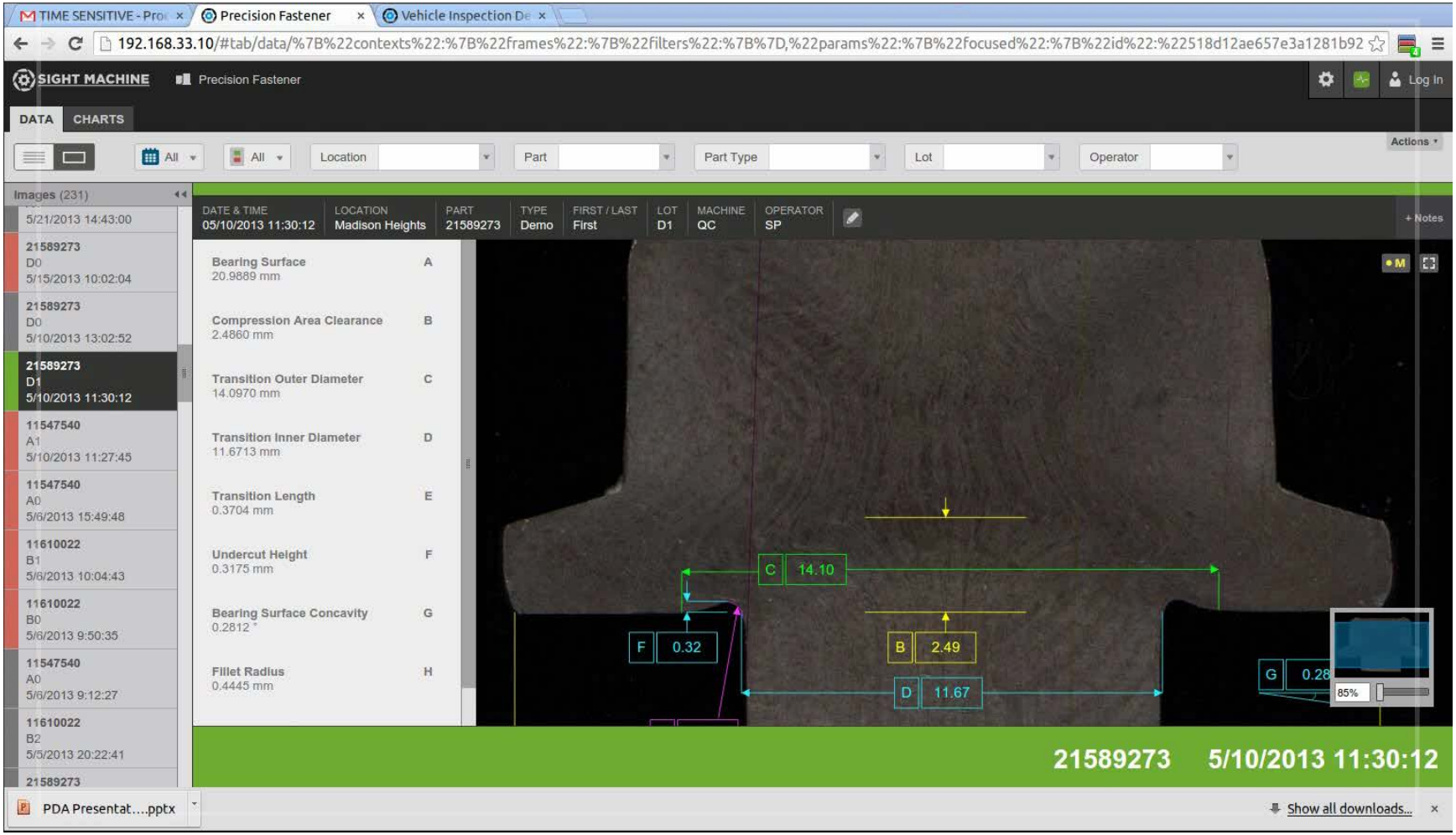
# Big Data reduces scrap

The goal: Avoid needless scrap but ensure we inspect for critical attributes

High accuracy provides the ability to inspect additional features of interest



# In action…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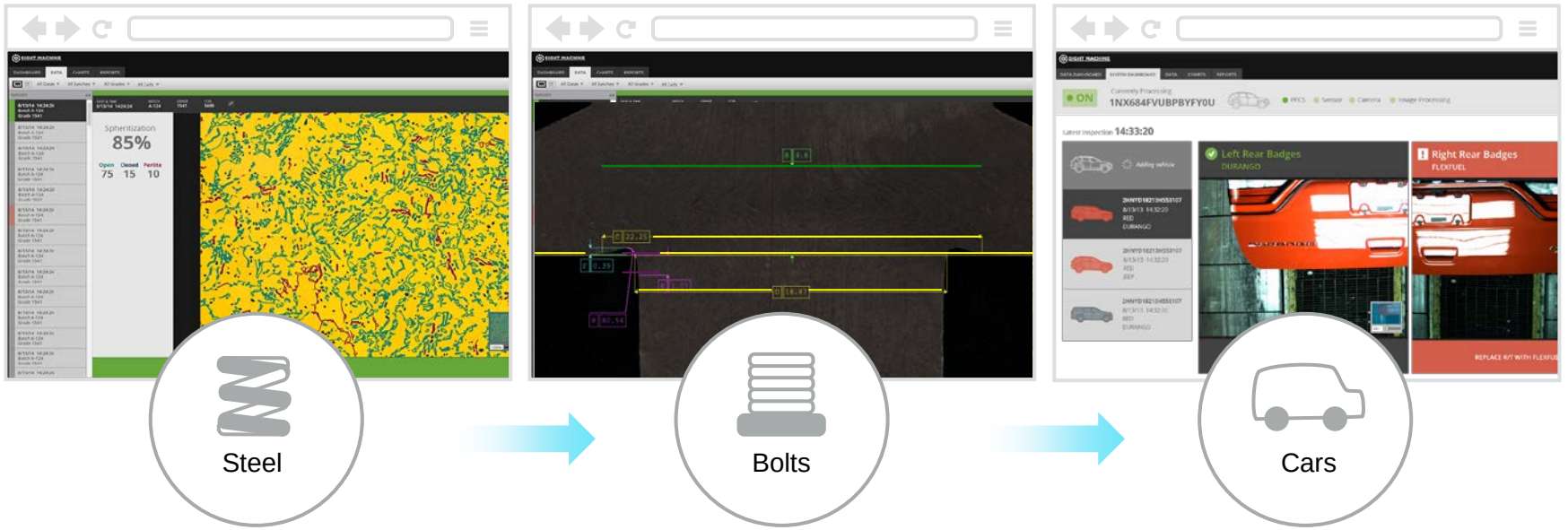
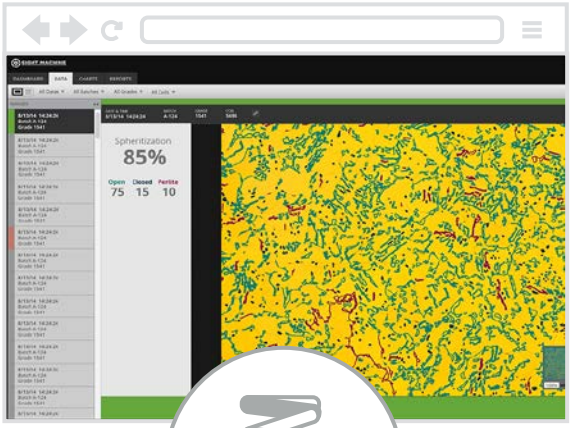
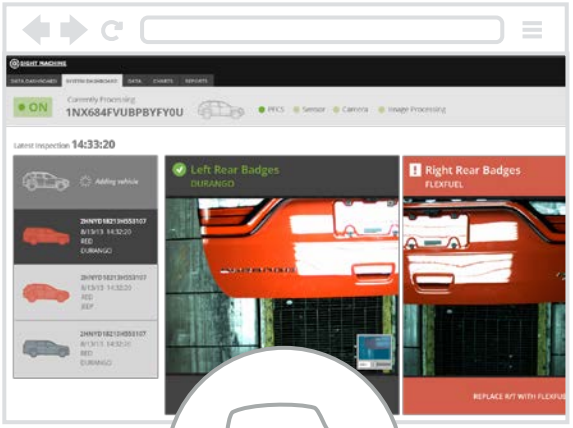
# Comprehensive quality control throughout the supply chain



# Comprehensive quality control throughout the supply chain



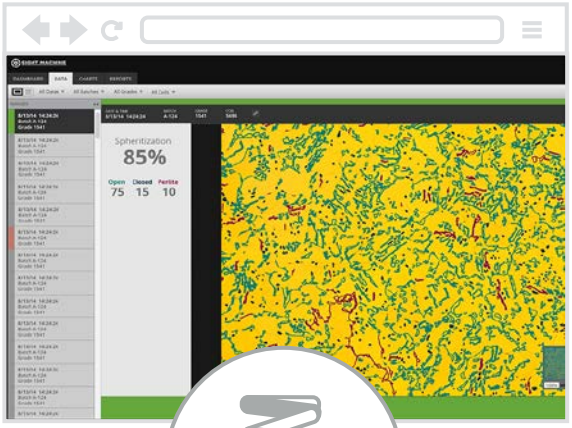

Steel → Bolts → Cars

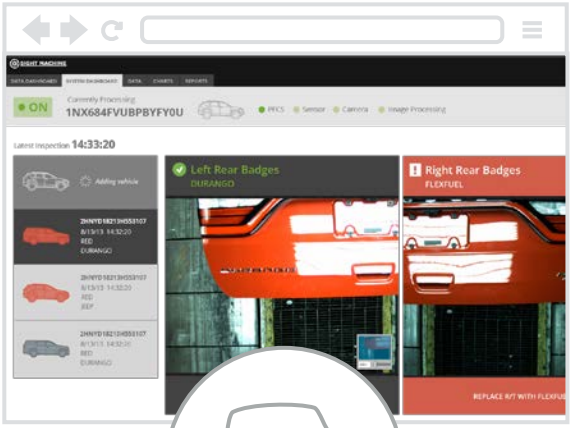
Raw Materials

Glassware

Drug Product

# Comprehensive quality control throughout the operations




Steel → Bolts → Cars

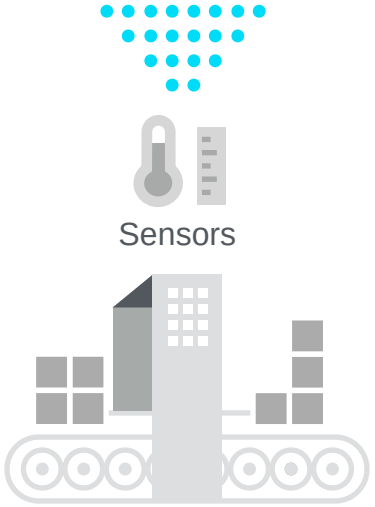
Bulk Drug Substance → Filling → Finishing

# Web frameworks provide insight across the factory and the supply chain

Real-time data display from multiple sources inside a factory, and from multiple factories around the globe

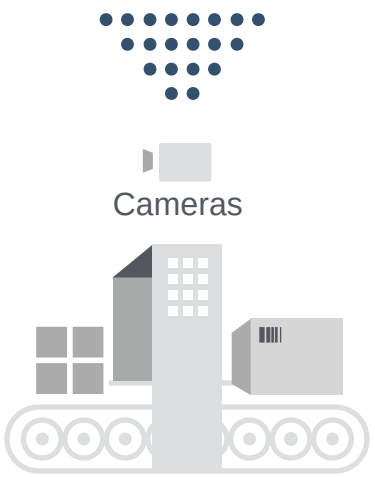
# Case Study: Leveraging machine data from visual inspection of parenterals

- Large biotech company reliant on automated inspection
- Operators load up the machine, which utilized high spin speeds and bright lights for cameras
- Then they went to lunch mid shift
- A few vials sat in the machine for close to an hour, subjected to far greater sheer forces and fluence than intended
- Anomaly detection in spin time or cycle time here is trivial if the data is flowing into a predictive analytics platform



# Case Study: Leveraging image data from visual inspection of parenterals

- Biotech company reliant on automated inspection of presence/absence of vial rubber stoppers.
- Receive a batch of stoppers in which a new employee at the provider has included a small number of the wrong type
- Fill an entire lot, cap and crimp these vials, at which point the difference in stopper is no longer visible
- If the data from the existing visual inspection systems were stored, this exercise is trivial.

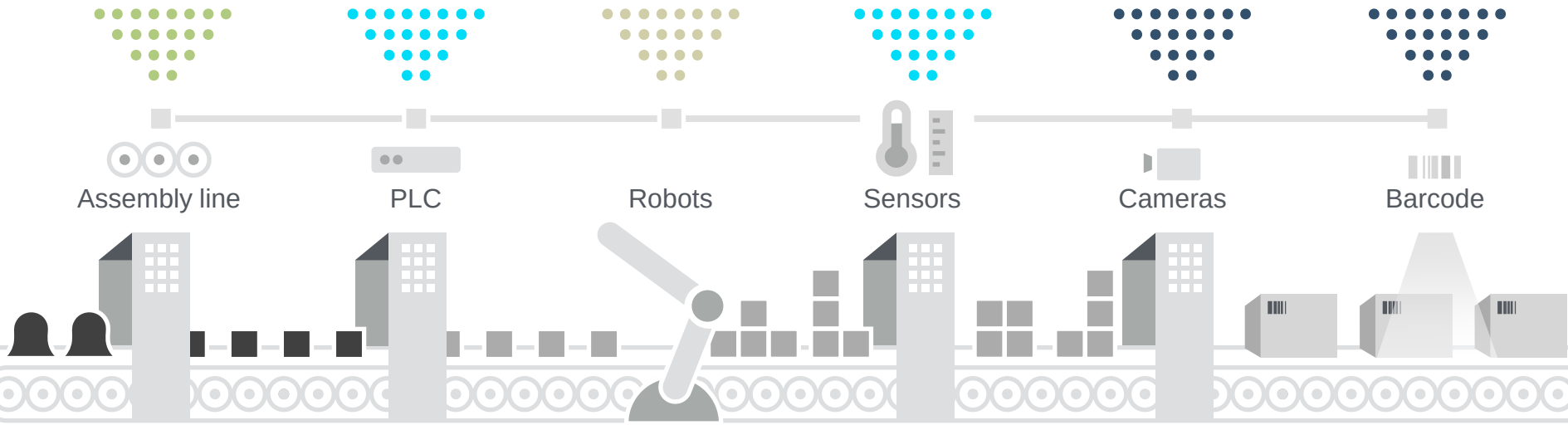


# Summary

- Internet of things / Industry 4.0 is in its infancy
- Storing information is the first step. Use cases will follow

What does this get you?

- Defensive recordkeeping
- Vision algorithm tuning
- Predictive analytics
- Regulatory compliance



# Save everything!