

SMART DISPOSABLES IN BIO-TECH & MEDICAL DEVICES

- beating the bellcurve -

by

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Content

Harm TenHoff:

- **Medical Device Introduction – the problem**

Pieter Noordam:

- **Technology Solution – advanced RFID**
- **Case Study**
- **Summary Benefits**

- **Discussion**



Medical Devices

A Successful Functional Concept:

System	+	Disposable/Consumable
Reusable		One-time-use
Sophisticated		Simple (?)
Expensive		Low-cost (?)
General use		Patient specific
External use		Internal use (sterilized)
Human Interface		Small (micro/nano)

Medical Devices

A Successful Business Concept:

System

+

Disposable/Consumable

Installed base secures market

System compatibility secures market

Low margin

High margin



Medical Devices

Examples Simple Home Use

System

Electric Toothbrush



Disposable/Consumable



Ear Thermometer



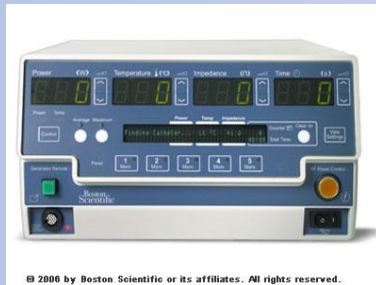
Medical Devices

Examples diagnostic/therapeutic catheters

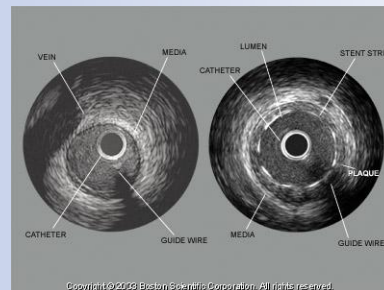
System

Disposable/Consumable

Cardiac Electrophysiology – Catheter Ablation



Interventional Cardiology – Intravascular Ultrasound (IVUS)



Medical Devices

Examples In Vitro Diagnostics

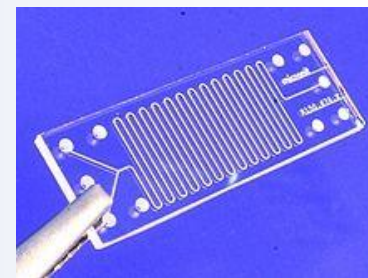
System

Disposable/Consumable

In Vitro Diagnostics (Home)



In Vitro Diagnostics (Point of Care)



Medical Devices

Examples Other Applications

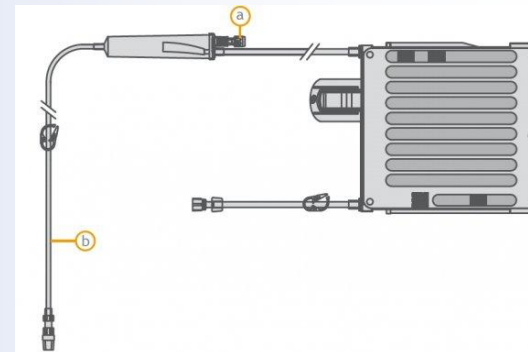
System

Disposable/Consumable

Hemodialysis



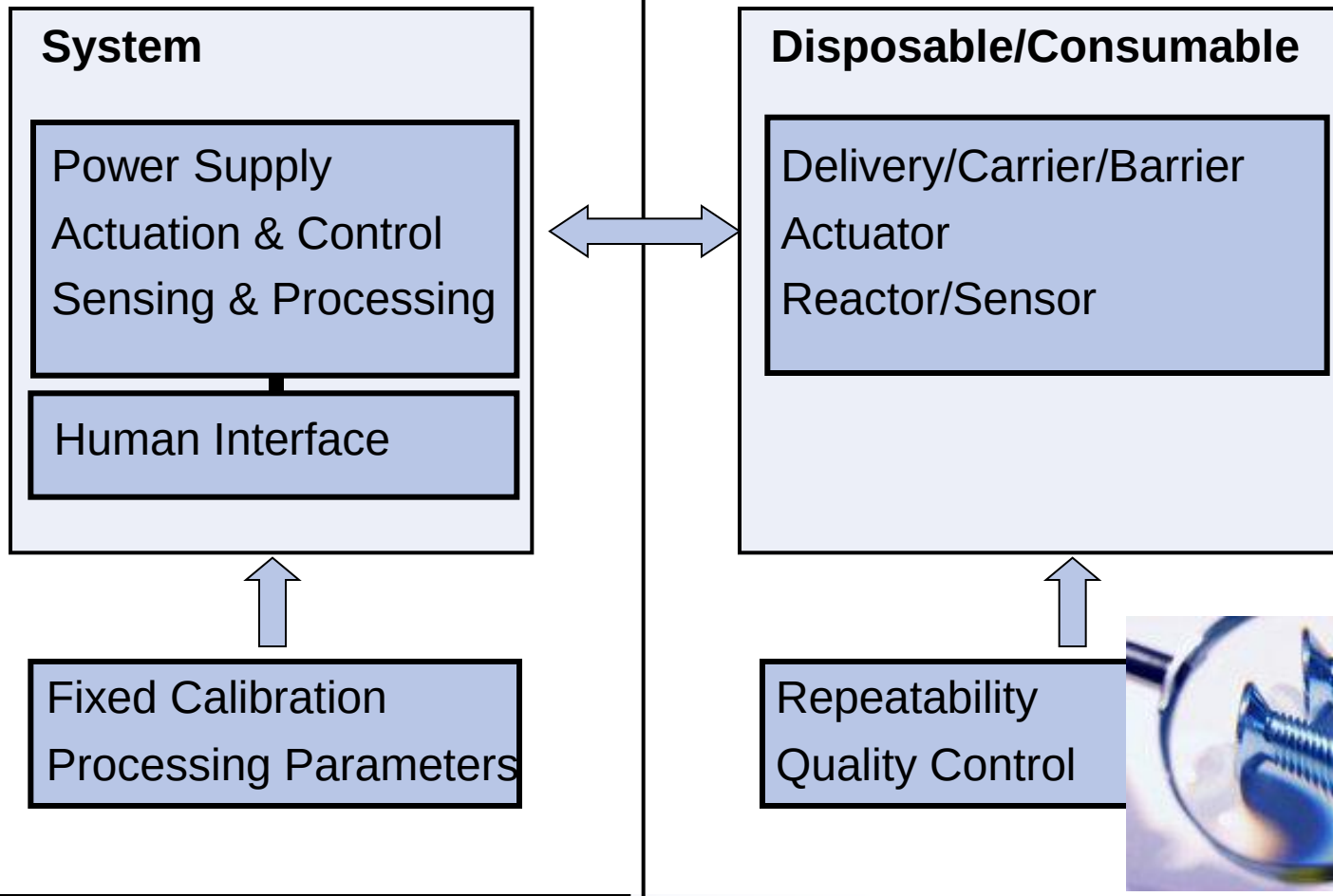
OR/ICU – Blood/Infusion Heater



Medical Devices

Standard Functionality

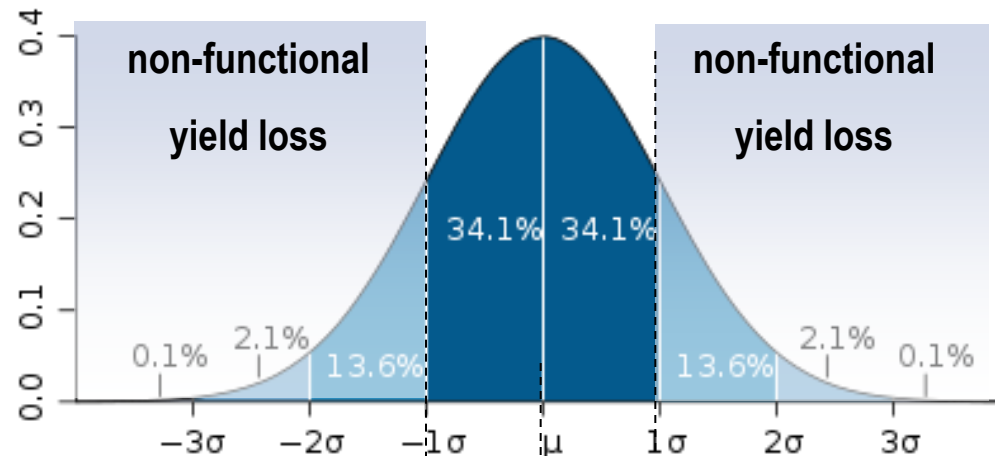
PRODUCT FUNCTIONALITY



Medical Devices

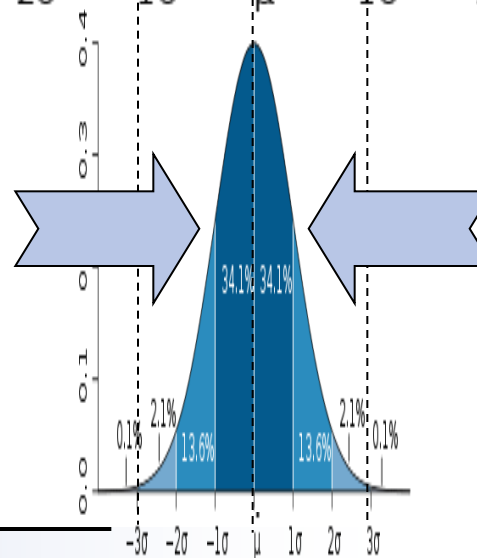
Standard Functionality

Bell Curve



100% inspection

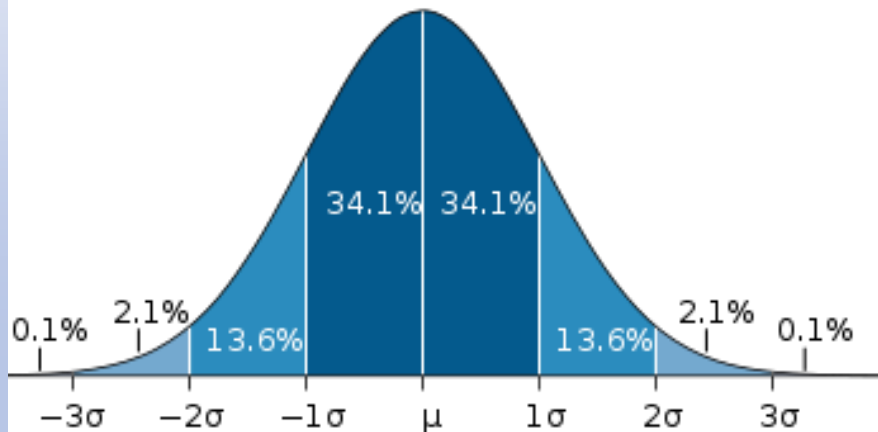
Improve process control



Medical Devices

Standard Functionality

Bell Curve



Trends (technology)



- Micro/Nano Aps
- Bio Aps
- Multifunctionality
- Personalized/Custom Aps

Trends (society)



- Lower Cost
- Stricter Control

Medical Devices

Medical Disposables:

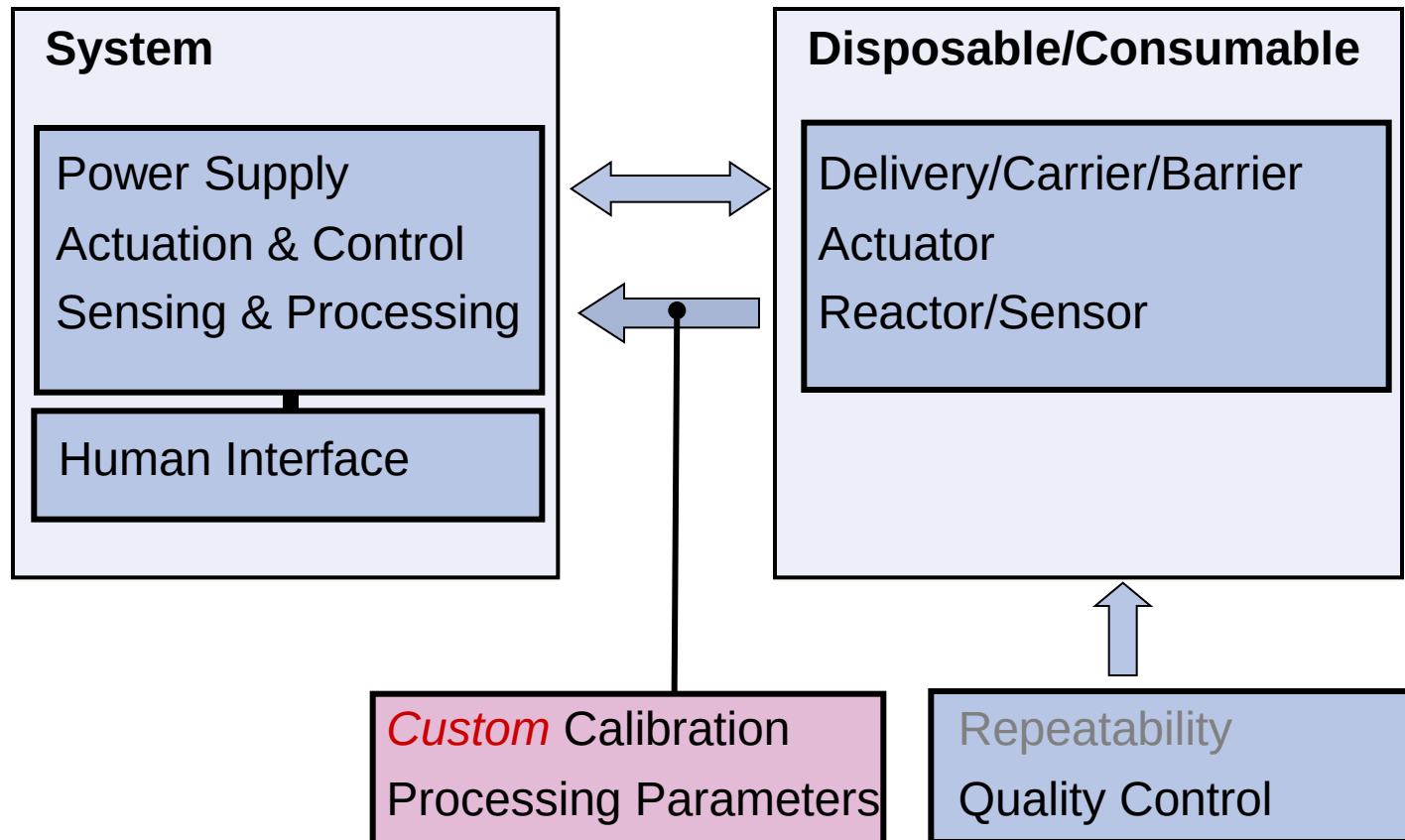
“... if they only could talk ...”



Medical Devices

Custom Functionality

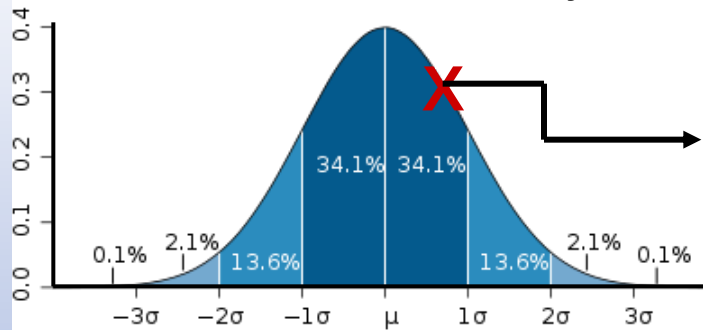
PRODUCT FUNCTIONALITY



Medical Devices

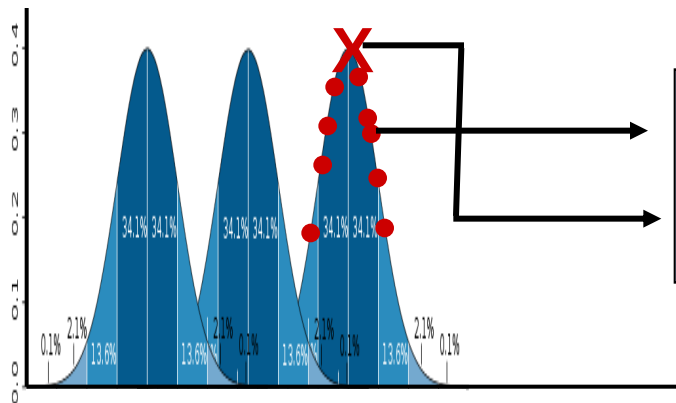
Custom Calibration

individual variability



- 100% measurement
- write unique value to consumable

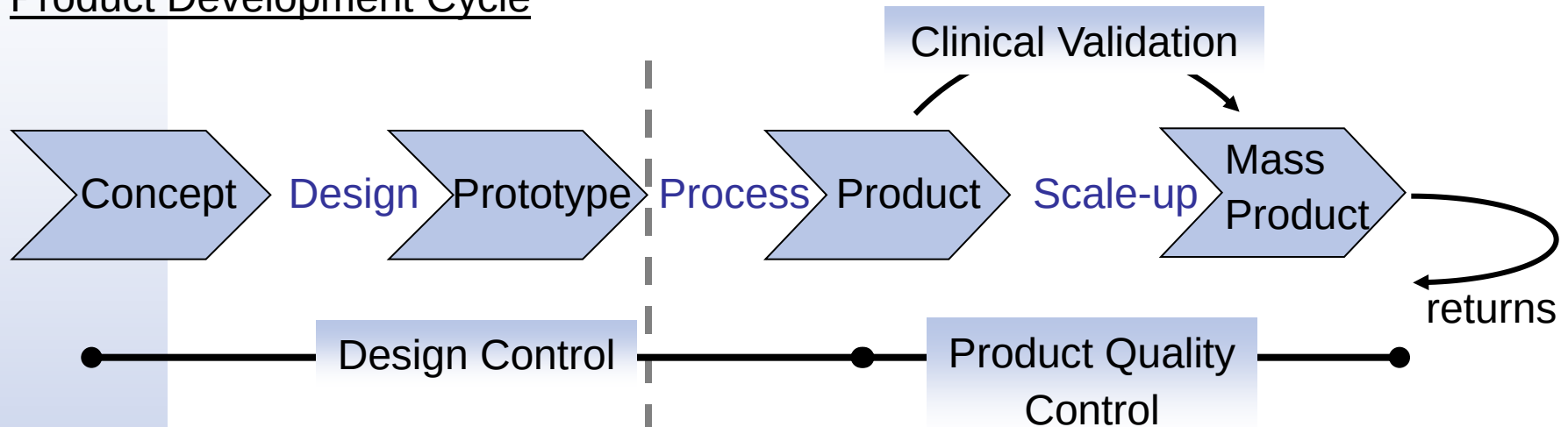
batch/lot variability



- determine curve from N samples
- write mean value to consumable

Medical Devices

Product Development Cycle



Compliance

- Functionality & Safety of Design

- Product Functionality & Safety
- Traceability/Documentation
- Handling returns/complaints

Need for product-bound information

Medical Devices

Medical Disposables:

“... if they only could listen ...”



Medical Devices

Product-bound information

Process generated:

- lot #, serial #
- production process steps & parameters
- usage calibration settings

Usage generated:

- usage process steps & parameters
- patient/clinical data
- error codes



Medical Devices

Available Technologies for Data Storage & Short-range Communication

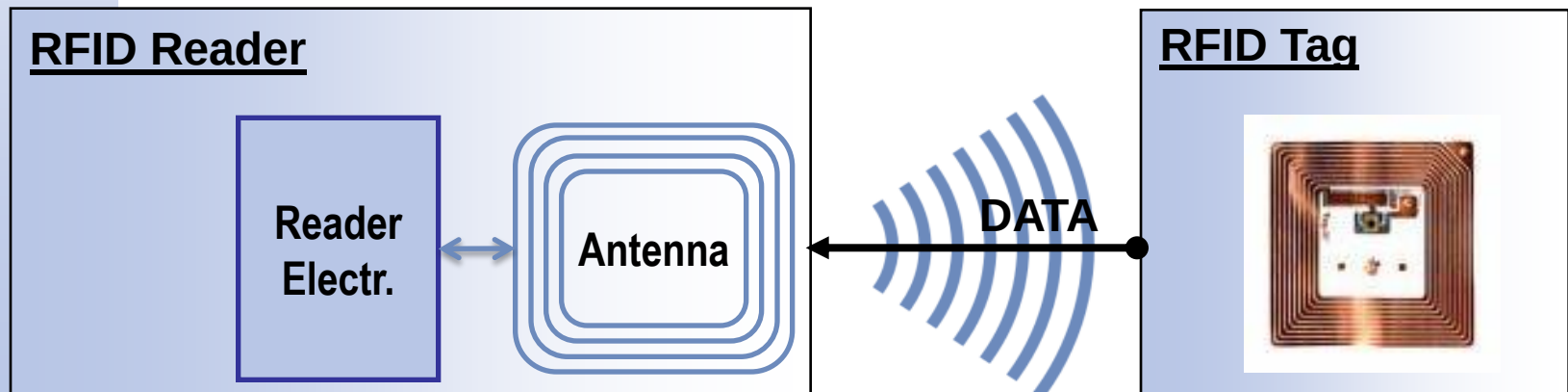


Technology	Read	Write	Contact less	Low Cost
Bar Code	+	-	+	++
Classic RFID	+	-	+	+
Embedded Logic	+	+	+/-	-
Advanced RFID	+	+	+	+

Technology

Radio Frequency Identification (RFID)

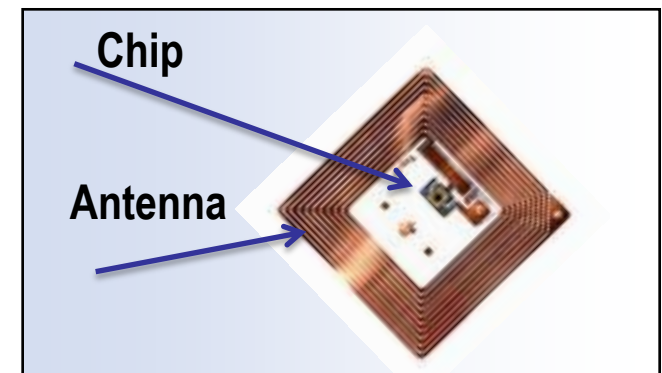
- Radio implies contactless
- RFID reader communicates with RFID tags



Technology

RFID Tags

- Chip and Antenna
- No Batteries (passive RFID)
- Contains an electronic number (ID)
- Contactless
- Functionality defined by standards (ISO)



Technology

Classic RFID Use: Tracking & Tracing

Logistics (e.g. WalMart , DoD)

→ Cheap

→ Reliable

→ Use once

Tags applications

(units/year)

Pallets/Cases 225M

Clothing 200M

Livestock 105M

Total: 2,350,000,000*

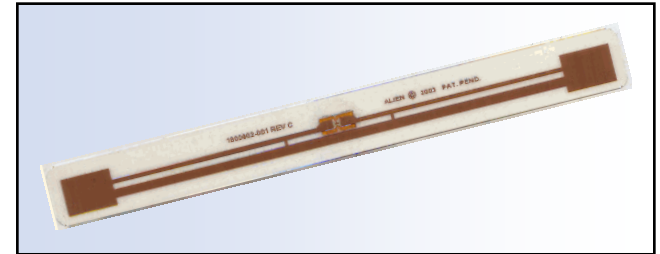
*2009, Source: IDTechEx



Technology

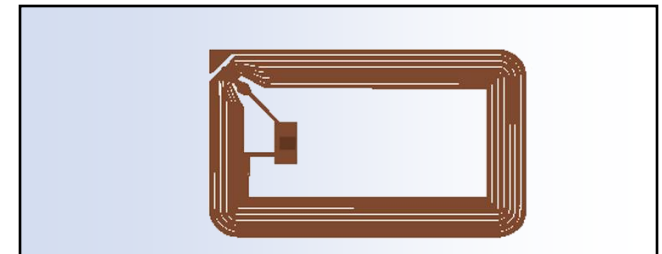
UHF - Ultra High Frequency – Classic RFID

- 920 MHz
- Range: 10 - 30 ft
- Transmits ID



HF - High Frequency – Advanced RFID

- 13.56 MHz
- Range: 0.5 – 2"
- Transmits ID
- Memory
- Transmits data from memory
- Writes Data to memory



Technology

Other Established RFID technologies

- Active RFID, Battery assisted
- LF, 125 Mhz, Lifestock
- With GPS, Worldwide Container Tracking



Technology

Advanced RFID – Current Use

- Electronic Passport
- Mass Transit
- Credit Cards



Technology

Advanced RFID - Multiple Form Factors

- RFID inlay
- Embedded in label (adhesive)
- Plastic cards (protected)
- Epoxy embedded



Technology

Advanced RFID - Latest Developments

- Sensors on tags
- Sterilizable tags (Gamma radiation)
- Printing RFID tags
- High Security

Strain Sensor



Gamma Tag



Printed Tag



Technology

Advanced RFID – Readers*

***Capable of reading and writing**

PC



Handheld



Industrial



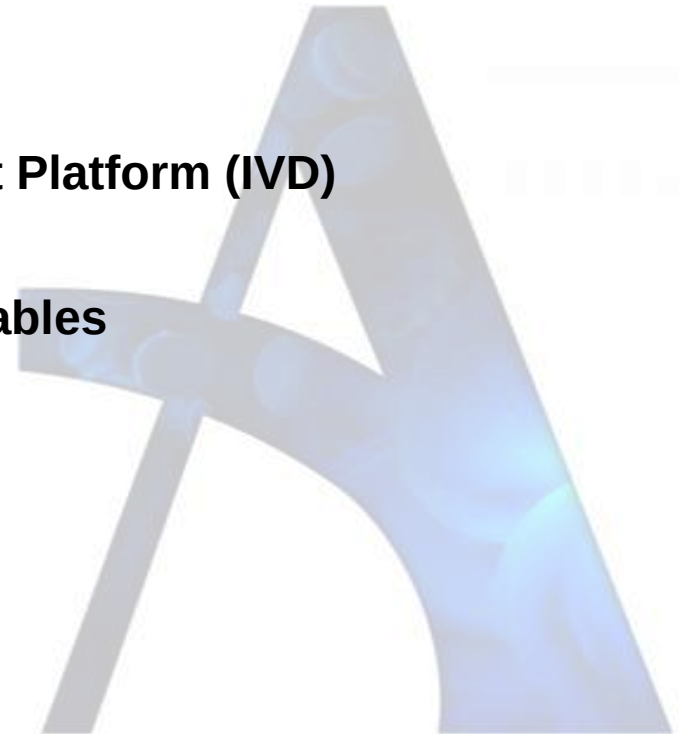
Embedded



Case Study



- Based in Castle Rock, Co
- Developing Rapid Appendicitis Test Platform (IVD)
- Dedicated Instrument and Consumables



Case Study



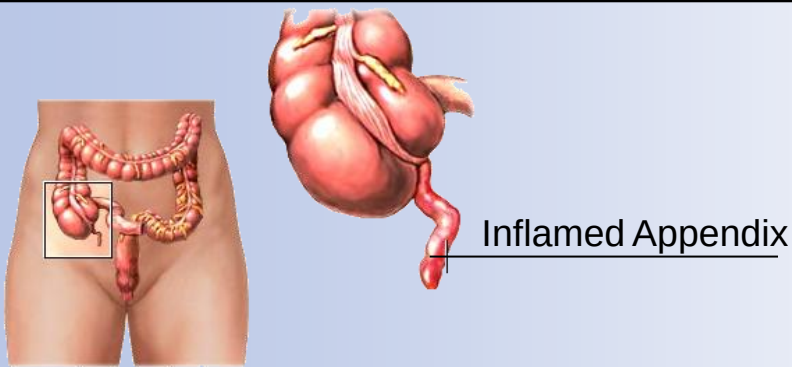
Appendicitis

- 5,000,000/year suspicion of appendicitis in US
- “Only” 320,000/year appendectomies in US
- Effects 9% men and 7% women in their lifetime**
- Late teens are peak age group**

Current: Hospital CT scan suspected cases; process 5 hours

Target: Hospital Lab test processed in < 1 hour.

Significantly reduce number of CT scans currently performed.



Case Study



Business Case

- Significant reduction CT scans
- Reduction X-ray exposure
- Fast Point-of-Care screening

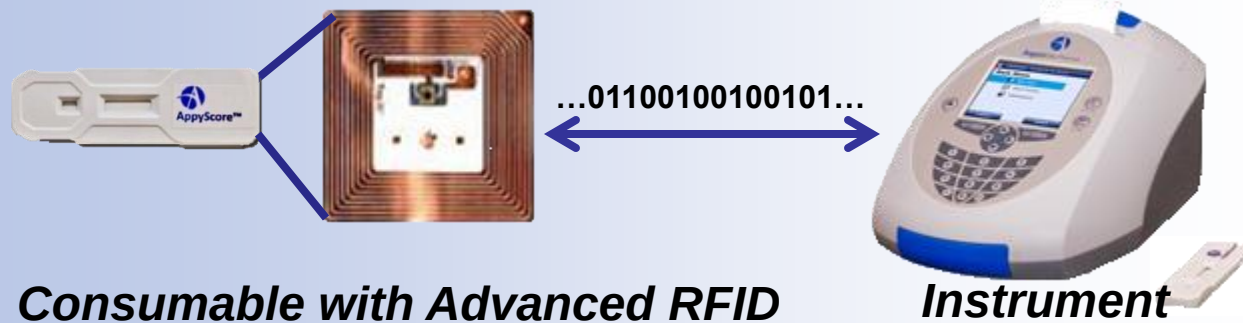


Case Study



Technology

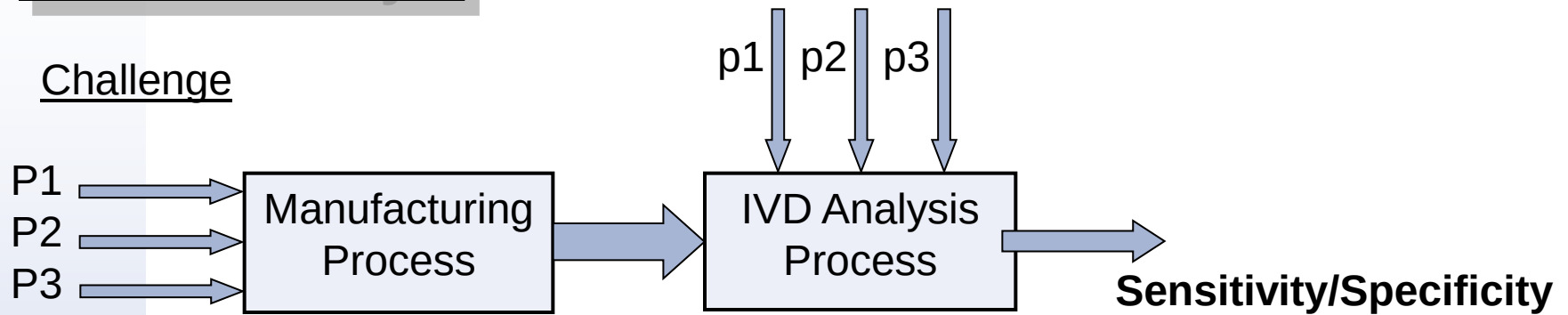
- Based on Spectrophotometry
- Using RFID on Consumable
 - Calibration
 - Compliance
 - Test Results (AppyScore™)



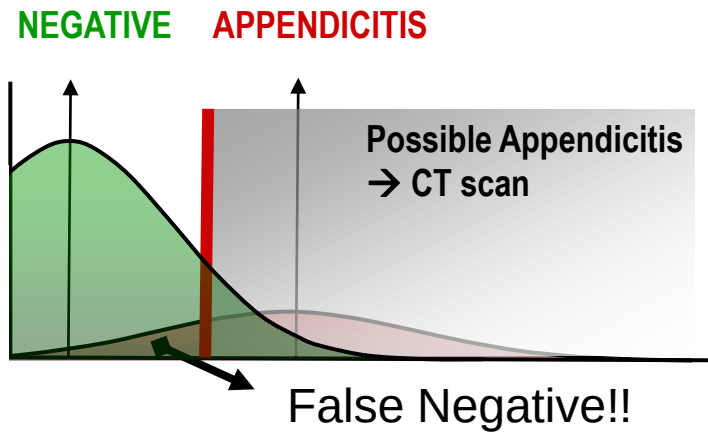
Case Study



Challenge



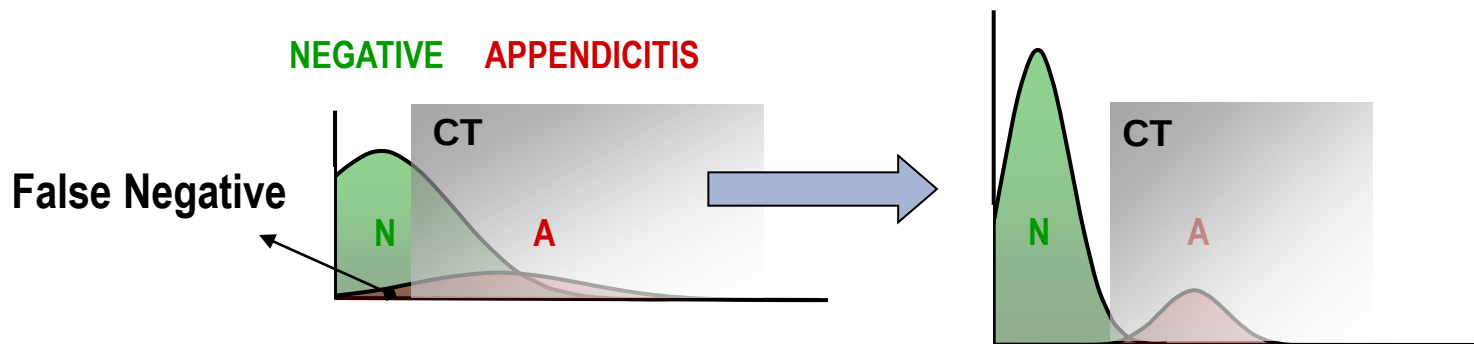
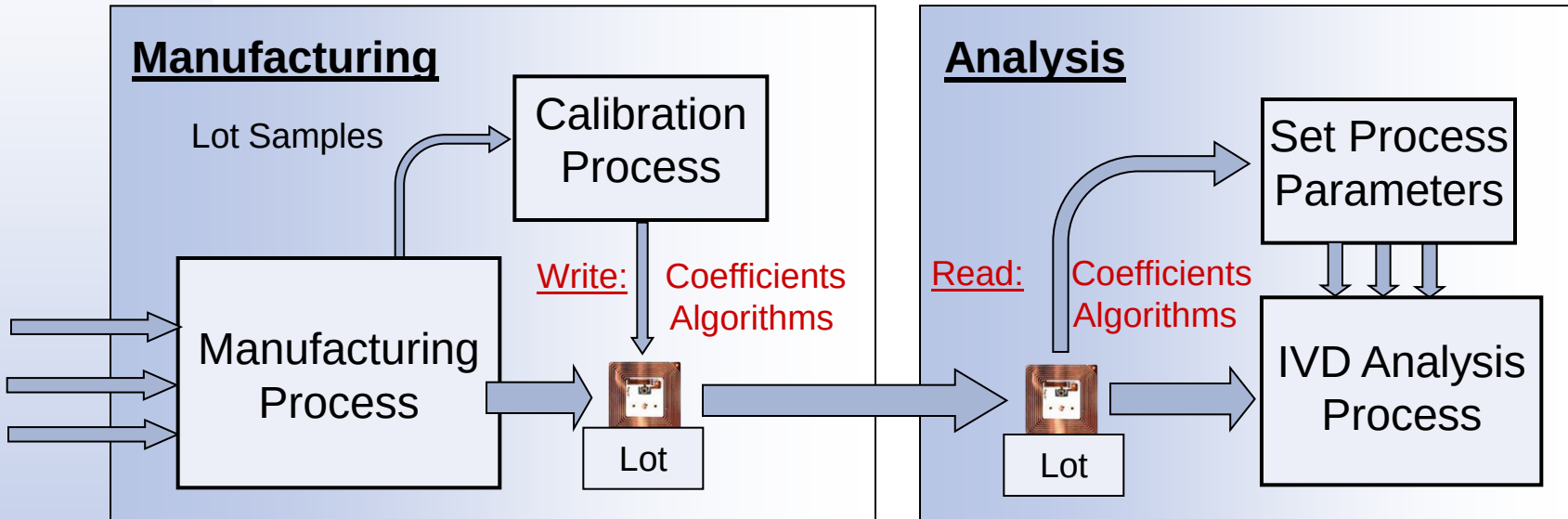
Lot Variability



Case Study



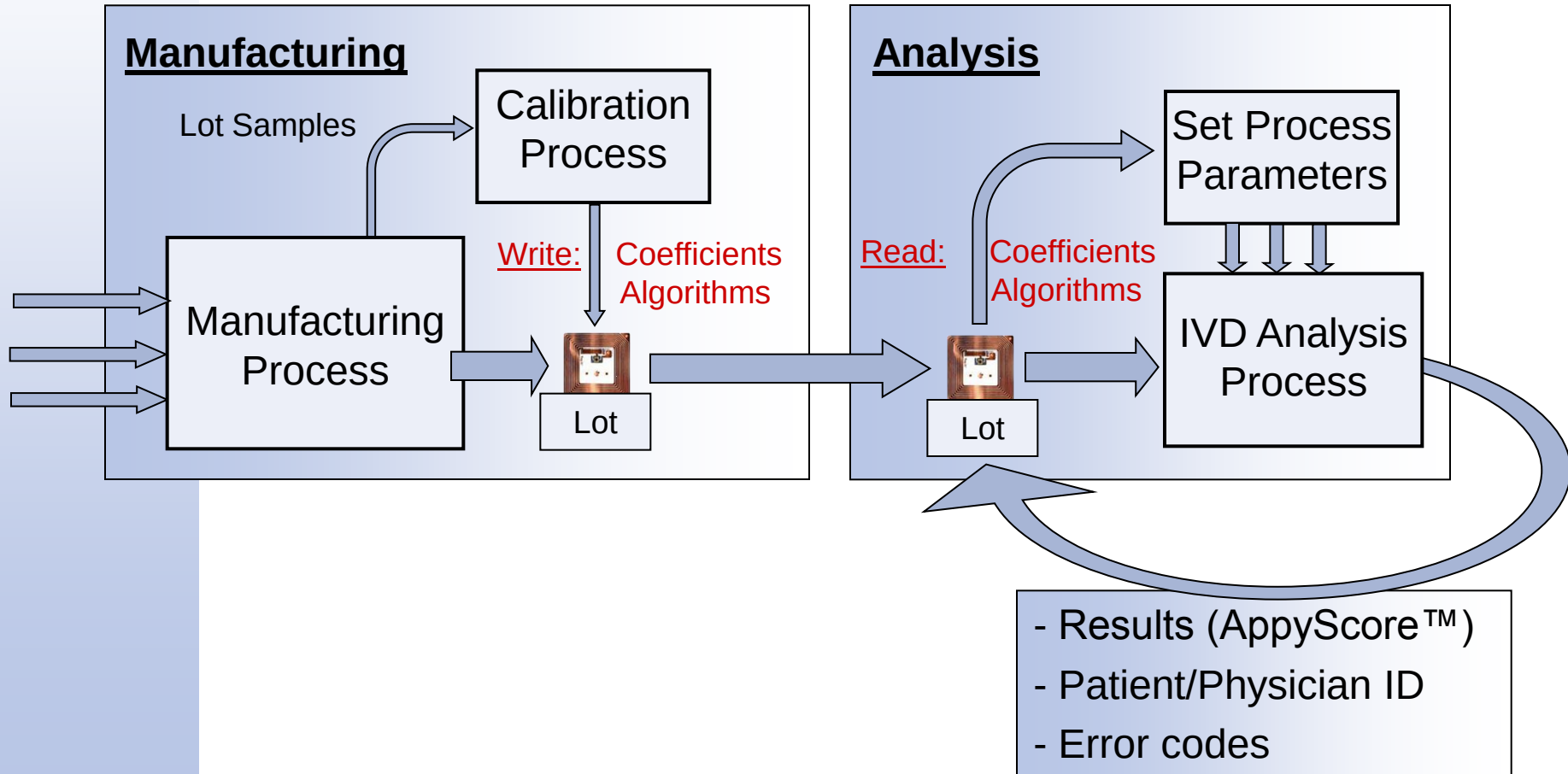
Empirical Data Analysis



Case Study



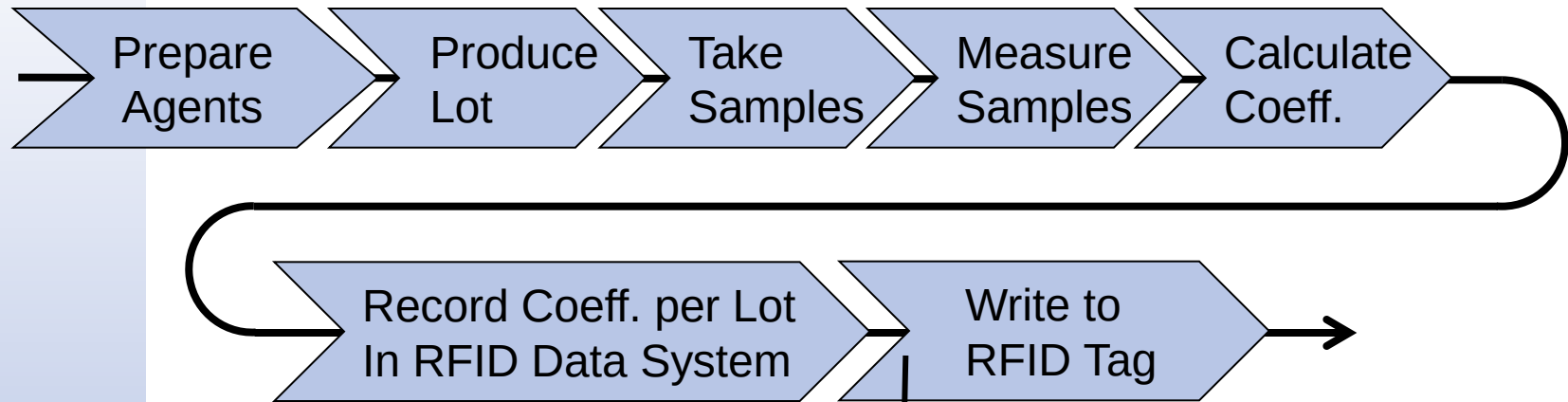
Empirical Data Analysis



Case Study



Manufacturing and Calibration Process

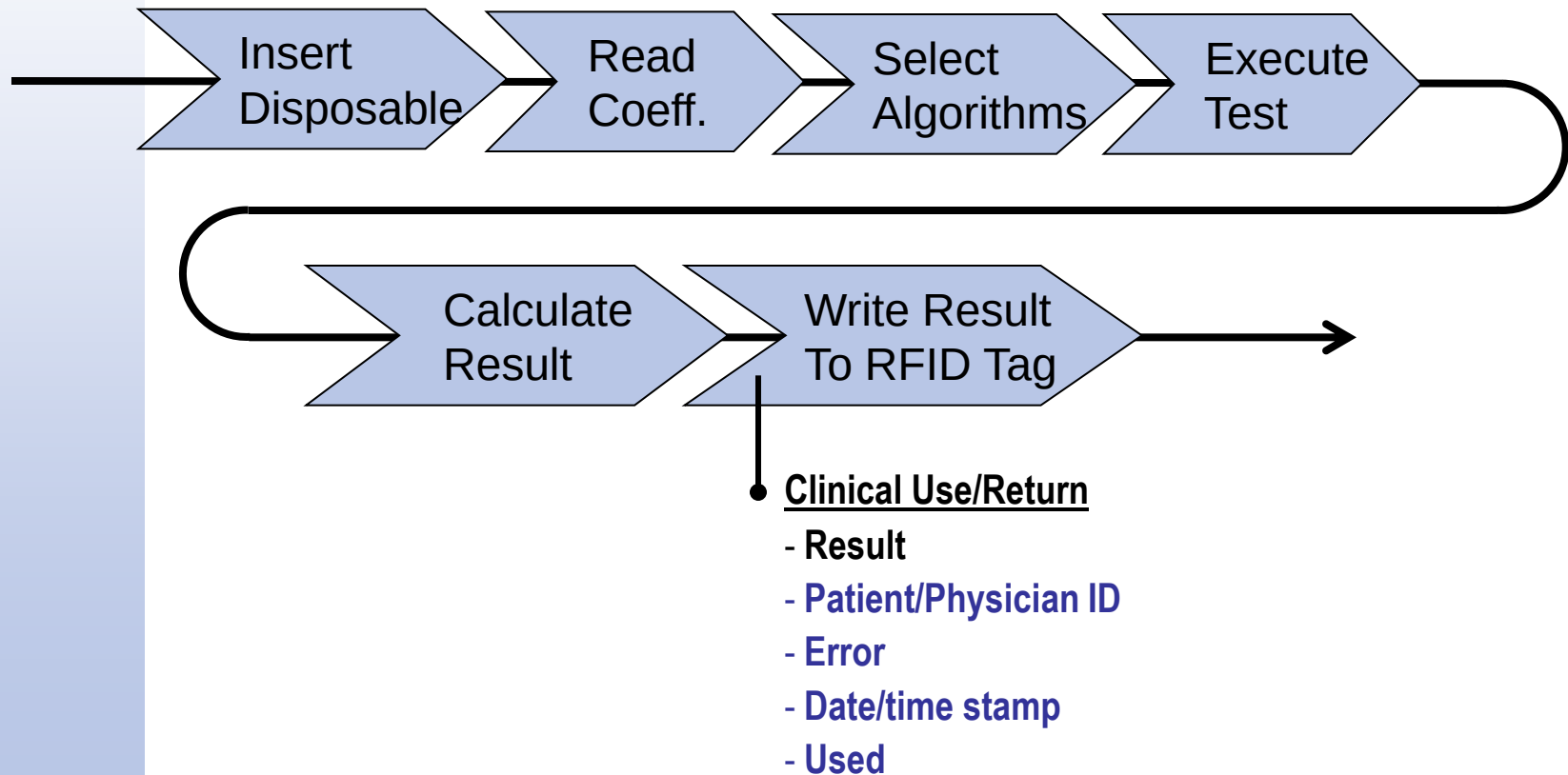


- - Functional/Calibration Parameters
- Compliance
- Lot ID
- Process parameters
- Material records
- Date/time stamp
- Versioning
- Expiration date

Case Study



IVD Analysis Process



Case Study

Aspen's use of RFID technology

- Manage Lot Variability through Lot Calibration
- Decoupling of Manufacturing and Calibration
- Use of data infrastructure through the processes
 - Calibration data
 - Compliance data
 - Manufacturing data

Greg Bennet, SVP Product Development & Manufacturing

“The RFID utilized in our system allows us to exchange a great deal of information to and from each cassette.

The ability to program the RFID through the cassette's final packaging simplifies the manufacturing process.

Best of all, this is completely transparent to the user”

Case Study



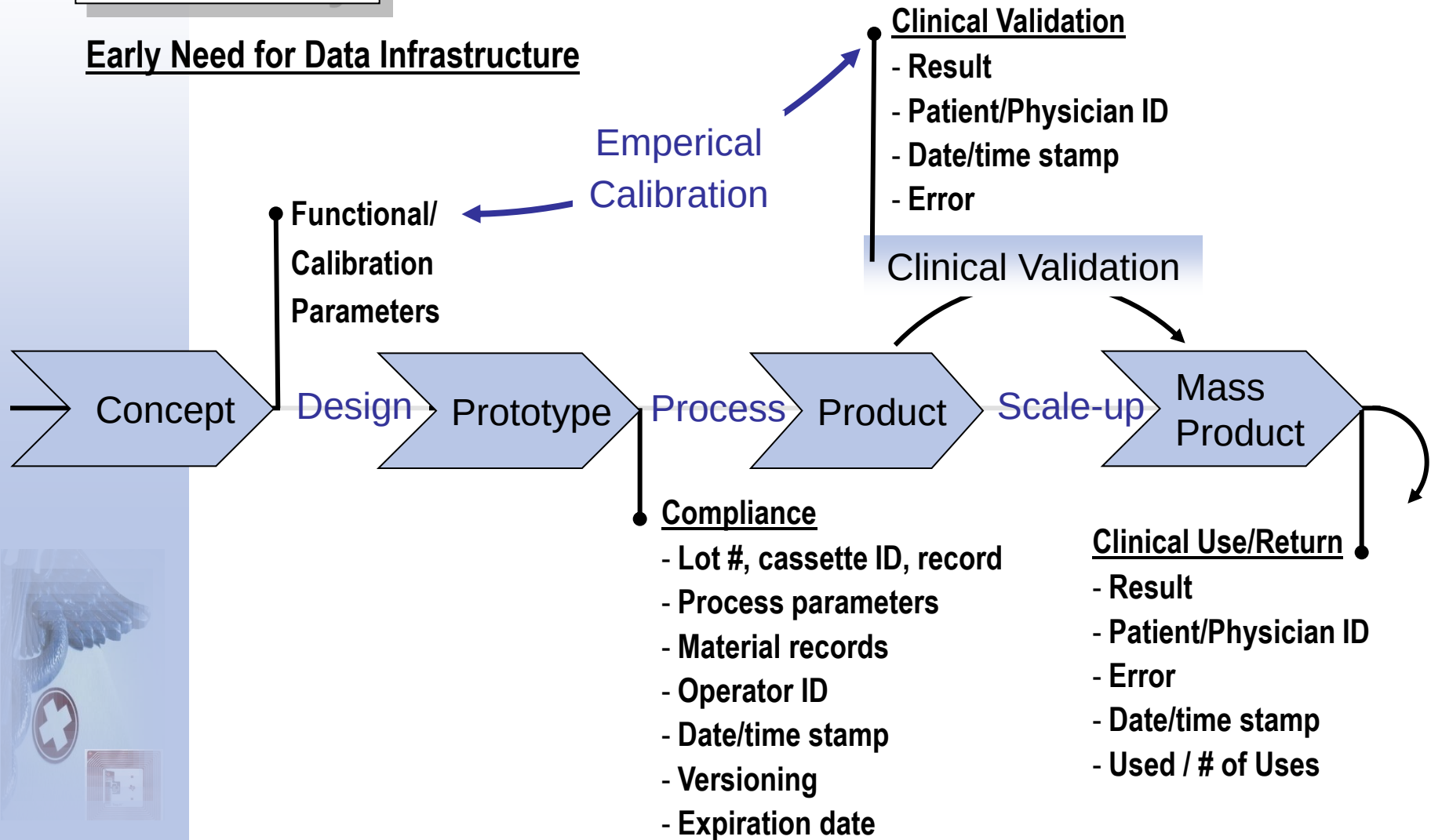
Conclusions

- RFID enables custom processing, yielding safe and effective products where classic manufacturing process control may be difficult, time consuming and expensive.
- The RFID data infrastructure provides a powerful and flexible compliance system.

Summary

PRUDUCT DEVELOPMENT CYCLE

Early Need for Data Infrastructure



Summary

PRUDUCT DEVELOPMENT CYCLE

Early Need for Data Infrastructure

Functional

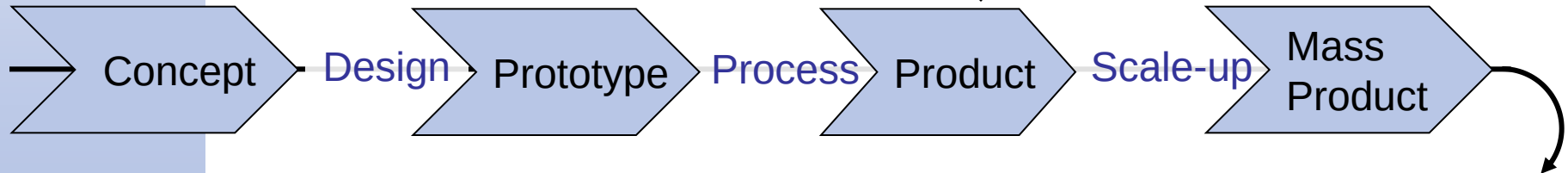
- Empirical Calibration

Clinical

- Clinical Data System
- Reporting

Compliance

- Data Mining/Analysis
- Dashboarding



Summary

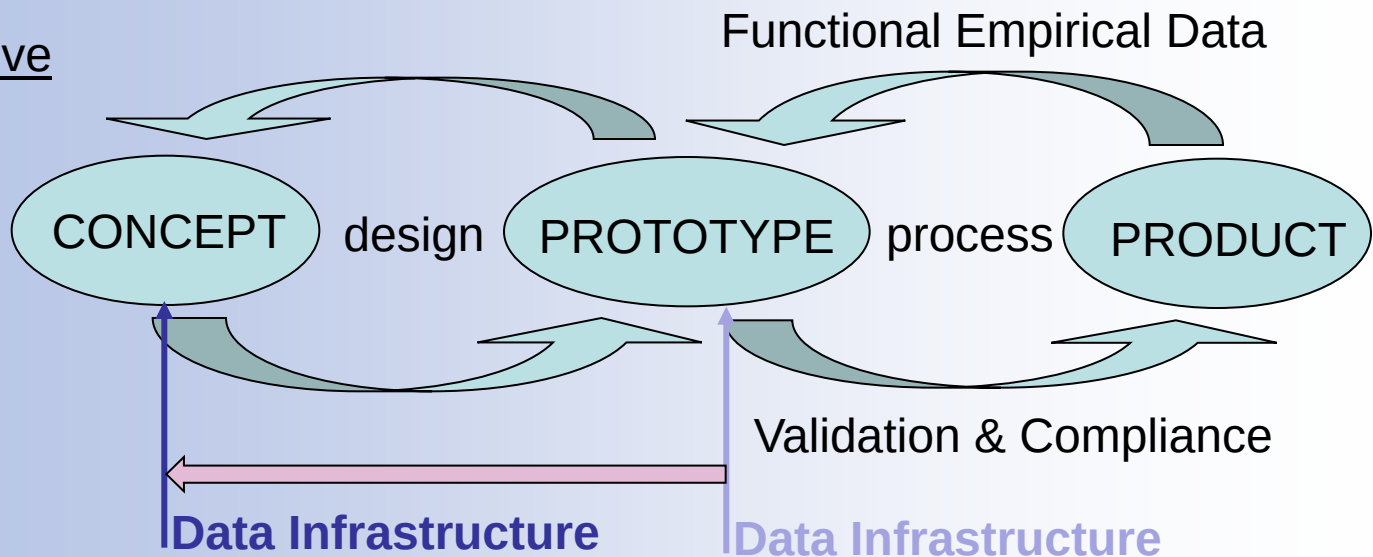
NON-OBVIOUS? VISIONARY?

Classic Product Development Models

Linear



Iterative



Summary

Can **functionality, reliability, yield, TTM** and/or **compliance** be enhanced by adding **smarts** to your products?



Custom Applications



THANK YOU !

... Q&A ...