

## **ON QUANTIFICATION OF TRACEABILITY**

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WE SEE IT!



## THE IMPORTANCE OF TRACEABILITY







#### **PREVENTS COUNTERFEITS**

Drug Counterfeiting Industry: > \$5 billion

- ~18.7% of drugs in Africa are substandard or falsified
- ~13.7% of drugs in Asia are substandard or falsified

#### **KEEPS STAKEHOLDERS ACCOUNTABLE**

Encourages good practices throughout the manufacturing and distribution process, holding every stakeholder accountable for any lapses in quality control.

#### **ENSURES TRANSPARENCY**

Visibility, Assurance to the consumer and regulators about the entire supply chain and quality control measures taken for the production and distribution of life saving products.



#### **INCREASES SUSTAINABILITY**

Reduces the need for sampling and testing for counterfeits throughout the supply chain. Reduction in counterfeits also results in lower destruction/waste of materials used for their production.





## THE EVOLUTION OF SERIALISATION

CODING





(01)09099999543217
(17)100521
(10)ABC123
(21)ABCDEFG123456789























## **QUALITATIVE vs QUANTITATIVE INSPECTION**

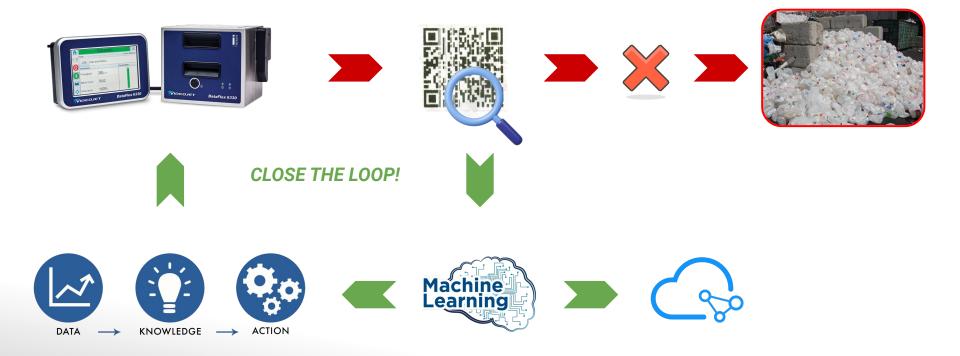






## **QUALITATIVE vs QUANTITATIVE INSPECTION**







### **QUANTITATIVE INSPECTION & TRACEABILITY**





BOTTLE INSPECTEDShape Variability 0.8%, allowed tolerance limit 2.0%<br/>Colour Variability 0.2%, allowed tolerance limit 2.0%TABLETS INSPECTEDAverage Size Variability 0.5%, allowed variability 1.0%<br/>Average Colour Variability 1.0%, allowed variability 2.0%<br/>Average Surface Consistency 2.0%, allowed variability 2.5%INDUCTION SEAL INSPECTEDSealing Temperature 84°C, allowed temperature range 80°C - 87°C<br/>Sealing Variability 3.0%, allowed variability 5.0%LABEL INSPECTEDPosition variability 2.0%, allowed variability 5.0%<br/>Printing variability 3.0%, allowed variability 5.0%<br/>Barcode scanned and verified<br/>Serialisation scanned and verified



## **TODAY'S CHALLENGES IN TRACEABILITY**





#### STAKEHOLDER AGREEMENT









**INTEROPERABILITY** 



REGULATION



IMPLEMENTATION COST



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#### **KEY TAKEAWAY:**

**QUANTIFICATION REDUCES WASTE AND PROVIDES ASSURANCE THROUGH DATA** 

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