ON QUANTIFICATION OF TRACEABILITY

Dr Anupriya Balikai
MANAGING DIRECTOR, SPOOKFISH INNOVATIONS
GLOBAL PHARMACEUTICAL QUALITY SUMMIT 2023

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

PRINTING

INSPECTION
QUALITATIVE vs QUANTITATIVE INSPECTION
QUALITATIVE vs QUANTITATIVE INSPECTION

CLOSE THE LOOP!
QUANTITATIVE INSPECTION & TRACEABILITY

**BOTTLE INSPECTED**
- Shape Variability 0.8%, allowed tolerance limit 2.0%
- Colour Variability 0.2%, allowed tolerance limit 2.0%

**TABLETS INSPECTED**
- Average Size Variability 0.5%, allowed variability 1.0%
- Average Colour Variability 1.0%, allowed variability 2.0%
- Average Surface Consistency 2.0%, allowed variability 2.5%

**INDUCTION SEAL INSPECTED**
- Sealing Temperature 84°C, allowed temperature range 80°C - 87°C
- Sealing Variability 3.0%, allowed variability 5.0%

**LABEL INSPECTED**
- Position variability 2.0%, allowed variability 5.0%
- Printing variability 3.0%, allowed variability 5.0%
- Barcode scanned and verified
- Serialisation scanned and verified
TODAY’S CHALLENGES IN TRACEABILITY

- Stakeholder Agreement
- Interoperability
- Implementation Cost
- Vulnerability
- Regulation

Block Chain
KEY TAKEAWAY:

QUANTIFICATION REDUCES WASTE AND PROVIDES ASSURANCE THROUGH DATA

Dr ANUPRIYA BALIKAI
anupriya@spookfish.vision
www.spookfish.vision