SIGNAKEY

A Unique Coding Solution for Pharmaceutical Operations

SignaKey® Founders' Story

Richard McDermott

1975 - Leeds University, PhD Mechanical Engineering

1976 - Immigrated to US to WR Grace

1981 Purchased MSP Industries from WR Grace

Owned & Operated 35 Business's

2002 - Met Maybaum at Infoglyph

2002 - Became Infoglyph Customer

2007 - Purchased 100% Infoglyph

2011 - Maybaum & McDermott Create SignaKey®

William Maybaum

1963 - Completes Service with US Airforce

1970 - Graduates MSU; B.S. System Analysis

1970-1990 - Large Telecoms & Network Consulting

1990 - Fidelity Systems, President Telecom

2001 - Co-founds Infoglyph

2002 - Licensed Infoglyph labels to Bytec

2007 - Infoglyph Purchased

2011 - SignaKey® is Created

SignaKey® for Pharma Overview

What Is a Signakey®?

- Highly Compressed, 2D Machine Readable Code.
- Uses Hexadecimal Data Symbols
- Extremely High-density Data Carrier - Unlimited Amount of Data per Mark
- Read by Conventional Camera Lens (e.g., Smartphone), CCD or Line Scan
- Used in Other Industries for 12+ Years (Direct Part Marking, Labels)
- Femtosecond Laser with Patented Controls Enable Optimal Solution for Pharmaceutical Glassware

Compare to other 2D Codes

- Smallest with Highest Error Correction
- Applied WITHIN Glass wall of Vial/Syringe/Cartridge; Cannot be Further Damaged by Rough Handling
- No Physical Impact to Glass or change to Chemical Properties - Minimal Regulatory Implication
- Low Contrast Mark Does NOT Interfere with Visual Inspection Processes.
- Withstands 320C Pharmaceutical Depyrogenation Cycle

Value of Unit Level ID

- Marked at Point of Glassware Creation
- ‘License Plate” to Enable Unit Level capture of Quality Attribute Data at Glass Supplier & Pharma
- Enable Zero False Rejections at AVI
- Tighter Investigation “Ring Fencing”
- Prevention of Mix-Ups
- Counterfeiting Deterrent - Overt Visual Hurdle
- Easily Tied to Line Level Serialization Program

HEAD-TO-HEAD COMPARRISON

12 Digits - 999,999,999,999 - One Trillion Numbers

Data Matrix

SignaKey®

- 1.2mm Size limited to 12 Digits
- MAXIMUM 50% Error Correction
- Non-encrypted
- Does not Survive Depyrogenation*

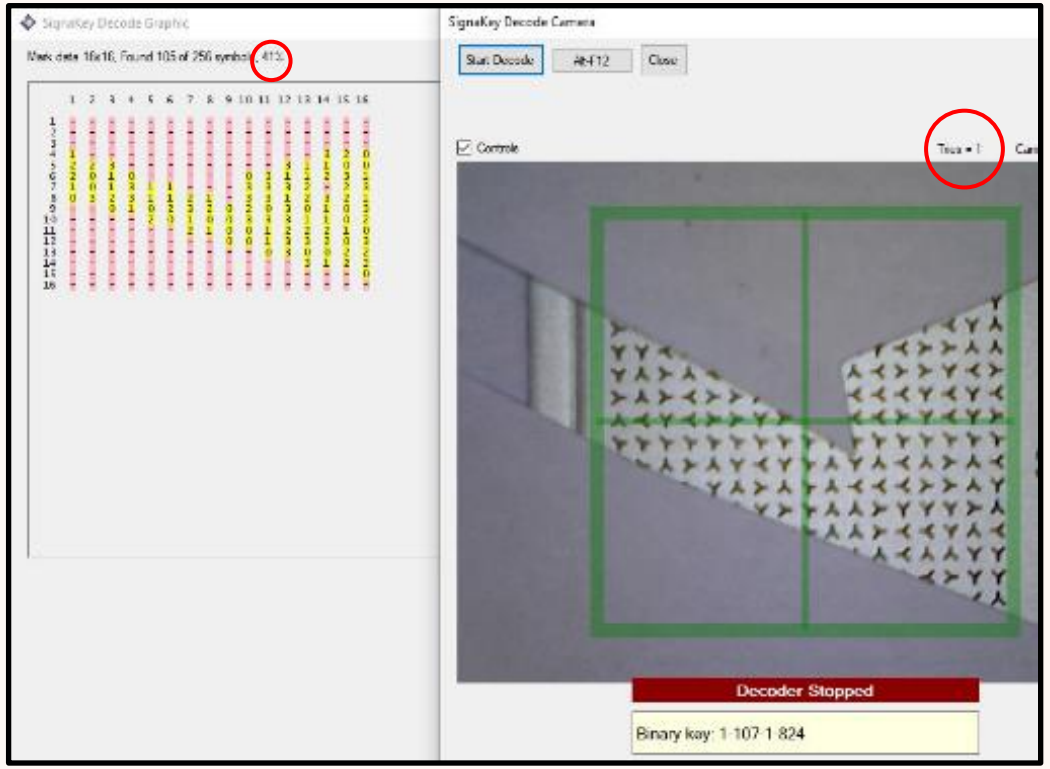
- 0.8mm Size - LIMITLESS Numbers
- 60% Error Correction
- Encrypted
- Survives Depyrogenation*

SignaKey®

Best Fit for Pharma Glass Applications

* When Applied within Glass

SignaKey® Error Correction



SignaKey® decode 1st Try even with 59% Error Correction

Various Proven Applications

Printed

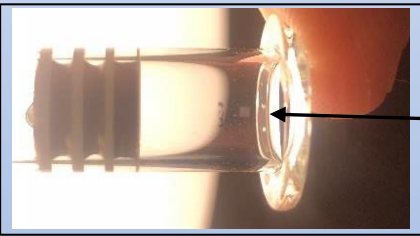
SARS Tobacco Tax Stamp
33 Million/Week
Overt & Covert Features

Cannabis Sample Tests
25.0 x 25.0
Tamper Evident Labels

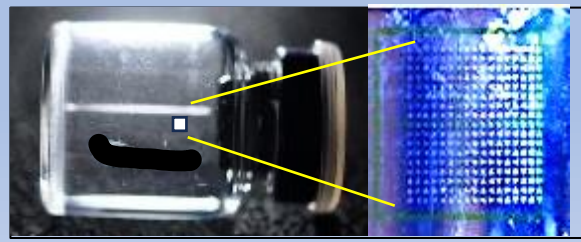
$52.00 Driveshaft
Assembly, Ford; >1 Million
Printed, Polymer Labels

Laser Marked

Stainless Steel, GM
10.0 x 10.0 mm
Fiber Laser



PFS, Large Pharma
0.8 X 0.8 mm
Femtosecond Laser

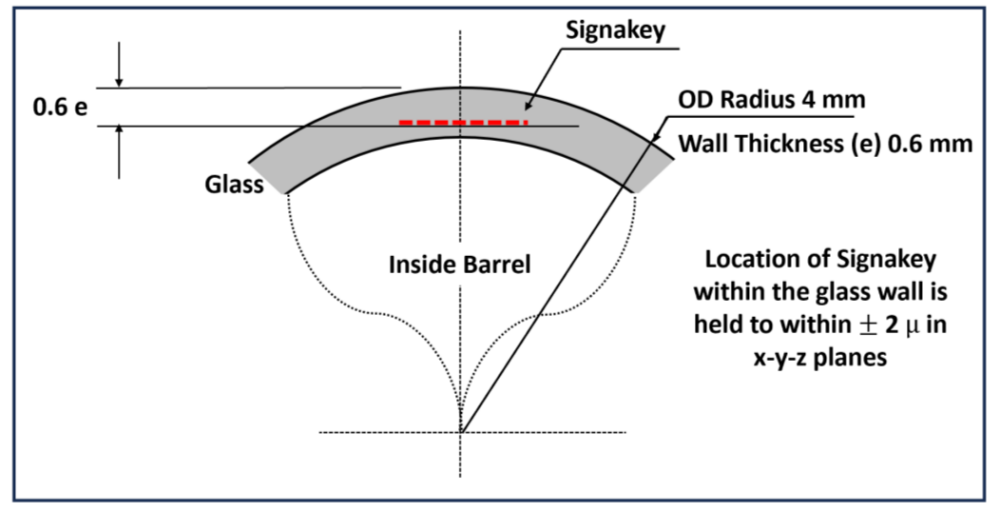


Vial, Large Pharma
2.0 X 2.0 mm
Femtosecond Laser

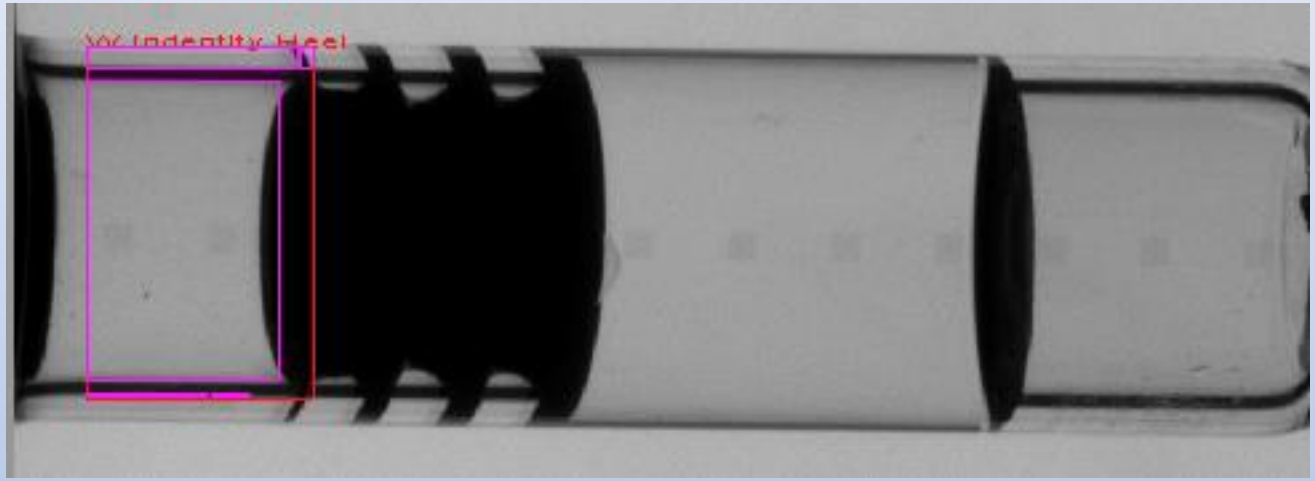
Controlled Laser Marking

LASEA Partnership
Control is Everything

- Patented Technology -
  - Femtoseconds Laser - Ultra High Frequency
    - Changes the Refractive Index of the Glass
  - NAGINELS® - **N**on-**A**ggressive **G**lass **In**ternal **E**ngraving **L**aser **S**ystem
    - Ensures no Microfractures of the Glass
  - Location of Signakey® within the wall held to within ± 2 µ in all x-y-z planes

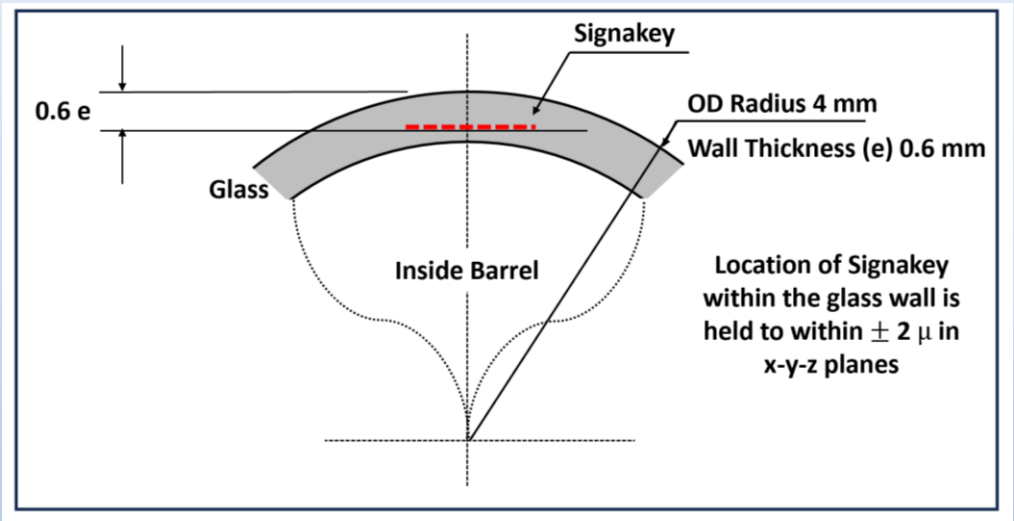


BIOPHARMA SYRINGE
(SignaKey Example)



0.8 x 0.8 mm Signakey®

Very Small Mark



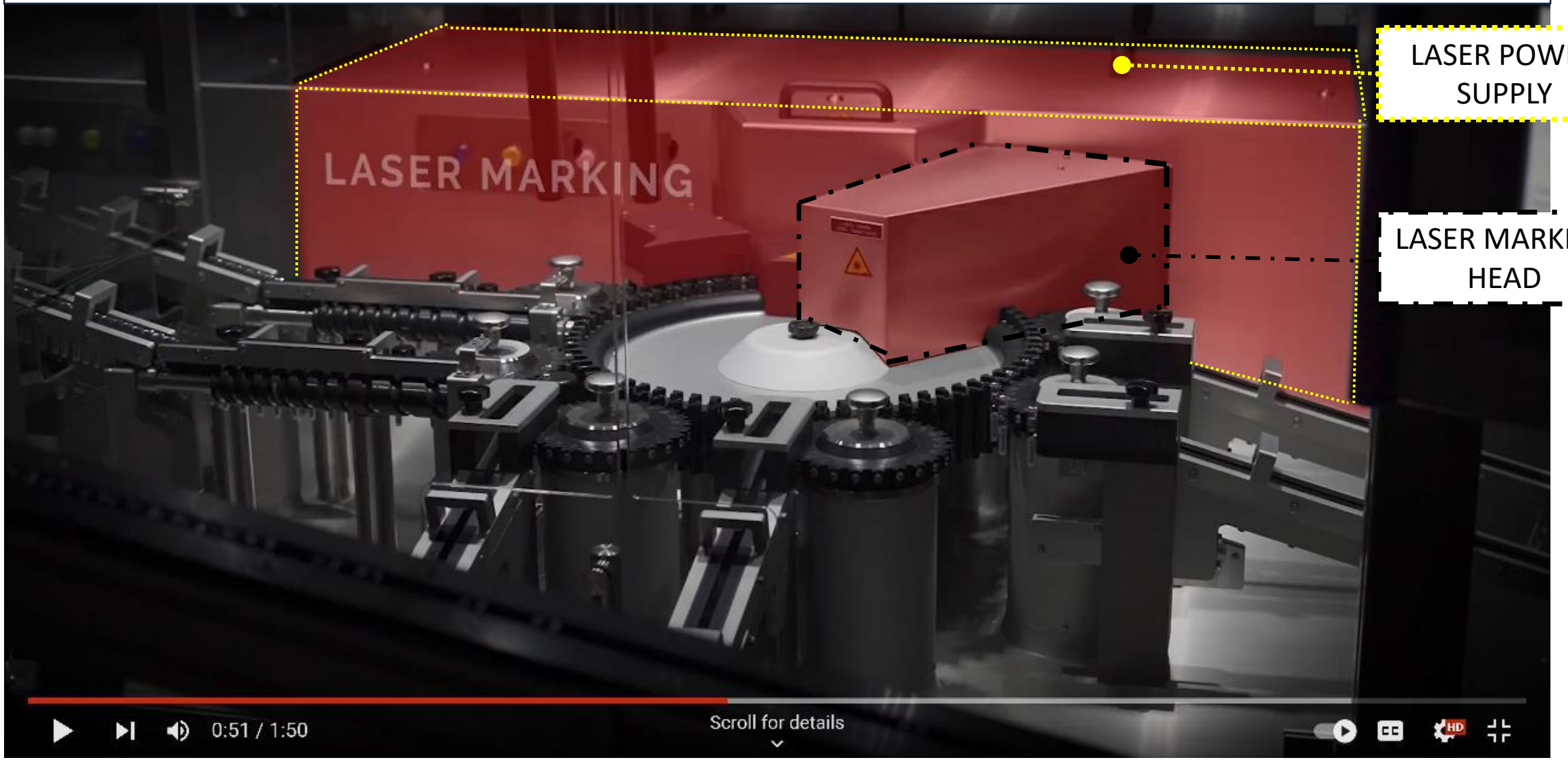
Resides FLAT within Glass Wall

Improved Readability -

No Radius Concerns as when a Far Larger Code Sits ON Glass

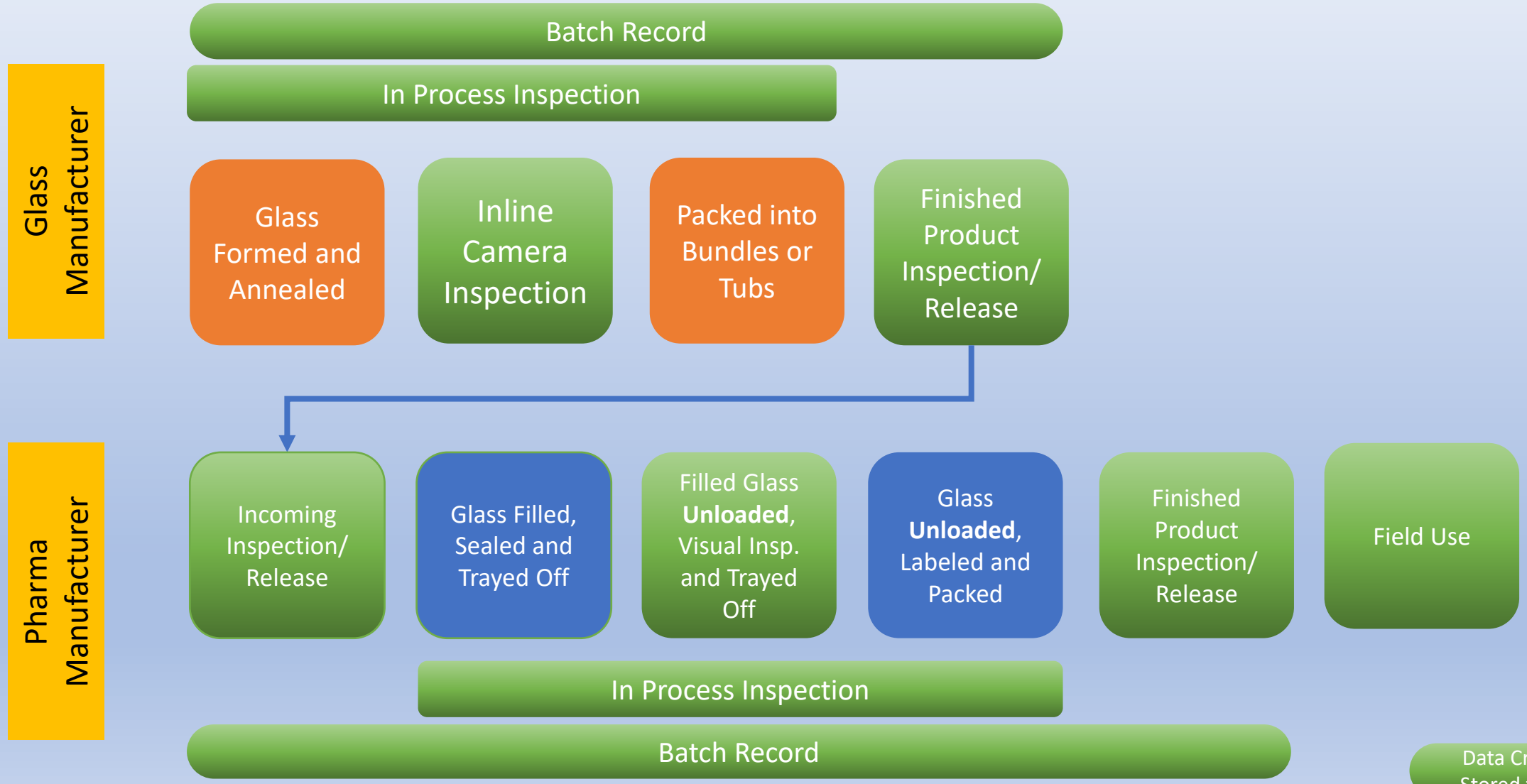
SIGNAKEY

FEMTOSECOND LASER COMPONENTS IN AUTOMATED LINE



A Glass Component's Point of View of Life

Key Operations and Data Capture Points



Serialize and Tie Captured Data to the Unit Level

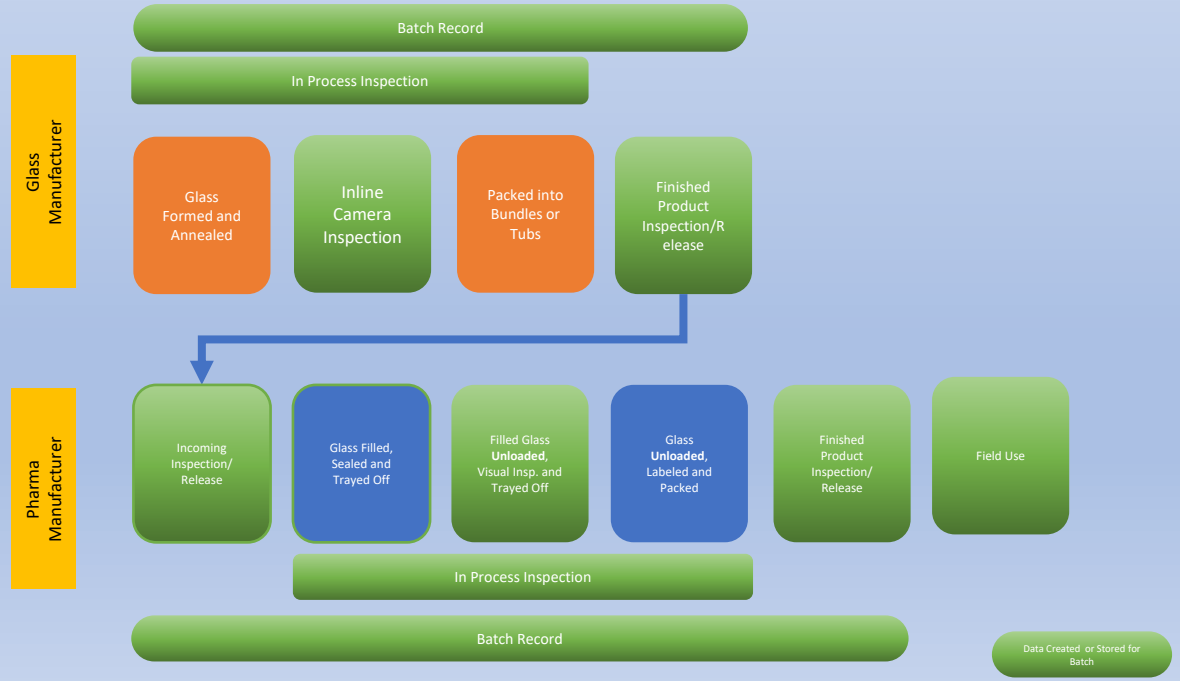
What Does it Get You Operationally?

- Create Full Component History (and that of those around it); Not Just Batch
- If you Track it, you can Trace it (when needed)
- Facilitates End to End Continuous Improvement Programs
- Identify Process “drifts” and React More Quickly to Trends
- Streamline Investigations and Reduce Quarantine Quantities
- Eliminate Glassware Incoming Dimensional Inspection
- Reach Zero False Rejects during AVI
- Mitigate Potential for Bright Stock Mix-ups

Example of Data that Can Tied to Glass Component

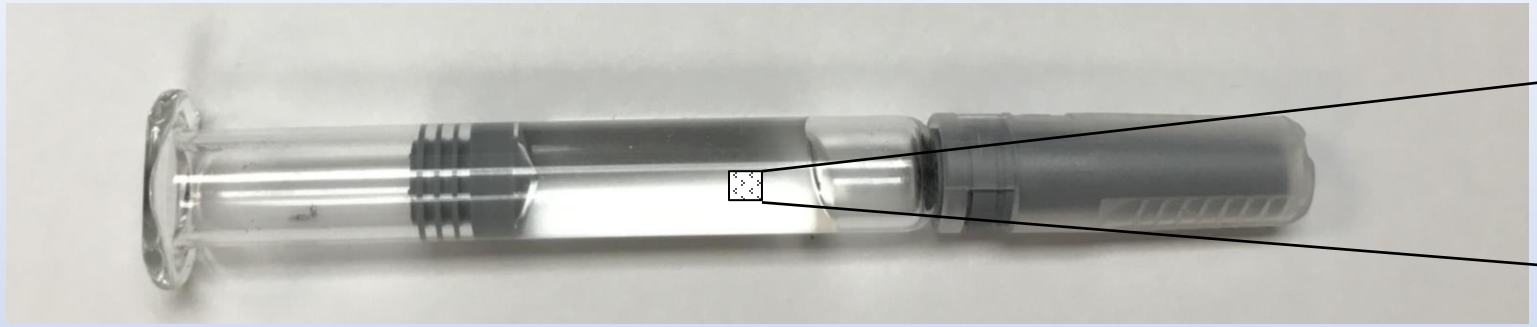
SN 54345123

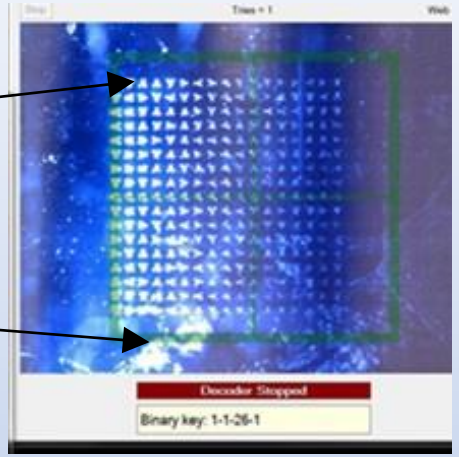
Time/Date converted
Time/Date Dimensional Data
Date Batch/Glass Released
Date Received/Inspected/Released
Date Batch/Glass Filled/Needle
Confirmation of Right Product/Batch
Date/Time Inspected with Data/Images Found
Confirmation of Right Product/Batch
Date/Time Labeled/Packed
Any Field Field Data (e.g., crack found)
Suspected Counterfeit Authentication



Marked Ready To Fill Syringes

Filling Example





1 - Syringes are Marked and “Registered” During Manufacturing Process

2 - Marked Syringes Locations Defined and Stored as Syringes are Organized for Tray at Syringe Manufacturer

3 - Filling Needle, Date/Time Captured for each location and tied to syringe ID

Critical Data to have for Investigations - Not Possible Today

SIGNAKEY

OPPORTUNITY FOR THE GLASS SUPPLIER

- The SignaKey® Technology is applicable to ALL pharma glass products.
  - Tubular & Molded
  - Vials, Syringes, Cartridges, Ampoules

- Pharma's typically will not Single Source a glass supplier
  - They Favor Industry-wide Solutions
  - Industry-wide Solutions Drive Down Overall Costs

- Licensing
  - Glass Suppliers License Technology from SignaKey® to Mark and Decode.
  - Pharma's License Technology from Signakey® to Decode.

- Adoption Rates
  - Early Adopter Incentives
  - Volume Driven Pricing