TraC – A disruptive new hand-held rapid measurement system to verify pharma equipment surface cleanliness

Presented by:

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President, Photon Systems

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Agenda

- Present method of cleaning verification
- Benefits of the direct, non-contact, surface analysis
- The method
- Automated calibration –chemical printers & mappers
- Some technical details
- On the horizon

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Rapid Cleaning Validation/Verification (RCV)

Problem:

Cleanliness must be verified between batches. The current process uses time consuming and error prone technologies (i.e. swabbing).

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The Solution

The goal

To augment or replace the present swab & test method for equipment cleaning verification with a faster and better controlled and documented method.

The solution

A handheld device that quantifies trace amounts of API in real time on manufacturing surfaces.

Result: Significantly reducing production down time.

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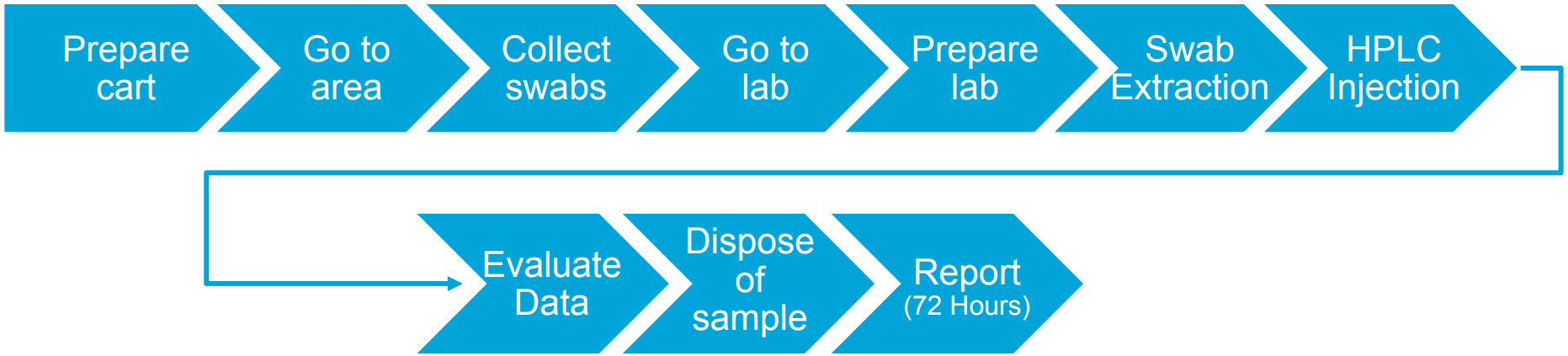
Current and future cleaning verification in plants

Steps in today's traditional swab & test methods



Steps for today's TraC sensor

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An introduction to RCV

The drivers for Rapid Cleaning Verification Methods

Quality

- Reduction of human errors
- Reduction of the “art” of sample acquisition and testing
- Decreased risk to production

Safety

- Decreasing the number of operations
- Improving knowledge
- Reducing/improving cleaning cycles

Cycle Time

- Processing samples on the “shop floor”
- Enabling business decisions at the point of process
- Decreased wait time

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Tricorder then vs “TraCorder” now
Sensing, Computing and Recording

TraC: A Trace Chemical Detector

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Benefits of TraC Sensor

A new way of
seeing things

Feature & benefits of TraC

- Non-contact surface analysis: 0 to 1 cm standoff.
- Hand held: < 2 lbs.
- Real-time: 1 sec test time.
- In situ: inside equipment at the equipment site.
- No consumables.
- Non destructive & non-contact: does not disturb sample.
  - ✓ Allows further testing by traditional methods.
- Limit of Detection: < 1 $\mu g/cm^2$
- Specificity: > 95% differentiability of APIs, excipients, etc.
- Built-in microcomputer & display.
- Built-in NIST Tracible functional test.
- GMP: good manufacturing practice.
- Long battery lifetime: > 36 hours

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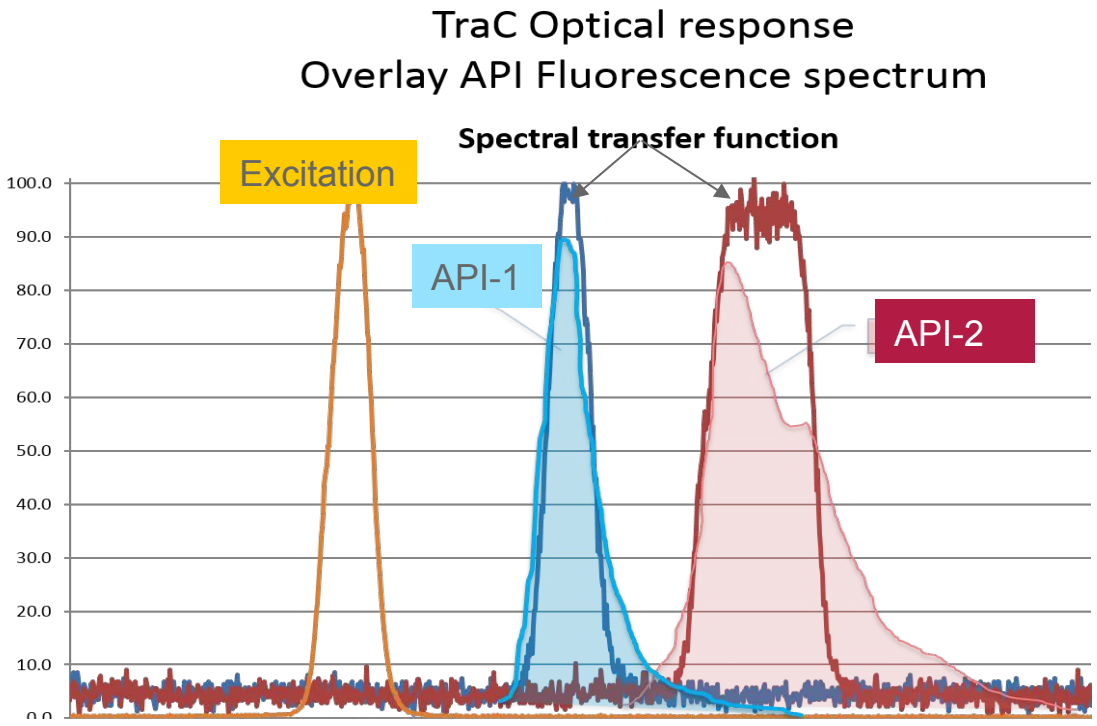
The method: deep UV multichannel fluorescence



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Method of Detection

FOR EACH SPOT/PIXEL/AREA ANALYZED:

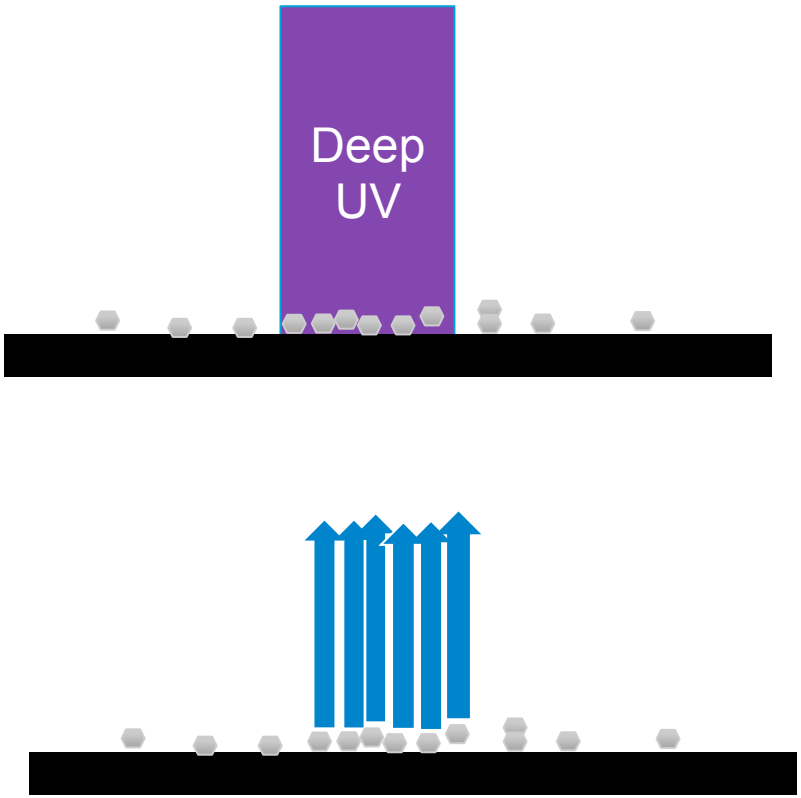
Step 1: Deep-UV source illuminates surface

Natural surface that may contain residual API (no preparation required)

Step 2. Deep UV interaction with sample causes native fluorescence emission, returning back to the Instrument, without the need for reagents.

Step 3. Collected light is collected in 180 degree backscatter, separated, and detected with a multichannel detector.

Step 4. Multichannel spectral data is processed & stored with site, API, & position information. Repeat for all sample locations in machine.



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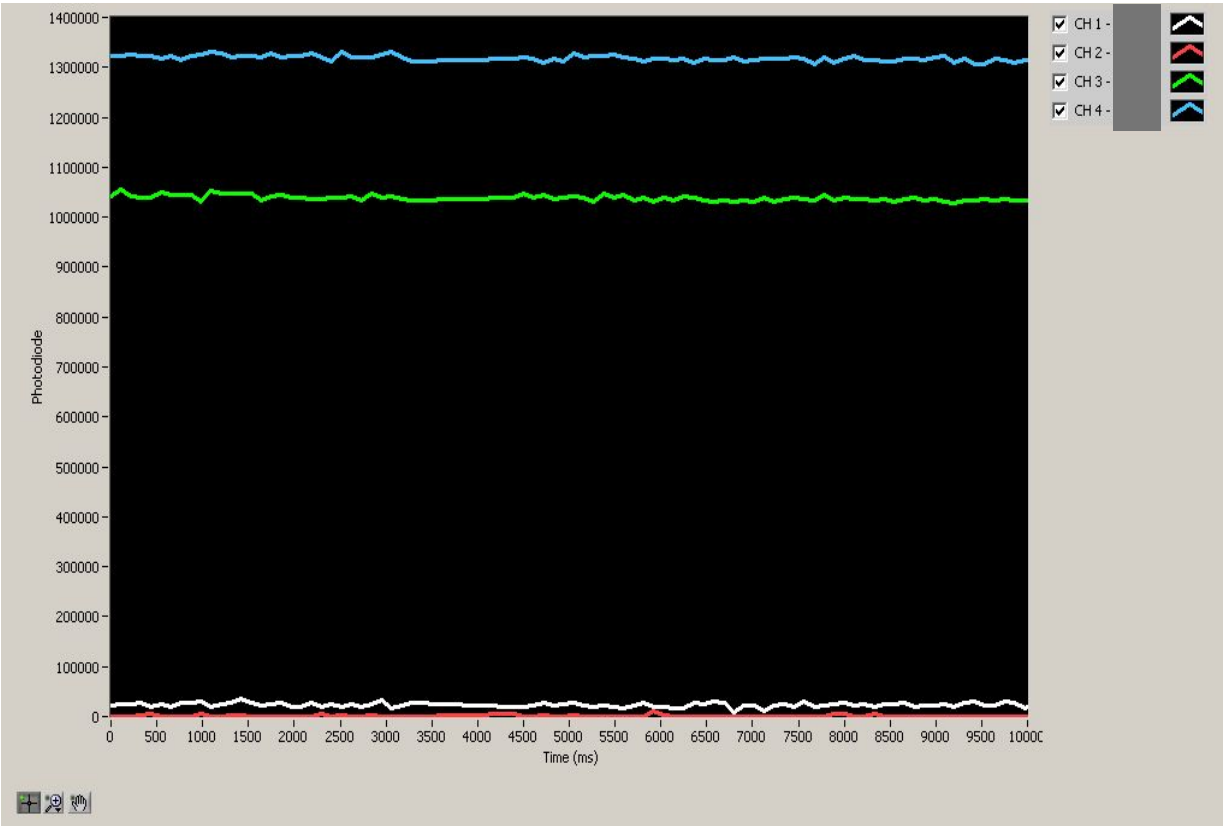
TraC Data Output

Typical Signal Output by channel vs. time (pts)



Typical signal to noise for APIs is > 400.

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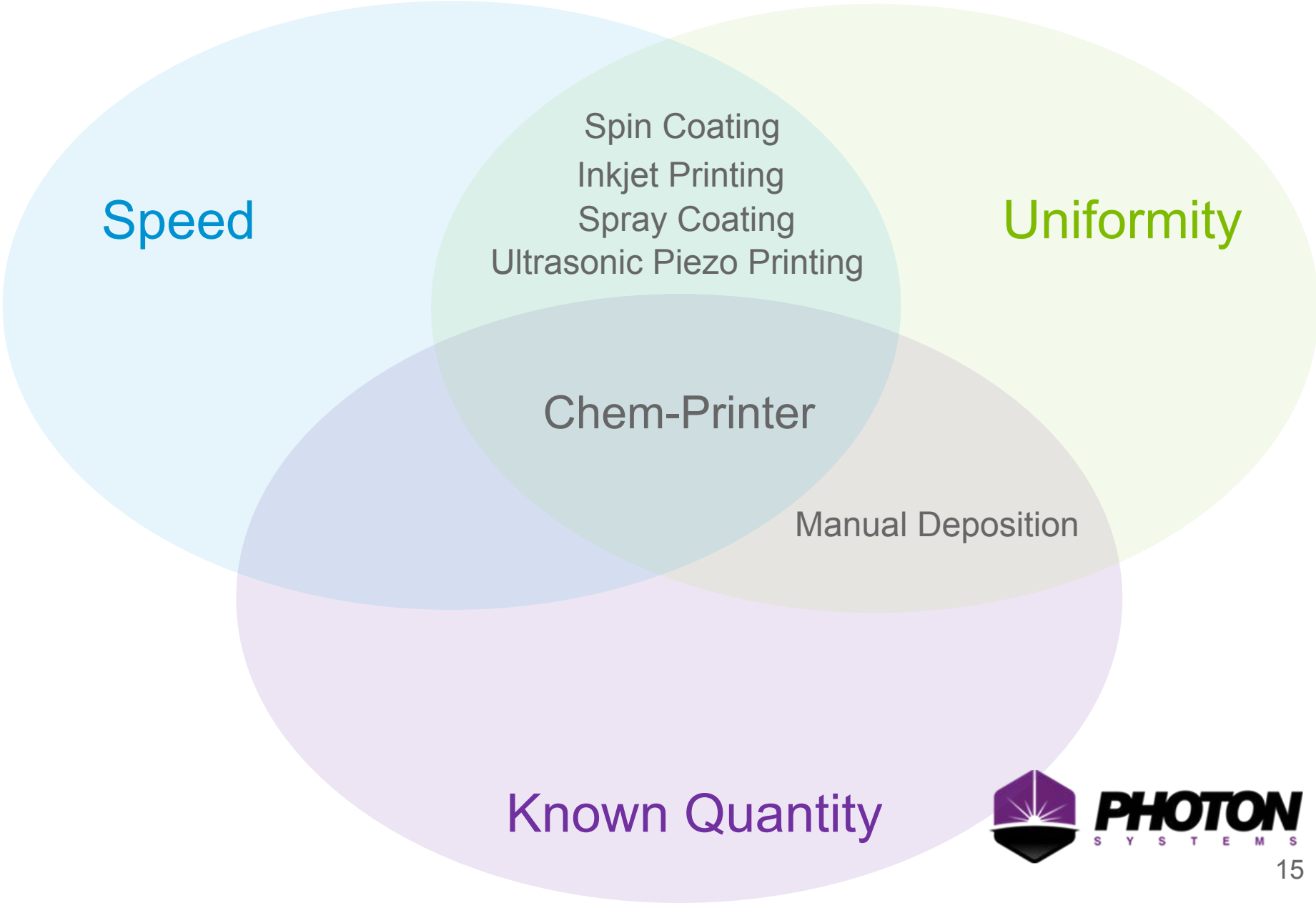
Taking the TraC from a data collection instrument to a calibrated instrument.

Problem:

Generating and scanning homogenous chemical concentrations on controlled surfaces that are representative of different pharma equipment.

Current state of chemical printing



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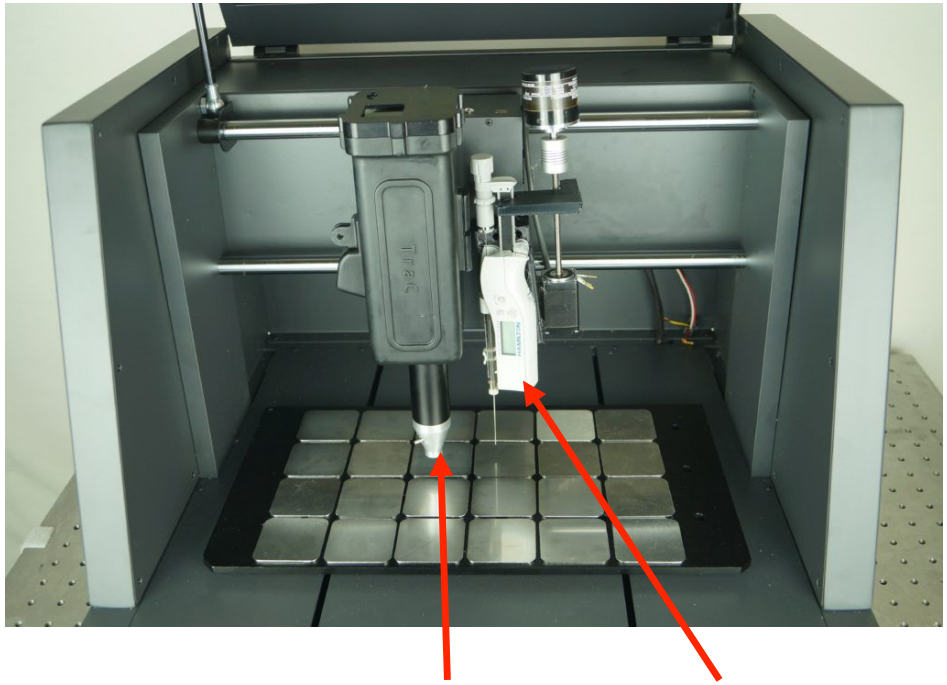
ChemCal: A chemical printer & mapper



TraC sensor ChemPrint head
on common XY mapping stage

Operational Scenario:

- Load APIs in Eppendorf rack.
- Load coupons onto tray.
- Press Start.
- The system outputs a full calibration curve in under 3 hours. (Print and scan 18 coupons.)

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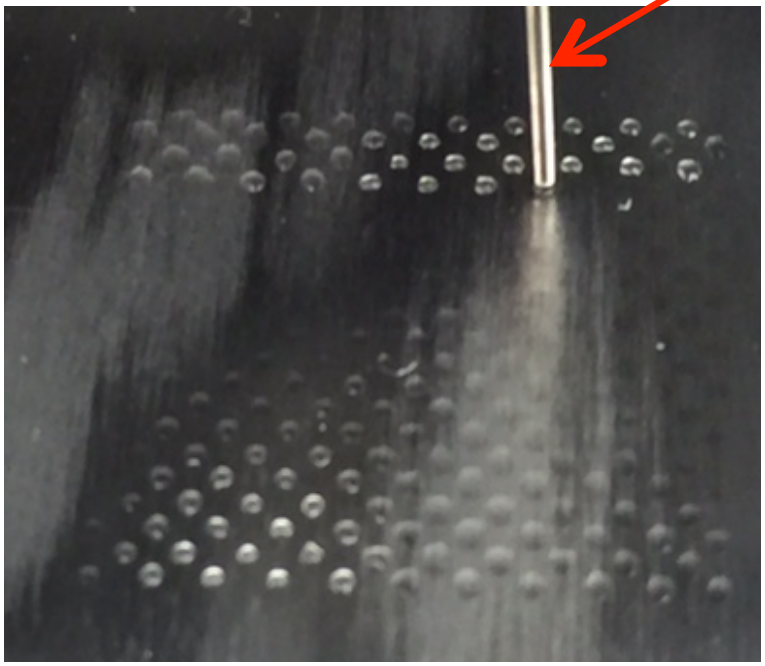
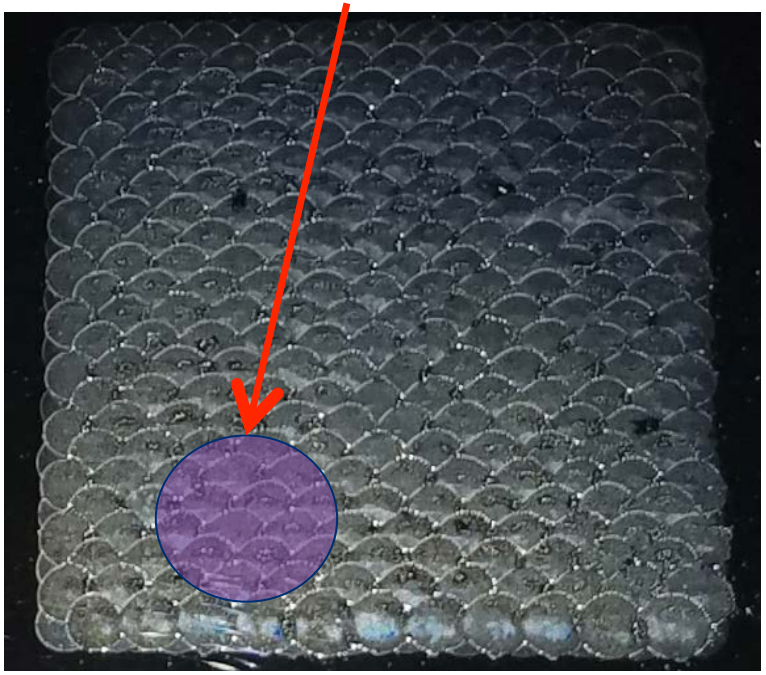
Printing

Up to 5x5 cm grid

NIST Tracible Syringe



TraC Beam Diameter



High surface tension solvent.
Individual drops.

Low surface tension solvent.
“Fish Scale Pattern” Overlapping drops

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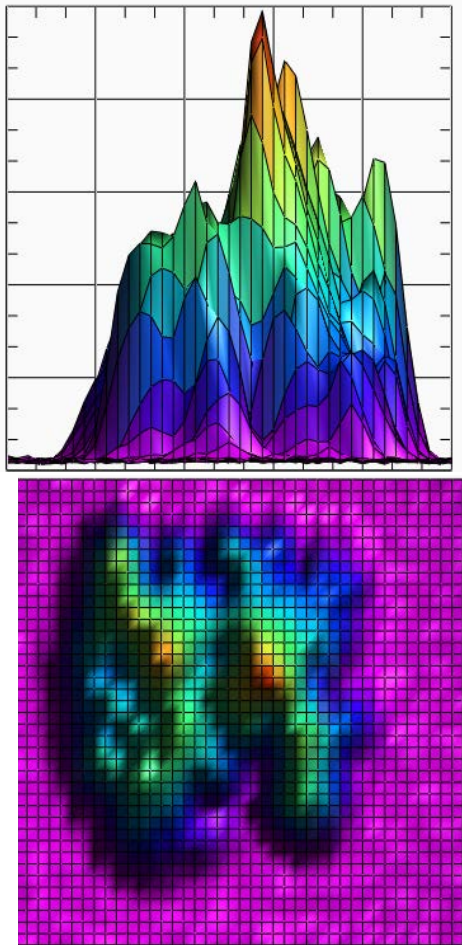
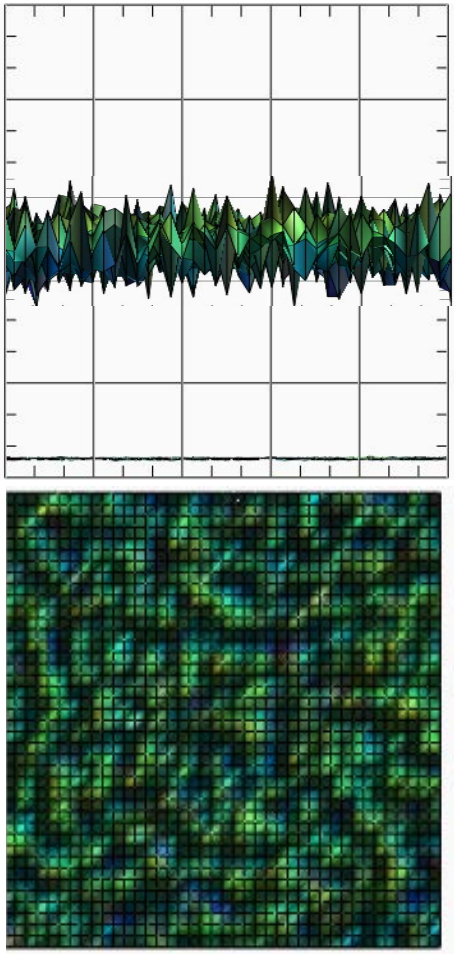
Heatmaps of 2d Chemical Scan

Non Homogenous Deposition



Automated Deposition



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ChemCal: A chemical printer & mapper

- Instrument for surface chemical concentration calibration
  - ✓ Includes a surface chemical printer
    - Produces known chemical concentrations on surfaces.
    - Generates 2D areal concentrations from <1 ng/cm^2 to > 10 mg/cm^2
    - Can Overlay/interleave 15 different chemicals. (APIs Excipients etc.)
    - Droplet size: 1 - 50 nL.
    - Multitude of Solvents (Water, Alcohols, Acetonitrile etc.)
    - Uniform chemical deposition.
    - Wide range of substrate surface materials.
    - Able to deposit on a wide range of surface topography (Mesh etc.).
  - ✓ Includes a chemical mapper to scan the TraC.
  - ✓ Enables automatic generation of a chemical concentration curve.

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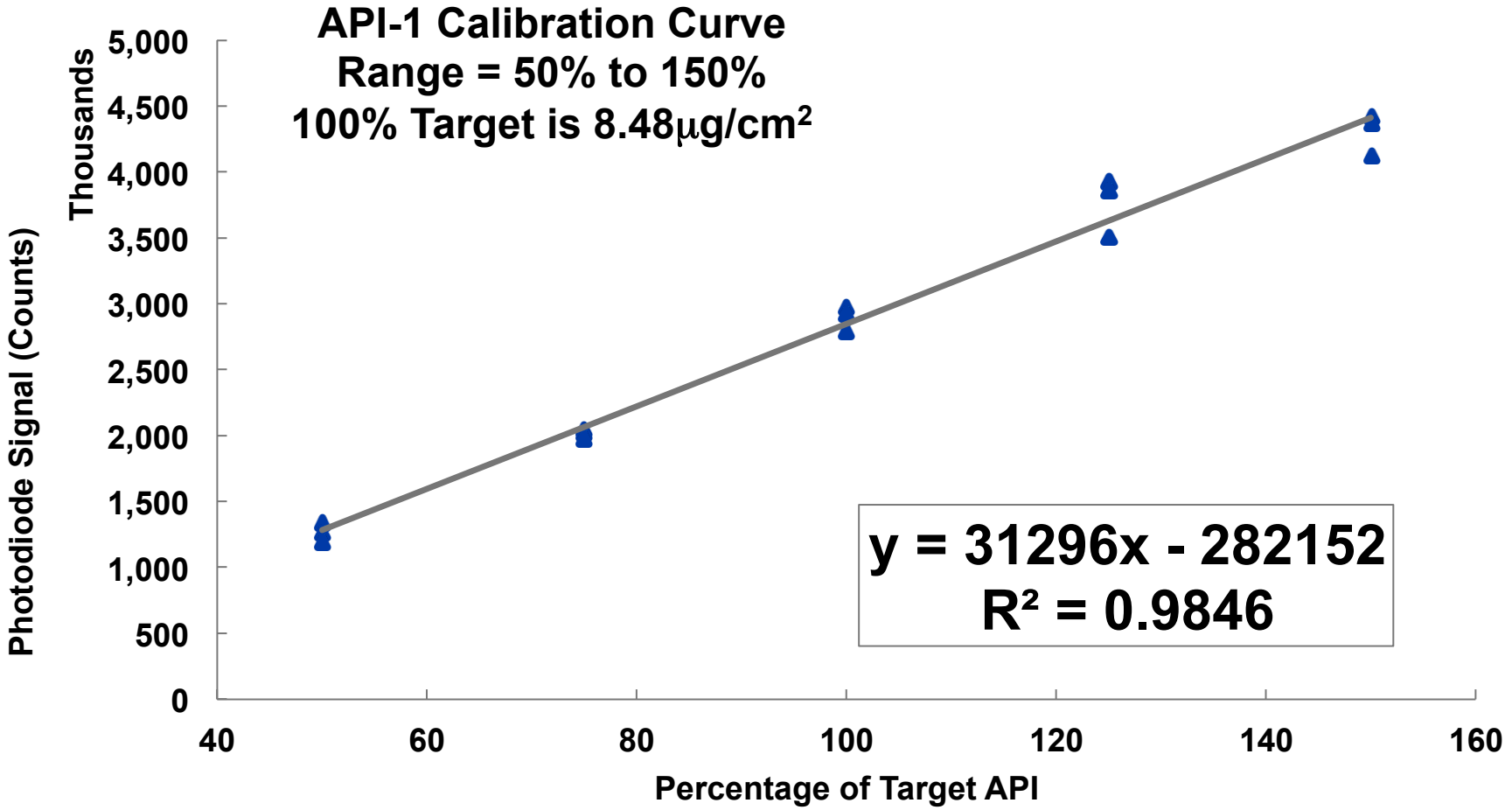
Automated API concentration calibration



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TraC-X: Our future "TraCorder"

Impact on future methods and compliance

Fully self-contained sensor with on-board computation and display of chemical concentration. Enabling go/no-go certification of results.

Provides dramatic savings in cost and speed for certification of machine cleanliness compliance.

Other applications:

Hot Spot cleaning detection.

Trace contamination non production areas (i.e. shipping and receiving).

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The crew

This instrument is the result of a technology development collaboration between Photon Systems and Pfizer

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