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

Presented by:

Ray Reid,
President, Photon Systems

Come see this at our booth # 514

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 – fully self-contained, real-time, results

Present & proposed method

Surface sampling for cleaning verification
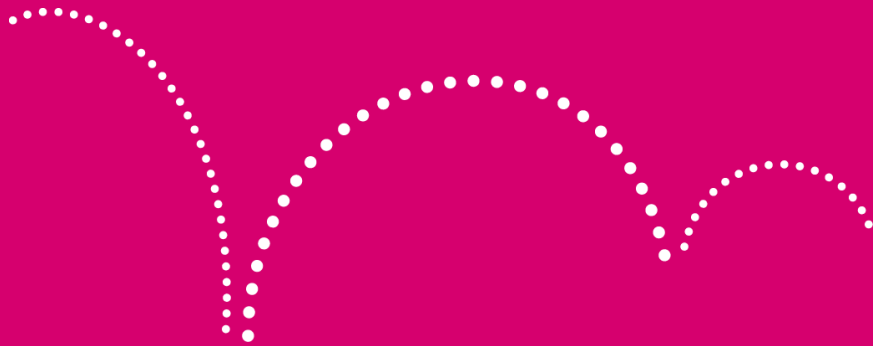
The goal

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

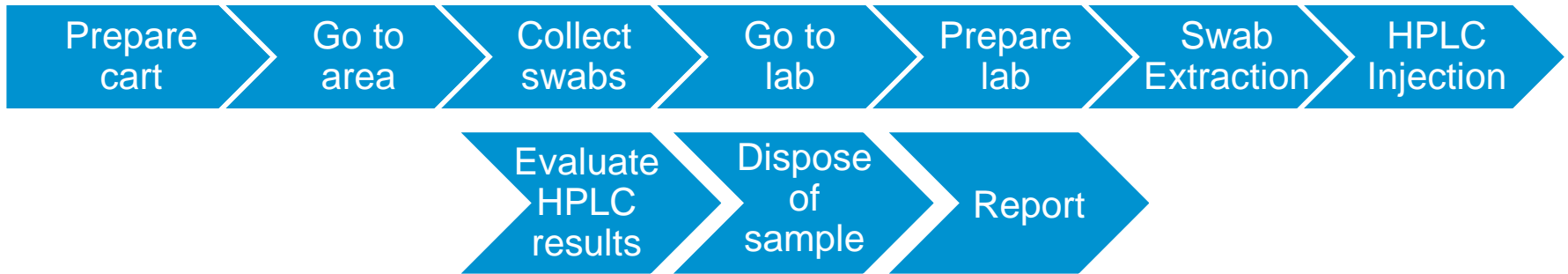## **The opportunity**

Develop a handheld system that can detect & quantify in real-time and without contact, trace levels of APIs on pharmaceutical manufacturing equipment and surfaces, with performances meeting current standards & pharmacopeia requirements

PHOTON
SYSTEMS

Present & proposed cleaning verification in our plants

Steps in today's traditional swab & test methods

Prepare cart → Go to area → Collect swabs → Go to lab → Prepare lab → Swab Extraction → HPLC Injection

Evaluate HPLC results → Dispose of sample → Report

Steps for today's proposed scenario using non-contact TraC sensor

Prepare cart → Go to area → Collect TraC Data → Evaluate Data → Report

PHOTON SYSTEMS

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
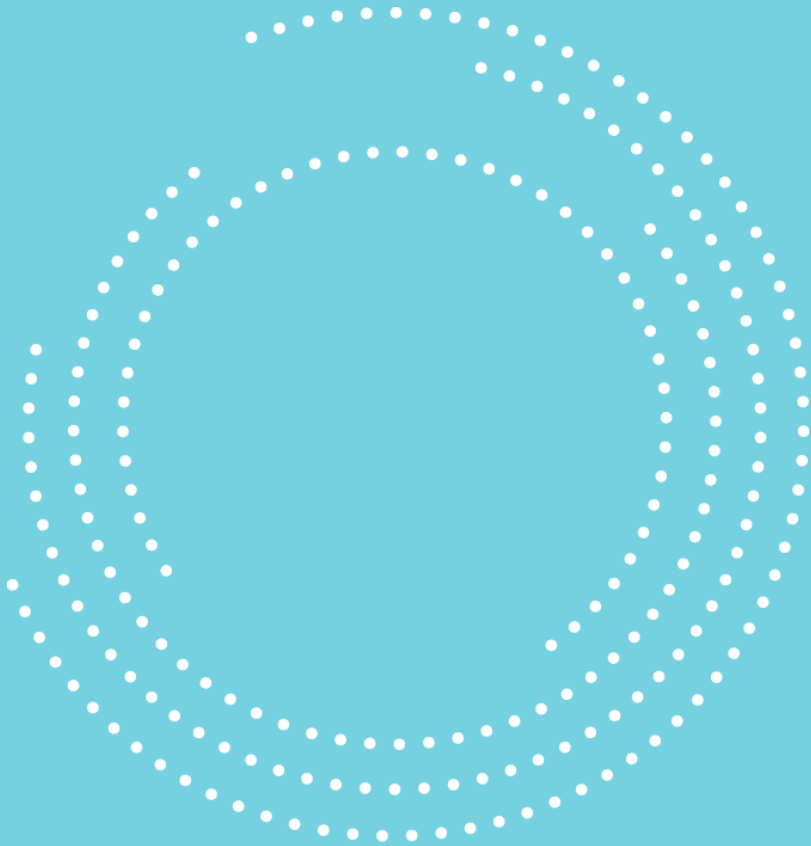- Decreased risk to production

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

PHOTON SYSTEMS

Tricorder then vs TraCorder now
Sensing, Computing and Recording

Benefits of TraC Sensor

A new way of
## seeing things

Feature & benefits of TraC

- Direct non-contact surface analysis: 0.5 to 2 cm standoff
- Hand held: < 2 lbs
- Real-time: <0.1 sec typical test time, <1 sec max
  - ✓ rapidly finds hot spots for further testing
- In situ: inside equipment at the equipment site
- No consumables: reagent-less and 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 for instrument control & future data processing and information display
- Built-in sensor global instrument function (bump) test
- GMP: good manufacturing practice
- Long battery lifetime: > 36 hours

PHOTON
S Y S T E M S

The method: deep UV multichannel fluorescence

TraC Optical response
Overlay API Fluorescence spectrum

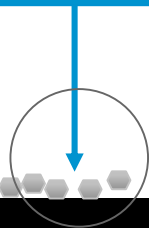**Spectral transfer function**
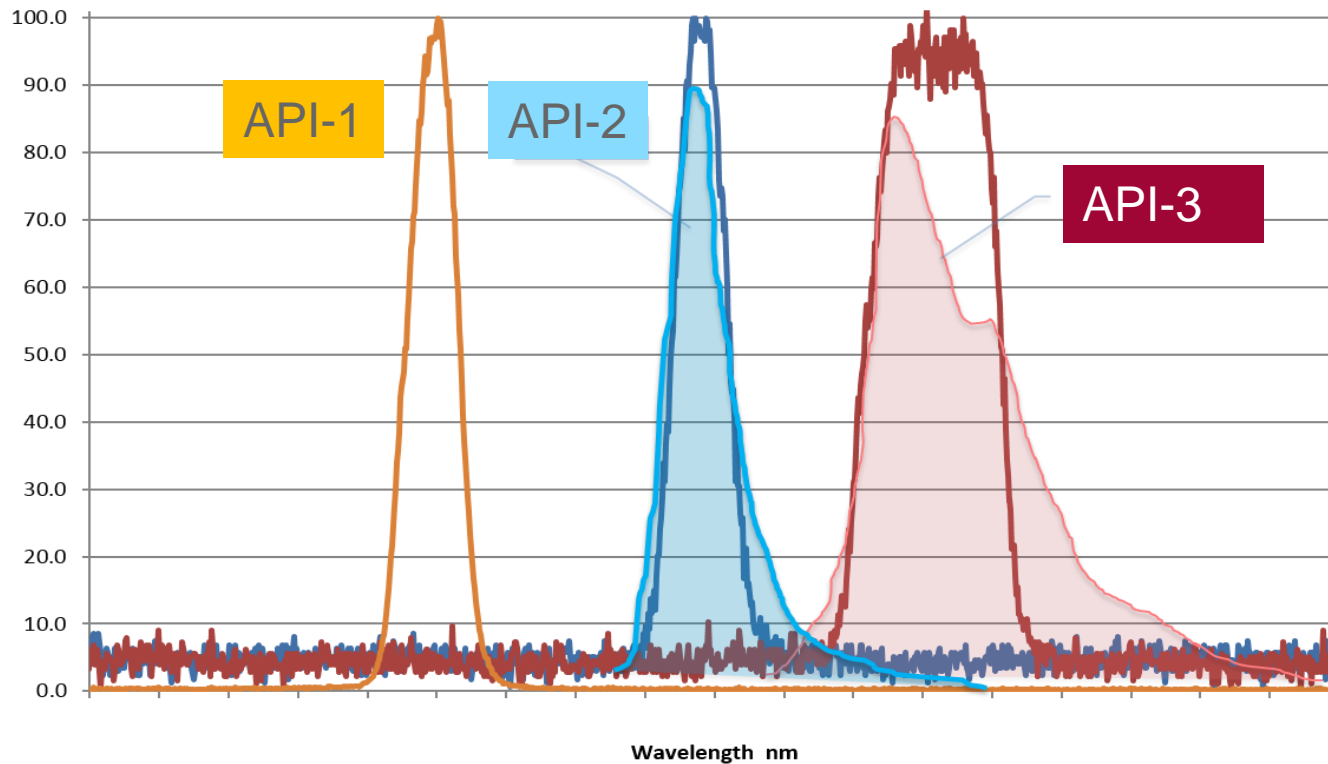
Method of Detection

FOR EACH SPOT/PIXEL/AREA ANALYZED:
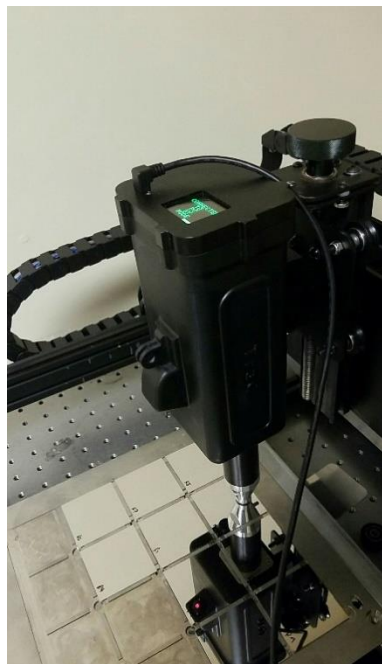
Step 1: Deep-UV source illuminates surface

Deep UV

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 positions in machine.
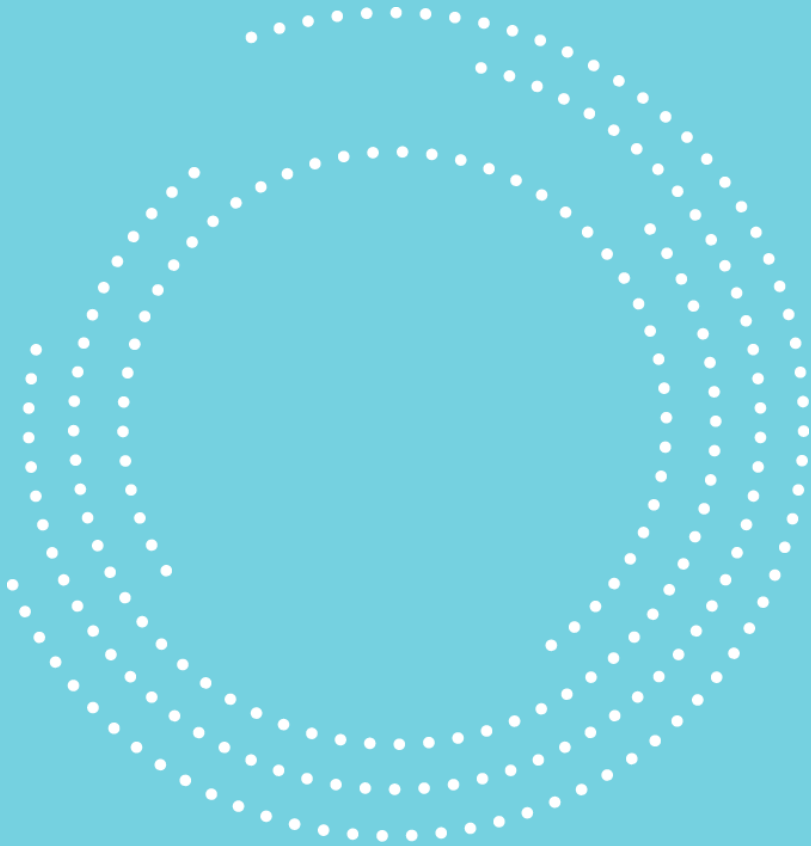
Step 5. Download data for processing with Pfizer cleaning verification software. Future sensors may be enabled for real-time, in situ, analysis.

PHOTON SYSTEMS
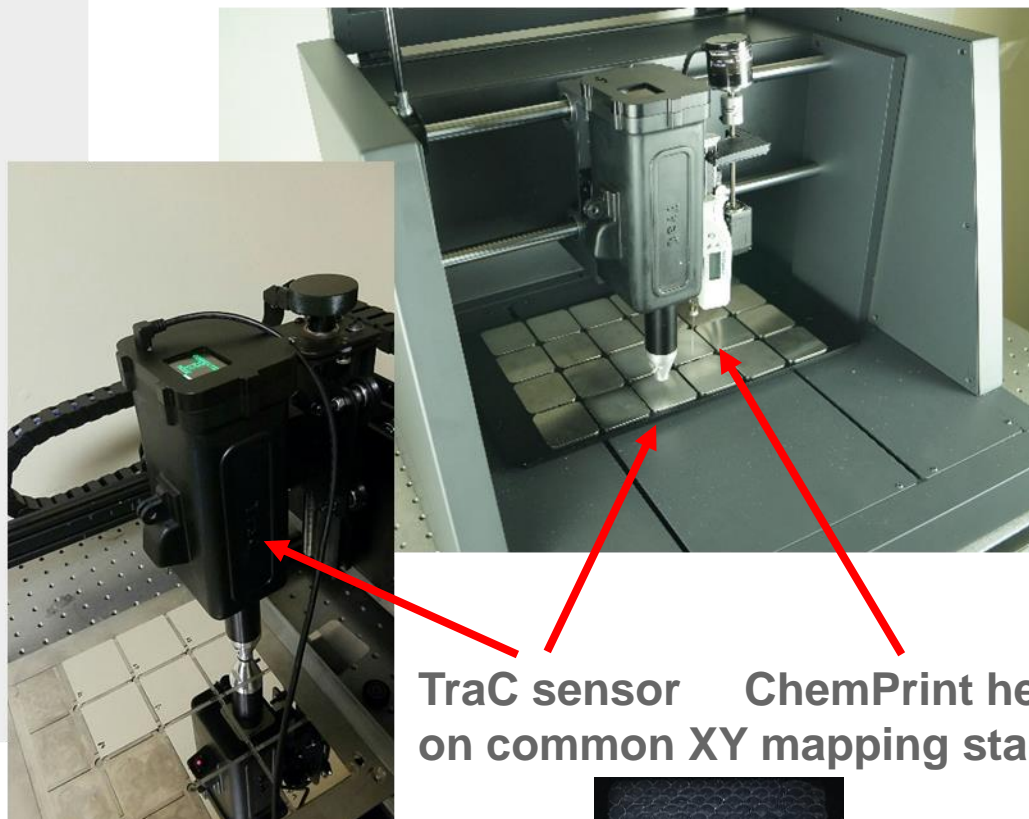
Validation of TraC

Sensitivity & Specificity

All hands on deck

Proofing the concept

ChemCal: A chemical printer & mapper

TraC sensor ChemPrint head
on common XY mapping stage

Come see this at our booth # 514
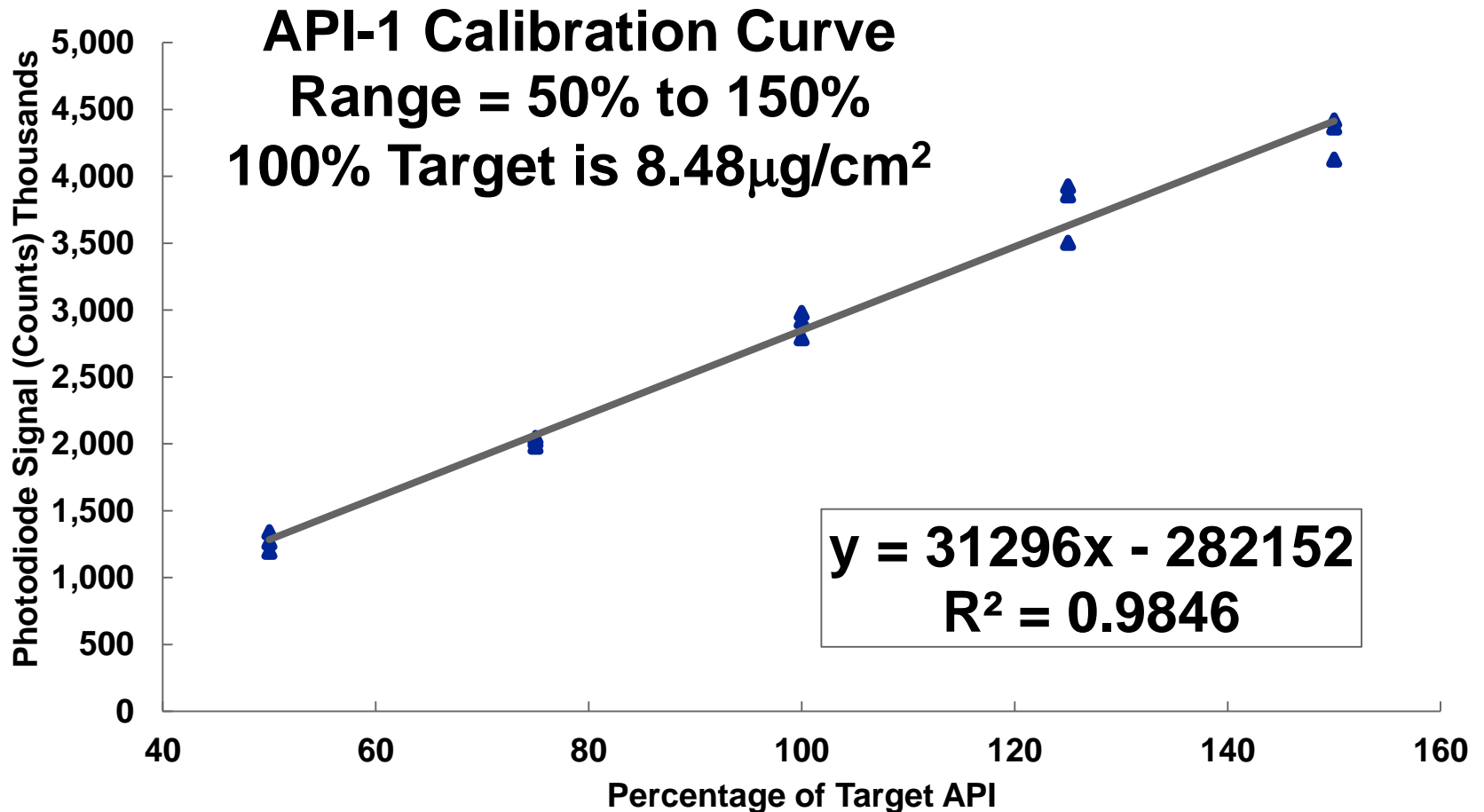
PHOTON
S Y S T E M S

ChemCal: A chemical printer & mapper

- An instrument for chemical concentration calibration
  - ✓ Includes a surface chemical printer
    - ○ Produces known chemical concentrations on surfaces
    - ○ Generates 2D arrays of known chemical droplets to produce known areal concentrations in the range from <1 ng/cm^2 to > 10 mg/cm^2
    - ○ Wide range of chemicals & mixtures: over 15 different chemicals interleaved or overlayed
    - ○ Droplet size: 1 - 50 nL
    - ○ Uniform, pseudo-homogeneous, chemical deposition
    - ○ Wide range of substrate surface materials
    - ○ Able to deposit on a wide range of surface topography
  - ✓ And a chemical mapper to calibrate the TraC over a wide range of chemicals & chemical concentrations.
    - ○ Enables automatic generation of a chemical concentration curve

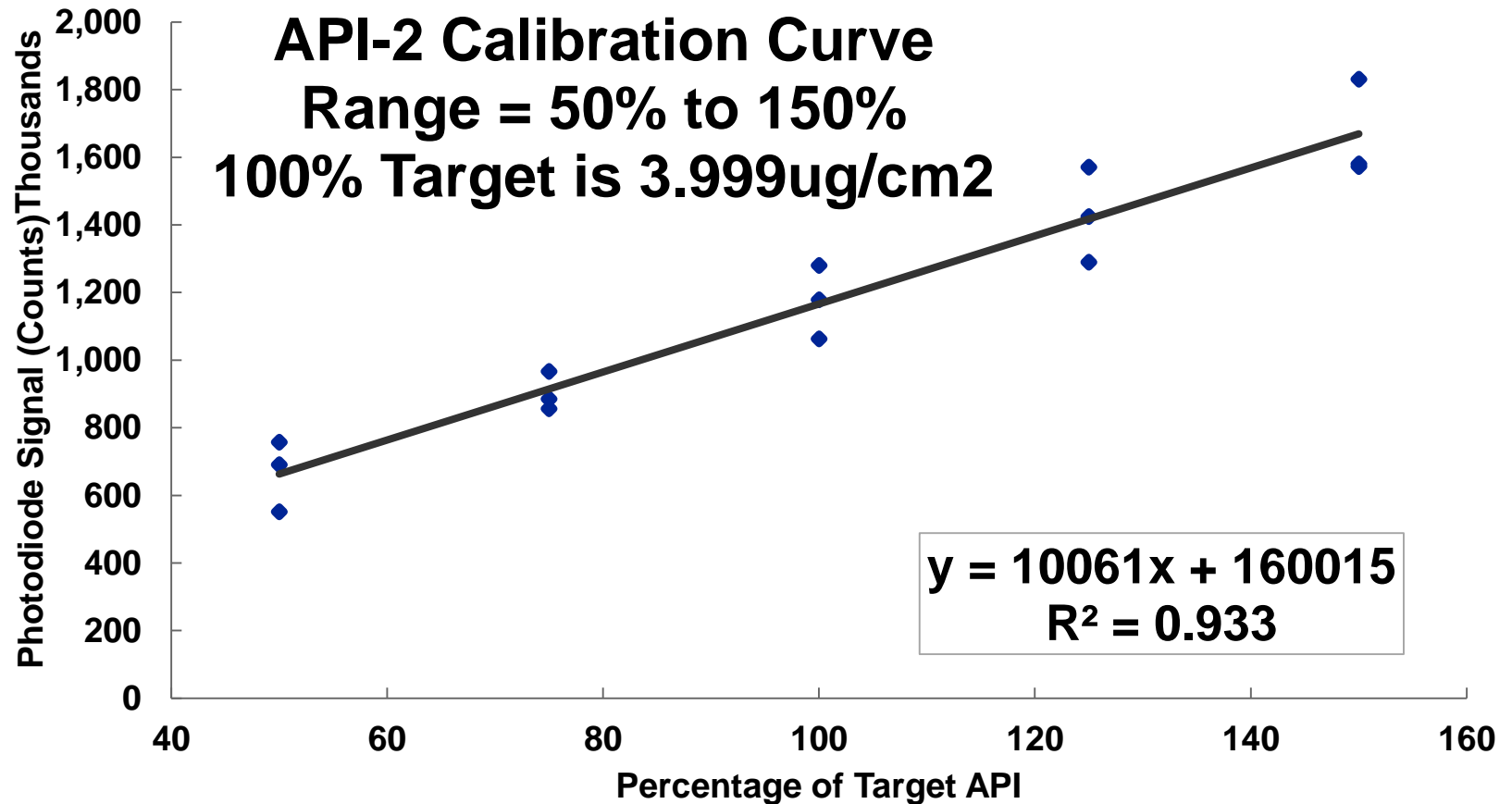**Come see this at our booth # 514**   *PHOTON* SYSTEMS

API-1 concentration calibration

API-1 Calibration Curve
Range = 50% to 150%
100% Target is 8.48μg/cm²

$y = 31296x - 282152$
$R^2 = 0.9846$

Photodiode Signal (Counts) Thousands

Percentage of Target API

API-2 concentration calibration

API-2 Calibration Curve
Range = 50% to 150%
100% Target is 3.999ug/cm2

$y = 10061x + 160015$
$R^2 = 0.933$

Photodiode Signal (Counts)Thousands

Percentage of Target API

On the horizon

To tomorrow, and beyond

TraC-X: Our future TraCorder

Impact on future methods and compliance

Fully self-contained sensor with on-board computation of display of chemical and concentration, along with logging information on the Pharma equipment ID, location of samples, date & time of data, and go/no-go certification of results.

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

20

TraC: A Trace Chemical Detector

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

Photon Systems:
Mike Reid
Prashant Oswal
Quoc Nguyen
Kim Sullivan
Kripa Sijapati
Ray Reid
Bill Hug

Pfizer PASG:
Steve Hammond
Joep Timmermans
Ben Lyons
Alan Rhoden
Gillian Miller
Conor McSweeney
Apu Sarwar