



# Emerging Technology and Software

Alyssa Fidanza (Amgen)

Busolo Wabuye (Merck)

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# Agenda

| Model, Make                                        | Presenter                     | Company   |
|----------------------------------------------------|-------------------------------|-----------|
| BlazeBasicG3, BlazeMetrics                         | Brad Greiner                  | AbbVie    |
| Direct Inject LC and iC LC, Telescope Innovations  | Brad Greiner                  | AbbVie    |
| CUB-20 / CUB-X Pharma Technology                   | Greg Doddridge                | AbbVie    |
| Eigenvector Research Diviner (software)            | Greg Doddridge                | AbbVie    |
| REDSHIFTBio HaLCon                                 | Christie Massie/Vicki Kennedy | Sanofi    |
| Protein Dynamic Solutions ProteinMentor            | Christie Massie/Vicki Kennedy | Sanofi    |
| LumaCyte Radiance                                  | Christie Massie/Vicki Kennedy | Sanofi    |
| SciY Automated Tablet Tester                       | Elyse DiMaso                  | BMS       |
| NIRRI                                              | Elyse DiMaso (Greg Lane)      | BMS       |
| Prozess LIF                                        | Elyse DiMaso (Dong Xiang)     | BMS       |
| Recimage Simulator<br>Recimage PAT<br>Recimage CPS | Edita Bottonjic-Sehic         | Recipharm |
| Expo Process Analytics uSolis                      | Caitlin Schram                | Vertex    |

| Model, Make                                  | Presenter                      | Company |
|----------------------------------------------|--------------------------------|---------|
| Incyte arc<br>Dencytee Arc                   | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| Repligen Maverick<br>ThermoFisher MarqMetrix | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| Amperometric Glucose sensor                  | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| AAA Analysis - Repigen Rebel                 | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| BlueVary Off-Gas Analyzer                    | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| Live Modeling Review                         | Alyssa Fidanza<br>Jakob Morris | Amgen   |
| NIRRI Atlas                                  | Andreas Schwaighofer           | Takeda  |
| Waters BioAccord + Beaumont                  | Gregory Pino                   | Takeda  |
| Ganymede AI Chromatography                   | Gregory Pino                   | Takeda  |
| 90 MHz Spinsolve benchtop NMR - Magritek     | Chuck Miller                   | Merck   |
| AspenTech Inmation                           | Chuck Miller                   | Merck   |
| Siemens gPROMS Digital Application Platform  | Chuck Miller                   | Merck   |

# BlazeBasicG3 --- BlazeMetrics

Evaluated by: Bradley Greiner, AbbVie

## Summary & Purpose of Equipment

*In situ* imaging of heterogeneous chemical systems (reaction, crystallization, and phase separation)

## What differentiates it?

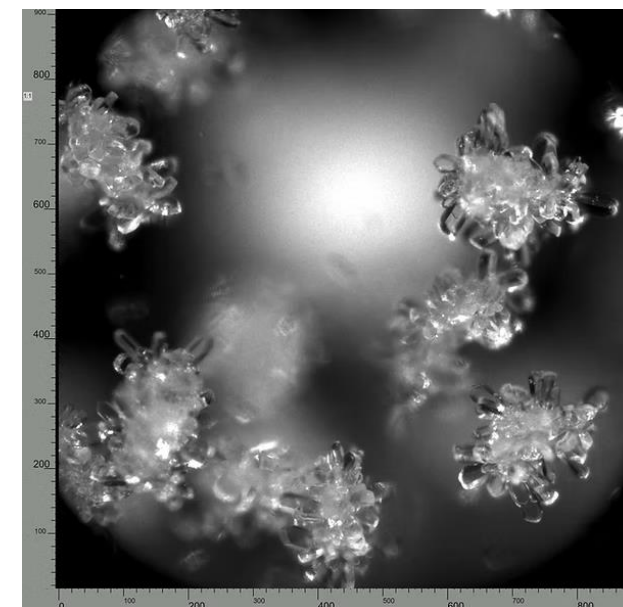
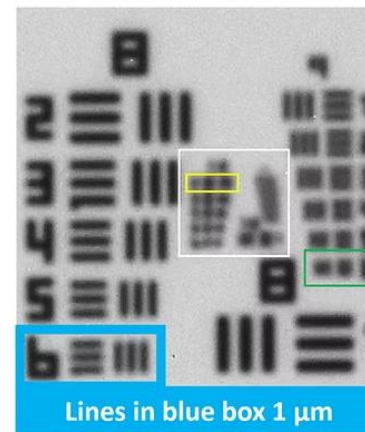
Compared to the analogous instrument (EasyViewer 100 and 400), this probe is a one size for all from 20mL vial scale all the way to 5L reactors. This probe also provides polarized light imaging allowing for differentiation between crystalline and amorphous material.

## What gaps & issues exist with technology?

The learning curve on the instrument's software is steep and scientists tend to go towards EasyViewer100 due to its seamless integration with Mettler Toledo AutoChem environment. BlazeMetrics does have communication capabilities built in to communicate with AutoChem software through OPC UA. But it requires IT administrative privileges and domain experts to enable the communication.

## Other info to consider:

The G3 (new unit) removed its Raman capability from its predecessors in order to provide better mobility and deployment of the instrument.



# Direct Inject LC and iC LC--- Telescope Innovations

Evaluated by: Bradley Greiner, AbbVie

## Summary & Purpose of Equipment

Rapid, real-time sampling and injection to LC for process profiling.

## What differentiates it?

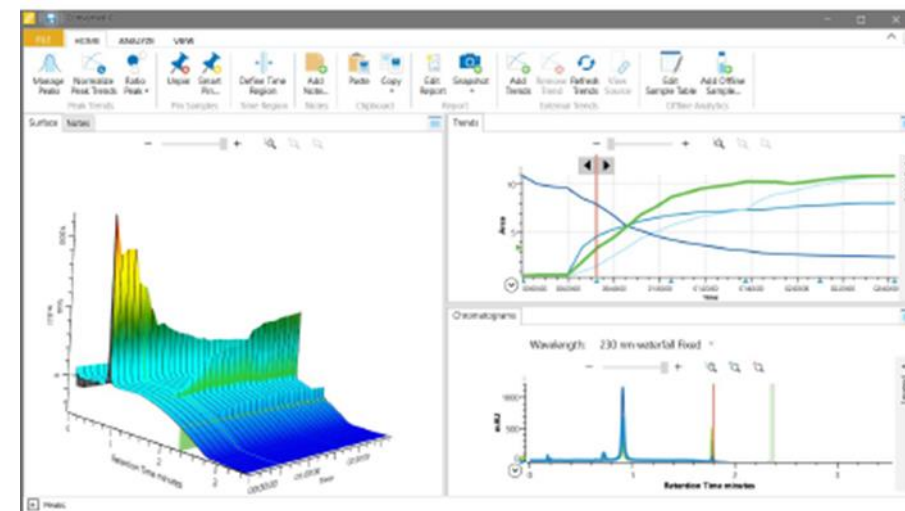
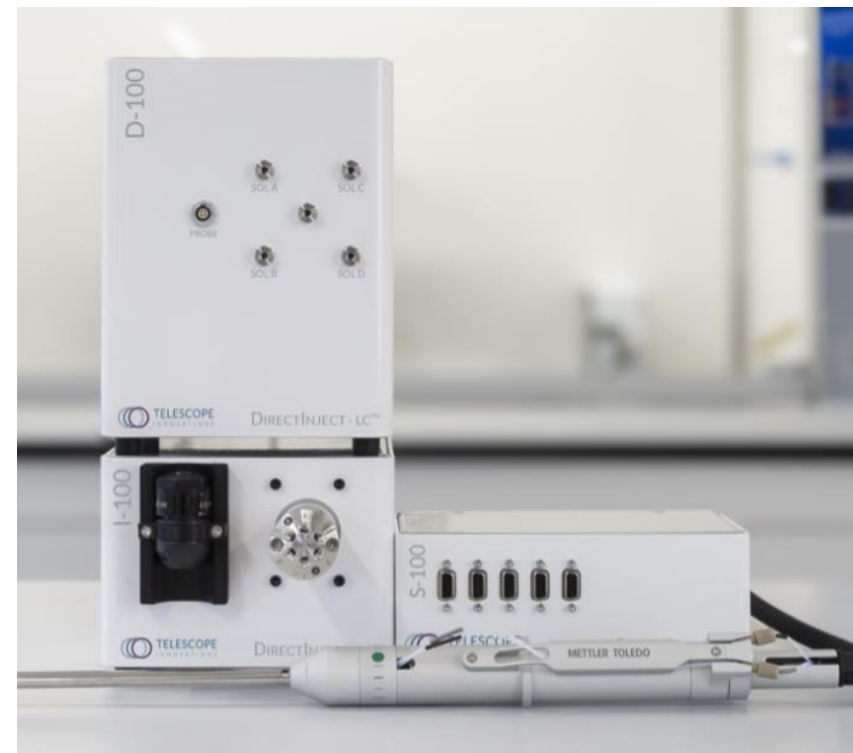
Uses a more powerful one directional pump than the Easy Sampler which increases sampling frequency. iC LC integration into Mettler Toledo software suite provides easy data visualization and feedback control opportunities in iControl.

## What gaps & issues exist with technology?

Capital investment is greater than other similar technologies. Other technologies allow for more elaborate sample preparations and workup.

## Other info to consider:

Unsure if Telescope Innovations plans to develop an Ex rated version for plant usage.



# **CUB-20, CUB-X --- Pharma Technology**

Evaluated by: Greg Doddridge, AbbVie

## Summary & Purpose of Equipment

Real-time analysis of physical properties (thickness, weight, hardness, diameter, length, porosity) and CU (by spatially-resolved NIR).

## What differentiates it?

Up to 20K tablets/hour for CU with up to 400 tablets/hour for porosity. The real-time porosity ability is the big differentiator with the CUB-X over the CUB-20.

## What gaps & issues exist with technology?

Evaluated the CUB-20 on-site in 2023 (presented at IFPAC in 2024). Need to evaluate the CUB-X on-site to determine any gaps & issues.

## Other info to consider:

- GMP Regulatory suitability/readiness
- Tools/software it works well with
- Discussion points you'd like to have
- Relevant experience related to the technology



# Diviner --- Eigenvector Research

Evaluated by: Greg Doddridge, AbbVie

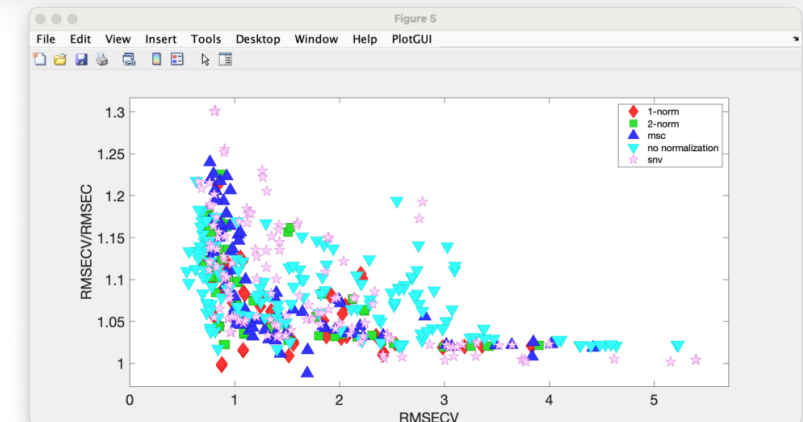
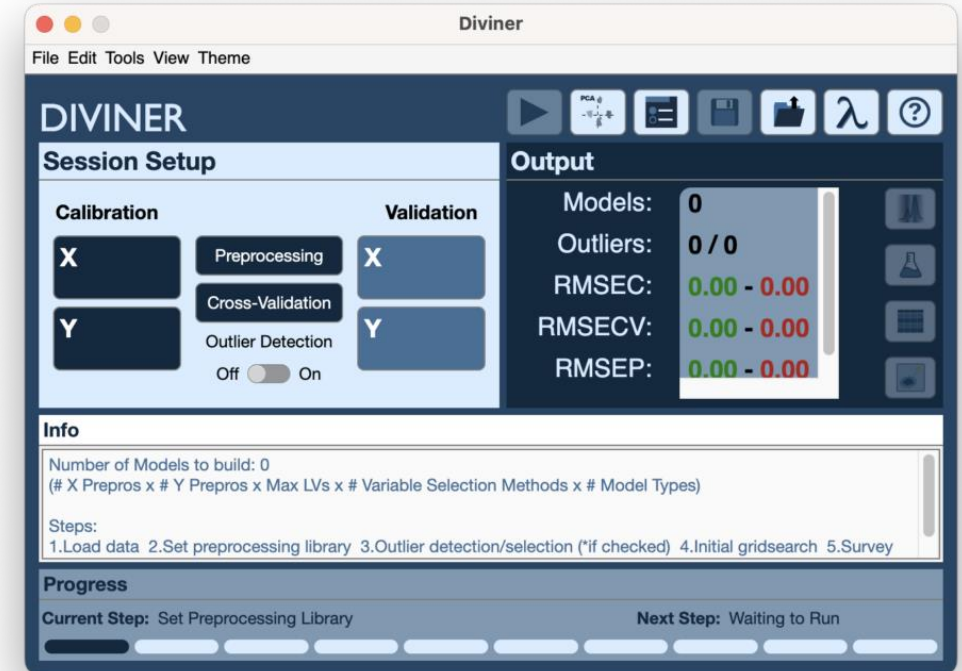
Summary & Purpose of Equipment  
Tool to help automate chemometric model building (e.g., optimize pre-processing).

What differentiates it?  
Easy-to-use GUI, variable selection with iPLS (if desired).  
Has shown internal utility to optimize pre-processing combinations for Raman spectra.

What gaps & issues exist with technology?  
Requires PLS\_Toolbox and licensing.

Other info to consider:

- GMP Regulatory suitability/readiness
- Tools/software it works well with
- Discussion points you'd like to have
- Relevant experience related to the technology



# HaLCon | REDSHIFTBio

## Summary & Purpose of Equipment

- Accurate protein analysis by liquid chromatography analyzer within 6 minutes
- Optional autosampler for increased throughput

## What differentiates it?

- Fully automated system (sample prep and analysis)
- Low sample volume consumption ( $< 100 \mu\text{L}$ )

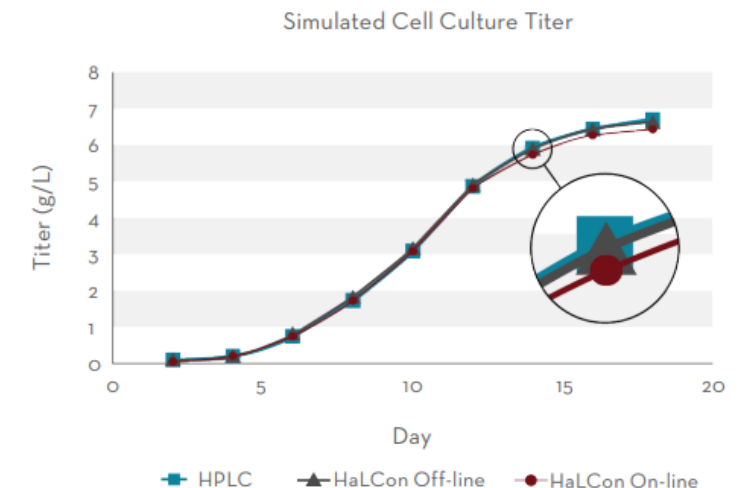
## What gaps & issues exist with technology?

- Worsening alignment with gold standard HPLC at higher harvest concentrations ( $> 5 \text{ g/L}$ )
- Molecule specific calibration curves required for improved accuracy

## Other info to consider:

- Democratizing accurate titer measurements in easy to operate form factor (e.g. similar to FLEX2)
- Evaluated by Lonza per conference presentation and vendor website

sanofi



# ProteinMentor | Protein Dynamic Solutions

## Summary & Purpose of Equipment

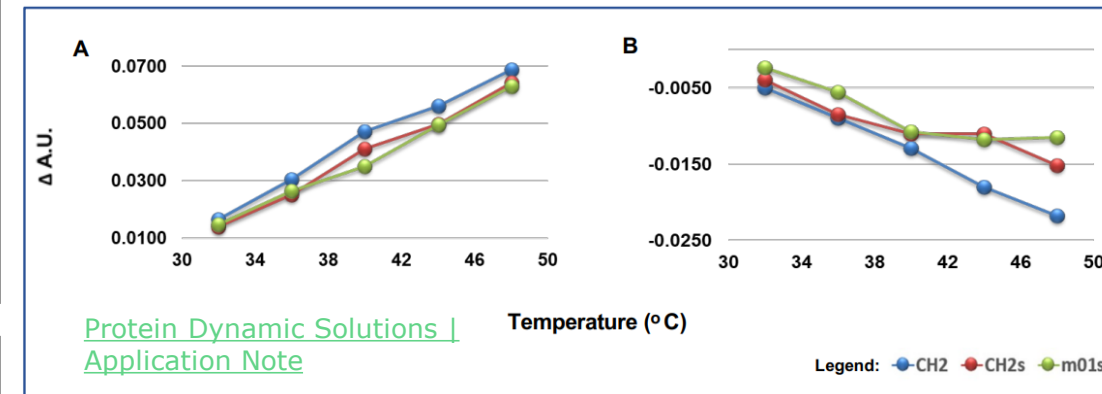
- ProteinMentor consists of a quantum cascade laser (QCL) microscope with an innovative slide cell array.

## What differentiates it?

- Allows for automated hyperspectral image acquisition
- Capability of looking at amide II region and conformational changes utilizing 2D correlation algorithms
- Target applications
  - Bacterial detection
  - Endotoxins
  - Deamidation
  - Stability
  - Aggregation
  - Protein structure

## Other info to consider:

- Has anyone tested this technology?



- Change in intensity using QCL IRM difference spectra associated with thermal stress

# Radiance | LumaCyte

## Summary & Purpose of Equipment

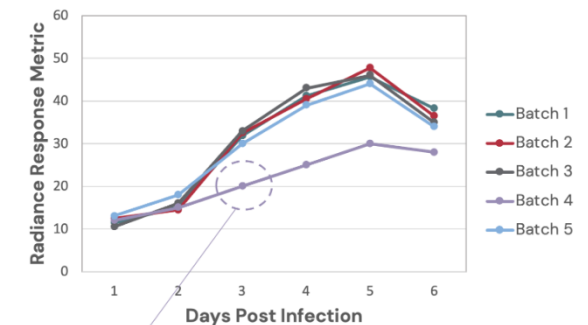
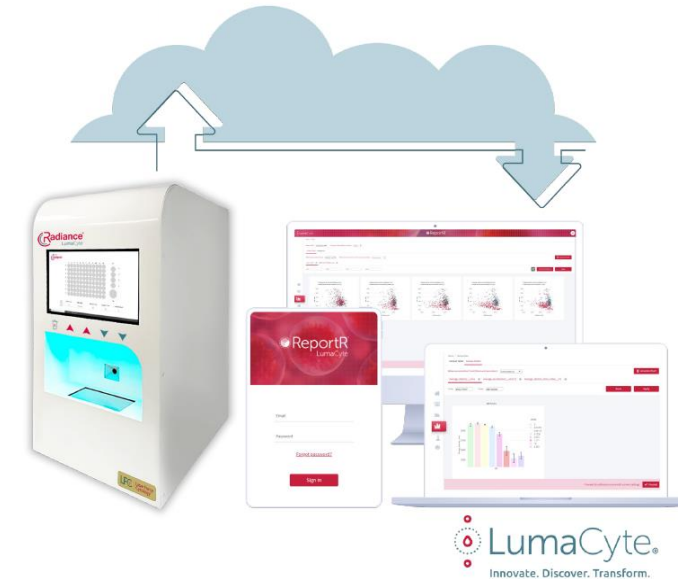
- Utilizes Laser Force cytology to reveal intrinsic biochemical and biophysical changes of cells (e.g. viral infection, cell differentiation, viability, etc)
- Incorporates ML to find patterns and predict cellular behavior

## What differentiates it?

- Real-time, label free cellular analysis
- Automated processing with 96-well plate compatibility

## Other info to consider:

- Promoted application areas include gene therapy and cellular therapy



Batch 4 falls outside the typical operating range 3 days post infection

# SciY Automated Tablet Tester

Evaluated by: Elyse DiMaso (BMS)

## Summary & Purpose of Equipment

Automated measurement of tablet weight and FT-NIR on Bruker MPA for tablet assay

## What differentiates it?

Automated, allows testing of large number of tablets without intervention from scientist

## What gaps & issues exist with technology?

Requires specific tablet holders and trays made by Bruker/SciY that need to be changed with every new tablet size

## Other info to consider:

Integrated in SynTQ



# NIRRIIN

Evaluated by: Greg Lane (BMS) – presented by Elyse D

## Summary & Purpose of Equipment

High-precision tunable laser spectroscopy to measure concentration of components in a liquid sample (such as sugars, proteins, and surfactants).

## What differentiates it?

Small sample size (15 uL), deconvolutes spectra, many buffer examples (His v. His\*HCl), rapid results

## What gaps & issues exist with technology?

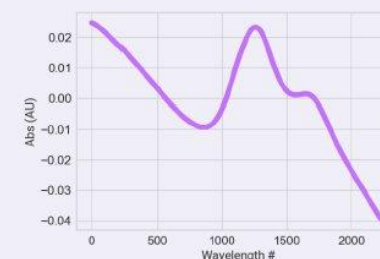
\$150k +  
Not in-line tool  
TBD

## Other info to consider:



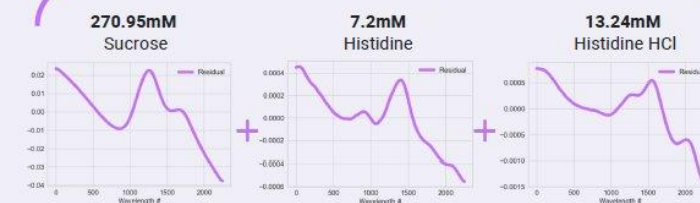
## Sample:

Sucrose (270mM) + Histidine (20mM) + HCl (pH adjuster)



sample spectrum

Deconvolves to:



# Prozess LIF (GAP)

Evaluated by: Dong Xiang (BMS) – presented by Elyse DiMaso

## Summary & Purpose of Equipment

Measurement of API in blends at concentration lower than 3% for blend uniformity – applied for real time blending

## What differentiates it?

Other tools have challenges measuring low dose

## What gaps & issues exist with technology?

Company has gone out of business – is this impacting others?

## Other info to consider:

ETC project on LIF in tablet press feed frame – currently not wireless (for blending)



# SOLVING PROBLEMS, INTELLIGENTLY THROUGH AN ECOSYSTEM APPROACH

## EDITA BOTONJIC-SEHIC

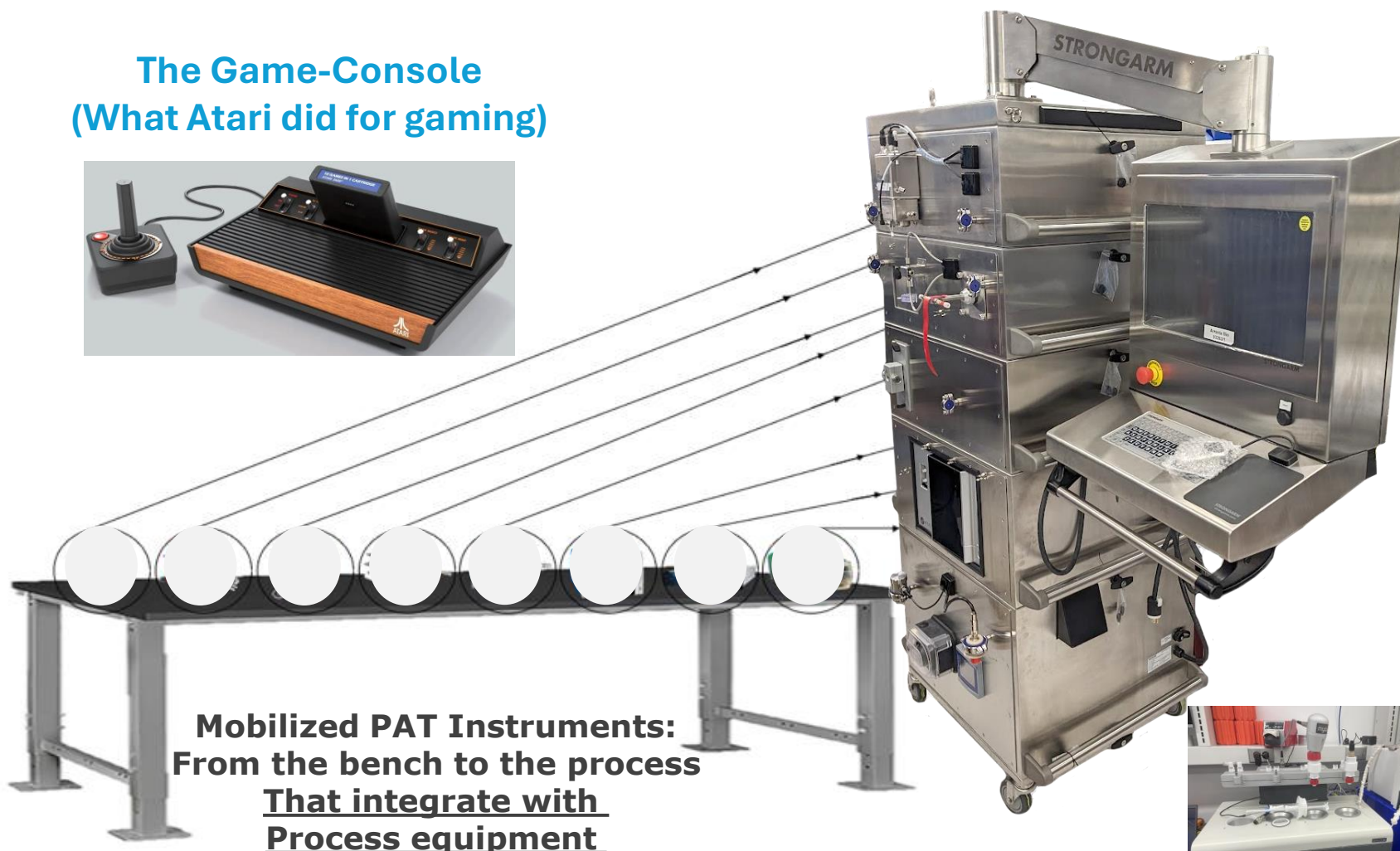
- **RecImagine™ Ecosystem:** An integrated suite of hardware, software, and simulations that accelerates development and manufacturing.
- **Speed & Efficiency:** Digital process simulation, high-throughput screening, and scale-down modeling condense development from years to months, and manufacturing down to a single day.
- **Innovative Tools:** Simulator, PAT, and CPS provide revolutionary speed and control.

| PRODUCT                                                | DESCRIPTION                                                                                                                  |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| <b>RecImagine Simulator</b>                            | A digital process development software capable of replacing most trial-and-error DOE with instant digital recipes            |
| <b>RecImagine PAT</b>                                  | An advanced, in-line multi-attribute process analytical skid that brings QC insights directly to the manufacturing floor     |
| <b>RecImagine Continuous Processing System ("CPS")</b> | A PAT-enabled continuous processing system capable of producing as little as 0.5g/day and up to 40g/day of mRNA drug product |



INTRODUCING PAT-SKID | THE CORE ENABLING TECHNOLOGY “QC ON WHEELS” THAT IS THE LINCHPIN SOLUTION INTEGRATES TO PROCESS EQUIPMENT

## The Game-Console (What Atari did for gaming)



**Mobilized PAT Instruments:  
From the bench to the process  
That integrate with  
Process equipment**



WHY IS IT A GAME CHANGER? | UTILITY, MOBILITY, ADAPTABILITY AND SPEED TO COLLECT/PROCESS ANALYTICAL DATA

## Process/Analytical Development

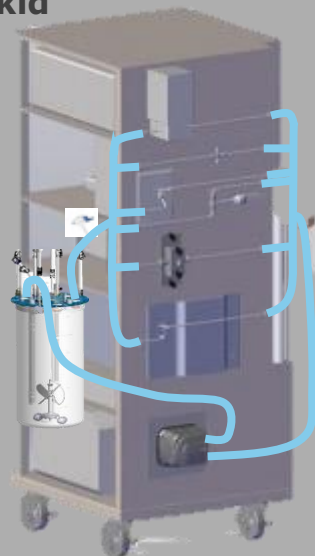


PAT Skid



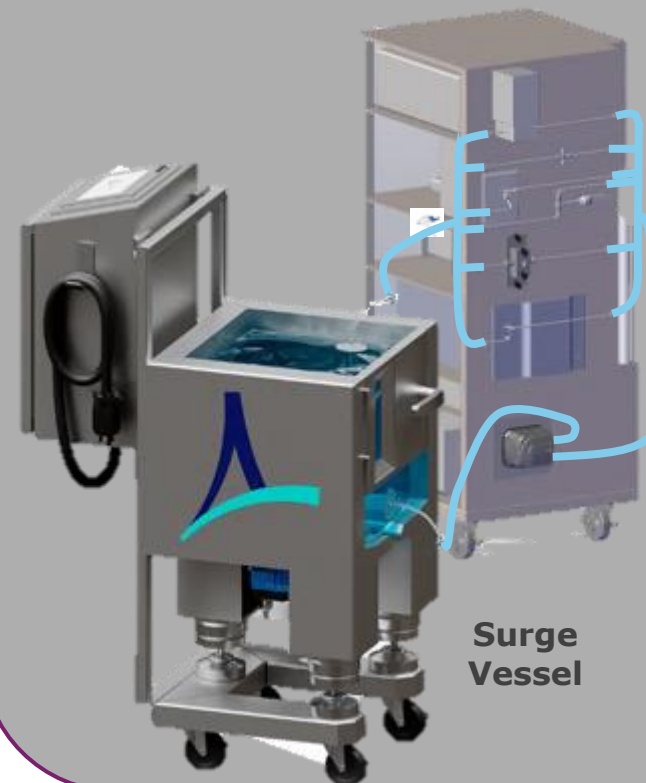
## QC Labs

PAT Skid



## Manufacturing

PAT Skid



# COMPLEX ANALYSIS; SIMPLE INTERFACE



## Single Software to:

- Connect instruments
- Capture data
- Execute recipes
- Provide models

Instantly converts  
raw data to critical  
quality attribute  
values

Feedback/Feed-  
forward Control

Digital Twins

PAT SKID/Upstream



PAT SKID/TFF



PAT SKID/TFF unit op



PAT SKID/LNP prep.



PAT SKID/LNP



# Expo Process Analytics $\mu$ Solis

Caitlin Schram (Vertex)

Probe interface to ensure representative/consistent sampling for inline PAT blend measurements in a continuous tableting line

New product launched 03Nov2025

From manufacturer's launch announcement:

The  $\mu$ Solis solves two challenges encountered when installing PAT probes directly in dense powder or granule streams:

- material flow irregularities including air gaps and pulsing lead to highly noisy spectroscopic baselines
- small PAT probe spot sizes relative to powder and granule blend heterogeneity cause non-representative sampling

Discussion Points:

Have any attendees evaluated this relative to the points above?





# PPAR Topics

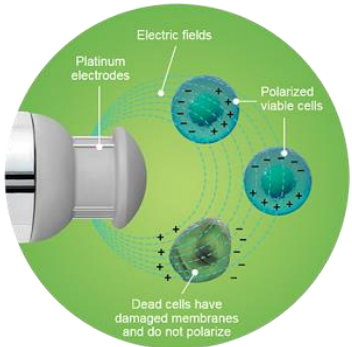
**ALYSSA FIDANZA, JAKOB MORRIS**

October 20<sup>th</sup>, 2025

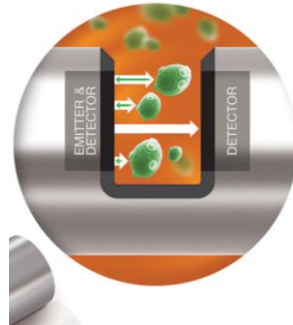
**AMGEN**

# Optical Density and Capacitance Modeling

## Incyte Arc -



## Dencytee Arc – Optical



VCD/Viability Predictions

### Challenges:

- **Data management** – intensive compilation required – bridging the gap between data teams and modelling team
- **Code interface** – suggested web app interface for user accessibility
- **Cell line to cell line, format to format variability** - prediction accuracy decrease for certain conditions

### Thoughts:

- How is this integrated into bench/pilot/commercial scale?
- Probe requirements
  - Running out of ports at bench and LS
  - How can we be more efficient with our data collection/usage?
  - Any other applications for capacitance/OD probes?

# Built-In Raman Models



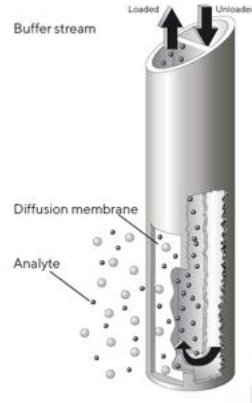
**Repligen Maverick**



**ThermoFisher MarqMetrix**

- Historical challenge of Raman – fitting the models
  - How do we expedite this workflow?
  - Scalability of models
- Any promising Raman technologies with built-in models?
  - Have seen some options with built-in models + offline reference features
- Repligen Maverick tested – software issues encountered that have complicated evaluation

# Amperometric Glucose Sensors



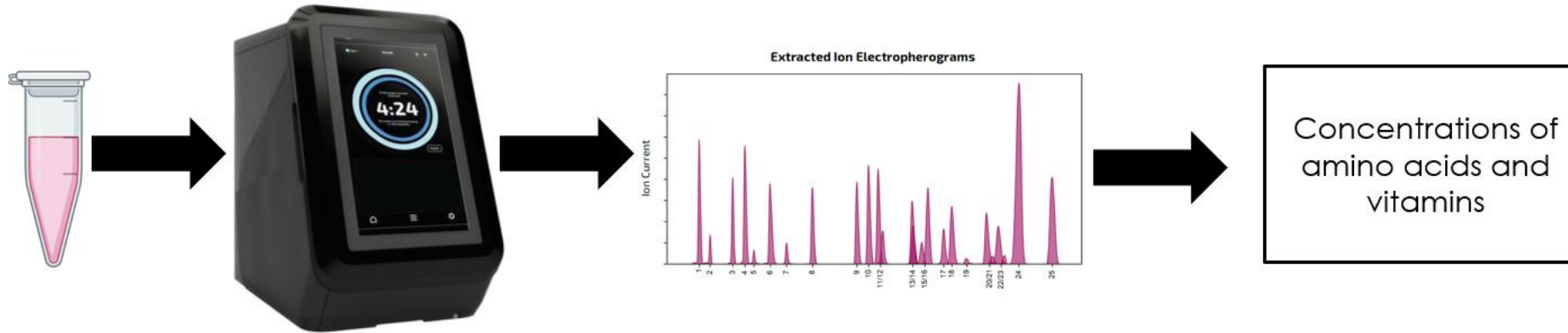
Amperometric glucose analyzer utilizing size-exclusion membrane to load analyte and external tubeset to transfer to biosensor

## Challenges

- **Sterility** – membrane is only barrier between non-sterile tubeset and culture, how is this being scaled/implemented?
- **Air** – analyzer very sensitive to air bubbles, especially prevalent in bench scale bypass module applications
- **Multiple points of failure** – any obstruction of tubeset, waste container, or other components impedes measurement – how are teams mitigating this issue?

Any other solutions for real-time glucose/lactate measurement or use cases for this technology?

# AAA Analysis – Repligen Rebel



## Advantages:

- High throughput – load 200 samples at once, 20-30 min per sample
- Easy to use – dilute and go
- Potential to automate some feeding?

## Challenges:

- Sensitive to operating environment
  - Temperature
  - IPA use
- Frequent hardware issues requiring vendor support

How do we best ensure consistent success with this instrument?

# Off-Gas Analyzer: BlueVary (or BluInOne Metal version)



## Summary & Purpose of Equipment:

- Measure oxygen and carbon dioxide in the exhaust to derive Carbon dioxide Evolution Rate/Oxygen Uptake Rate/ Respiratory Quotient (CER/OUR/RQ) and real time kLa.

## What differentiates it:

- Noninvasive metabolic fingerprint of culture performance
- No sampling required.
- It enables soft sensors for biomass or substrate consumption.



## What gaps & issues exist with technology:

- No standardized software to automatically perform calculations based off the combination bioreactor MFC and BluVary.
- Condensation / Moisture management in the setup

# Live Modeling: Review

## Siemens SIMATIC SIPAT

- Hub software
- 21 CFR pt 11 compliant
- Modular and scalable system
- Requires integration with advanced modeling/control tools for closed loop control
- Implementation can be complex due to required process expertise

## Bruker SyntQ



- Hub software
- 21 CFR pt 11 compliant
- Scalable from Lab → Commercial
- Supports feedback control
- Vendor agnostic orchestration of PAT instruments & models
- High licensing costs
- High level of expertise needed due to complexity

## Databricks



- Data ingestion, ETL, and query tool
- Requires data to be accessible via API or Data tables
- Streaming data access available
- Integration with Git for version control
- Comprehensive app development environment

## Applied Materials/ Perceptive PharmaMV



- Advanced model-based control software
- Supports complex control strategies
- Integration ready with SIPAT
- No proven GMP use cases yet, but built with GMP in mind
- Industry Gap in APC usage

## SIMCA/SIMCA Online



- Powerful real time MVDA tool
- Can provide real time predictions
- No direct control action – relies on operator action
- Model lifecycle management remains a challenge

## Honorable Mentions

- Aveeva PI Data Historian
- SEEQ
- Quartic.ai

# NIRRIN Atlas



Andreas  
Schwaighofer

## OVERVIEW

- Real-time at-line bioprocess monitoring supports upstream and downstream applications like **protein titer, buffer and excipient concentration**.
- **Laser-based NIR spectroscopy** for high-resolution, high-sensitivity detection in aqueous biopharma samples, overcoming water interference issues
- Designed for regulated GMP environments, offering consistent, traceable results suitable for **quality control and process development**.
- Currently available instrument enables **at-line analysis**, an instrument upgrade for on-line and in-line monitoring is planned

## APPLICATIONS

- UF/DF (DS/DP)
- Formulation Development
- Surfactant Monitoring

## EXPERIENCE

- Takeda is currently demoing the instrument for UF/DF (DS) and fill/finish applications

## WEB LINKS

- <https://www.nirrin.tech/atlas/>
- <https://www.nirrin.tech/resource/video-hptls-nir-reinvented/>



### Proteins

mAbs, peptides, ADCs



### Amino Acids

Histidine, arginine, methionine



### Sugars

Sucrose, trehalose, sorbitol



### Surfactants

Tween 20 and 80, Poloxamer 188

# Waters BioAccord + Beaumont

## Technology

The Waters Beaumont (beta) is an online sample prep instrument. It is capable of prepping samples by moving sample volumes from the autosampler to the Beaumont, doing the digestions and incubations then injecting the sample into LC for online analysis.

It is capable of preparing samples for titer, glycan, SEC, MAM of all flavors and HCP analysis.

## Vendors

- Waters

## Status

- The Beaumont is still in Beta testing with the hopes to release it in late 2026-2027.

## Experience

Takeda has been providing input on the system for a few years now. We have performed LC/MS testing with the system in Jan 2025. Planning on receiving one of the beta units in 2026 for demo testing.



**Gregory Pino**



# Ganymede AI Chromatography

## Technology

Ganymede's "lab-as-code" approach provides a circular workflow that automates data movement between instruments and laboratory systems. They are able to use AI and machine learning to automate the analysis of chromatography data, which traditionally involves repetitive and manual data processing tasks. This includes steps like peak identification, baseline correction, and integration of chromatographic data.

## Vendors

- Ganymede

## Status

- Ganymede's AI for Chromatography software is in a late-stage development and pilot-testing phase.

## Experience

Takeda is planning on purchasing and implenting the software in 2026.

## Webinar Link:

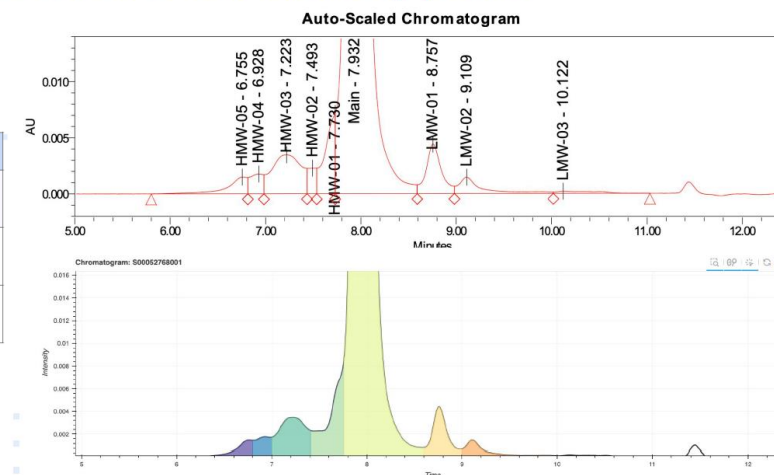
<https://www.linkedin.com/events/aiforchromatographydatasystems7242222273586171904/about/>



Gregory Pino

Ganymede methods can be refined for better detection of low intensity peaks.

|                       | Exp 1638 (35 Chrom Report) |                   | Exp 1749 (65 Chrom Report) |                   |
|-----------------------|----------------------------|-------------------|----------------------------|-------------------|
|                       | Manual Analysis            | Ganymede Analysis | Manual Analysis            | Ganymede Analysis |
| Purity Percentage (%) | 92.75                      | 92.73             | 91.93                      | 90.14             |
| Total Peaks Annotated | 280                        | 247               | 198                        | 179               |



Eliminate 1700+ hours of work per year while improving consistency and data integrity.

| Challenge                                           | Solution                                                                           | Value                                                                                                                                                                                                                 |
|-----------------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manual peak identification                          | <b>Codification of peak identification</b> rules and continued learning            | <ul style="list-style-type: none"><li>Remove <b>subjectivity</b> from analysts</li><li>Easier method transfer across global Takeda sites</li><li>Greater reproducibility for regulatory and audit readiness</li></ul> |
| Manual integration of peaks                         | <b>Automated</b> peak identification and integration                               | <ul style="list-style-type: none"><li>Improved data consistency</li><li><b>Free up analysts</b> for high value work</li></ul>                                                                                         |
| Data transfer between systems (Empower, Excel, ELN) | <b>Direct data extraction</b> from Empower and <b>automated data flow</b> into ELN | <ul style="list-style-type: none"><li><b>Eliminate transcription errors</b></li><li><b>Faster turnaround time</b></li><li>Up to additional 15% time savings per run on data movement</li></ul>                        |
| Increasing sample load and longer run times         | <b>Scalable</b> automation framework; ML models improve with data ingestion        | <ul style="list-style-type: none"><li><b>Supports increased sample throughput</b></li><li>Improves lab capacity utilization</li></ul>                                                                                 |

# 90 MHz Spinsolve Benchtop NMR - Magritek

Evaluated by Jessica Roth, Merck

## Overview

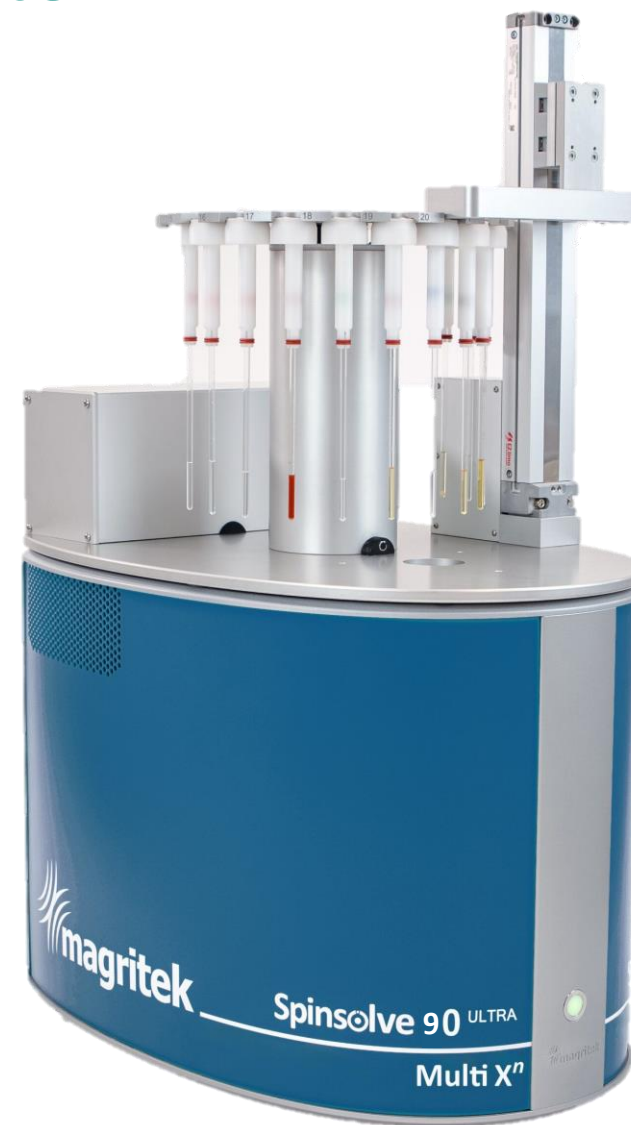
- The power of Nuclear Magnetic Resonance (NMR) technology put in the hands of non-experts
- Rapid evaluation of small molecule species and excipients with little to no sample preparation

## What Differentiates It?

- Internal lock eliminates requirement for deuterated solvents
- $T_1$  and  $T_2$  filter capabilities
- Rapid at-line or in-line measurements
- Low cost, no specialized facility or cryogenics

## Gaps and Issues

- Lower resolution and sensitivity compared to high field instruments
- Temperature fluctuations impact shim quality



# AspenTech Inmation- Operational Data Hub

Evaluated by Chuck Miller, Merck

## Overview

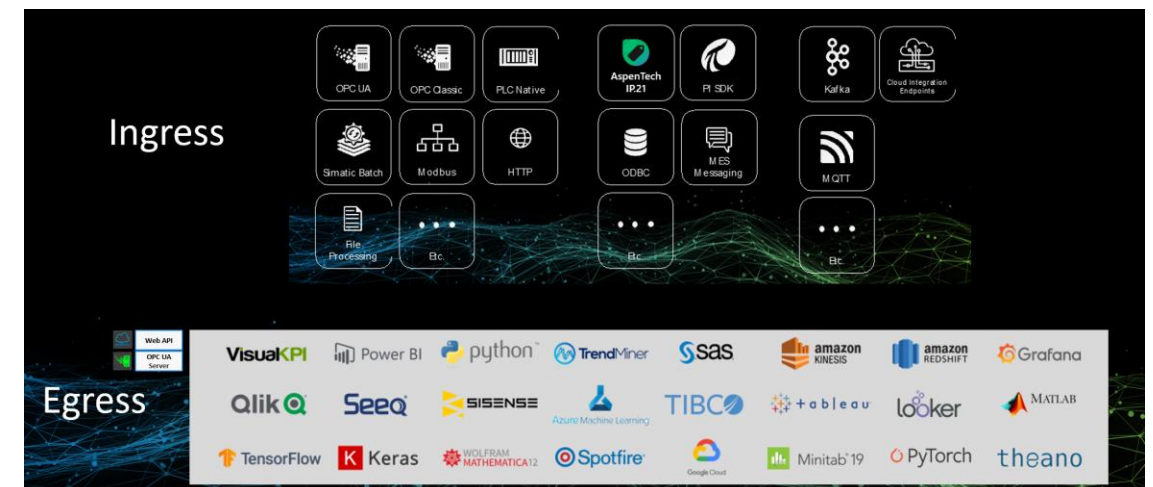
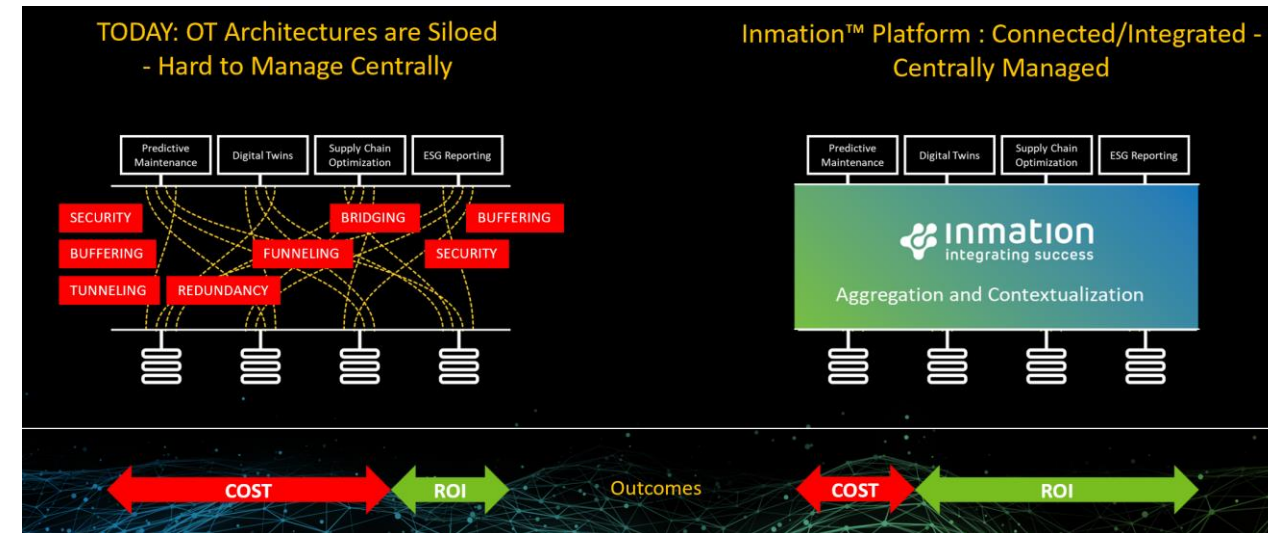
- Operational Data Hub solution for aggregating, contextualizing, curating and brokering data in support of digital transformation
- Addresses IT/OT challenges in era of ever-expanding shop floor data generation (including PAT!)

## What Differentiates It?

- Rapid scalability to enterprise scale (??)
- Supports diverse Data Governance policies
- Supports wide range of data ingress and egress options
- Data security features on-board : encryption, authentication and authorization
- Built-in OEE and KPI solution

## Gaps and Issues

- Many configuration elements- requires services \$\$
- Need to define custom data models
- Limited to LUA scripting language, MongoDB internal database



# Siemens gPROMS Digital Application Platform (gDAP)

Evaluated by Fay Metsi-Guckel, Chuck Miller, Merck

## Overview

- Implementation environment that manages execution, data cleansing and processing, scheduling of multiple calculations and validation of results – returning results to the plant automation system
- Currently in PoC for hosting a “Digital Shadow” soft sensor application, with LOS towards Digital Twin deployment

## What Differentiates It?

- Seamless integration within Siemens digital ecosystem- including gPROMS mechanistic models
- Supports wide range of on-line digital initiatives: nonlinear model predictive control (gNLMPC), real time optimization (gRTO), utilities planning and advisor (gUTILITIES), dynamic real time optimization (gDRTO), state estimator and soft sensor (gSESF)

## Gaps and Issues

- More difficult integration of non-gPROMS process models (ex. Python scripted models)

