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Abnormal UV peak shape detection using Align & Zoom, PI Vision feature, GSK

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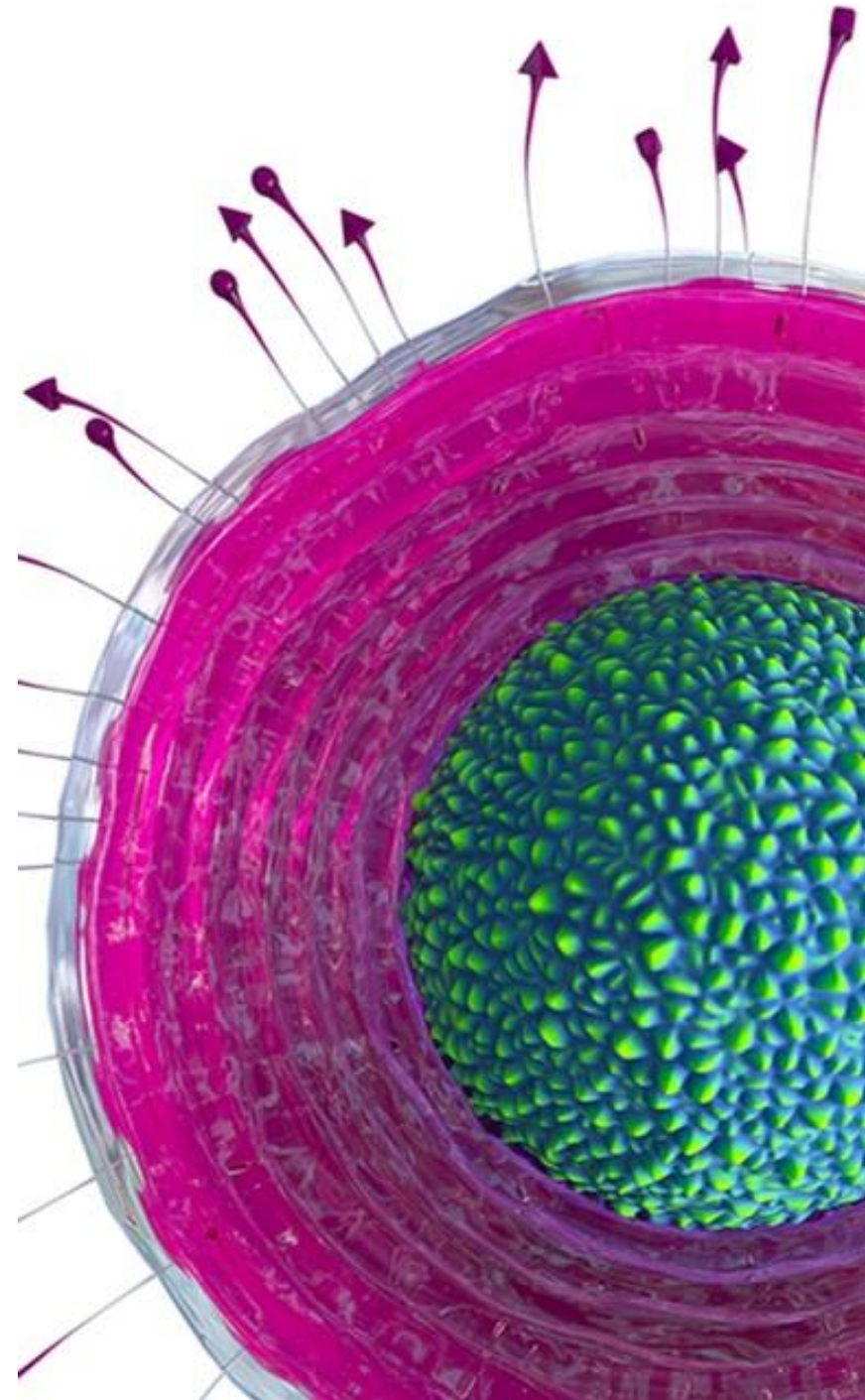
Senior Manager, Product & Process Robustness

- This work was sponsored by GlaxoSmithKline Biologicals SA
- Marie-Anne Colocouris is an employee of the GSK group of companies
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About our company



- GSK is a science-led global healthcare company with a special purpose to improve the quality of human life by helping people.
- The Pharmaceuticals business has a broad portfolio of medicines in respiratory, HIV, immuno-inflammation and oncology.
- The Vaccines business delivers vaccines worldwide, helping to protect people from a range of diseases at all stages of life.



Vaccines: our global presence



More than 15,000 people working at 13 sites strategically positioned around the world





About GSK Vaccines



Vaccines

- Vaccination prevents 2-3 million deaths every year
- Largest vaccines portfolio to help protect people against 21 diseases
- Largest vaccine pipeline with 20 candidate vaccines
- Supply to 160 countries in the world
- 12 manufacturing sites, 3 R&D centers, 15 000 employees
- 2 million doses produced everyday

Wavre Site

- Largest vaccines production site in the world
- 550 000 m² or 70 football fields
- 9 000 employees in Belgium
- 80% of GSK vaccines production volume



Basic steps of vaccine production

Primary

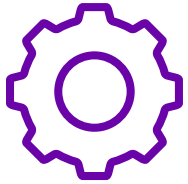


Secondary



Continued Process Verification

Is the third stage of Process Validation that has a central purpose to ensure that processes are in a constant state of control



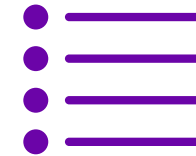
Challenge

- Access to (real-time) manufacturing data is time consuming, requires to be trained to multiple supervision systems (DCS, SCADA, Reporting Tools...) to export the data and manually add production context. Data is accessible and used by data experts only.



Solution

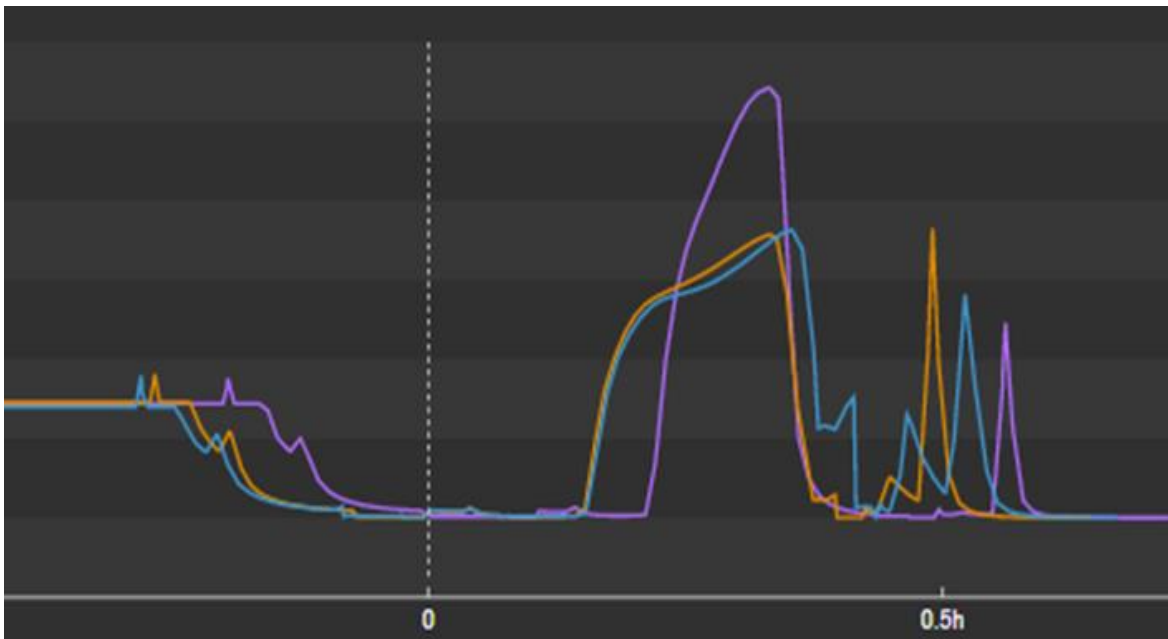
- PI Vision allows to access the manufacturing data of all processes with their metadata, with limited training.
- Process Experts can compare batches by overlaying them, in real time or after the events using the Align and Zoom feature of PI Vision



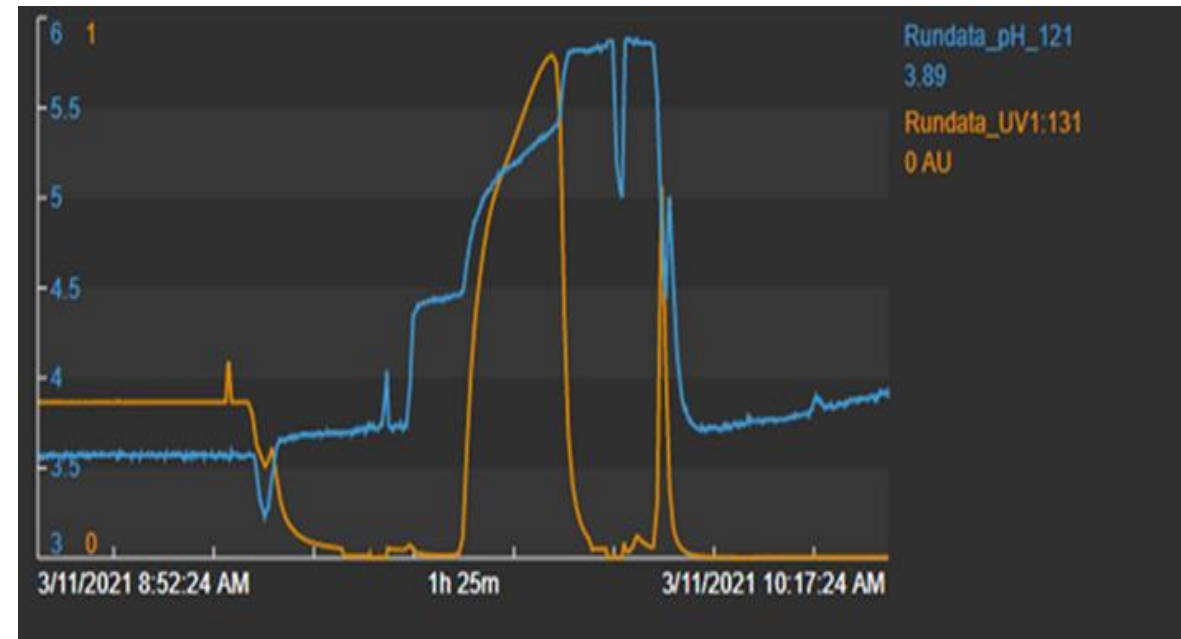
Benefits

- Data can be used by anyone, regardless his/her data education background.
- PI Analytics and Align&Zoom feature allows rapid detection of abnormalities not detectable by classical alarm systems

Business Challenge : Increase Process Knowledge & Understanding

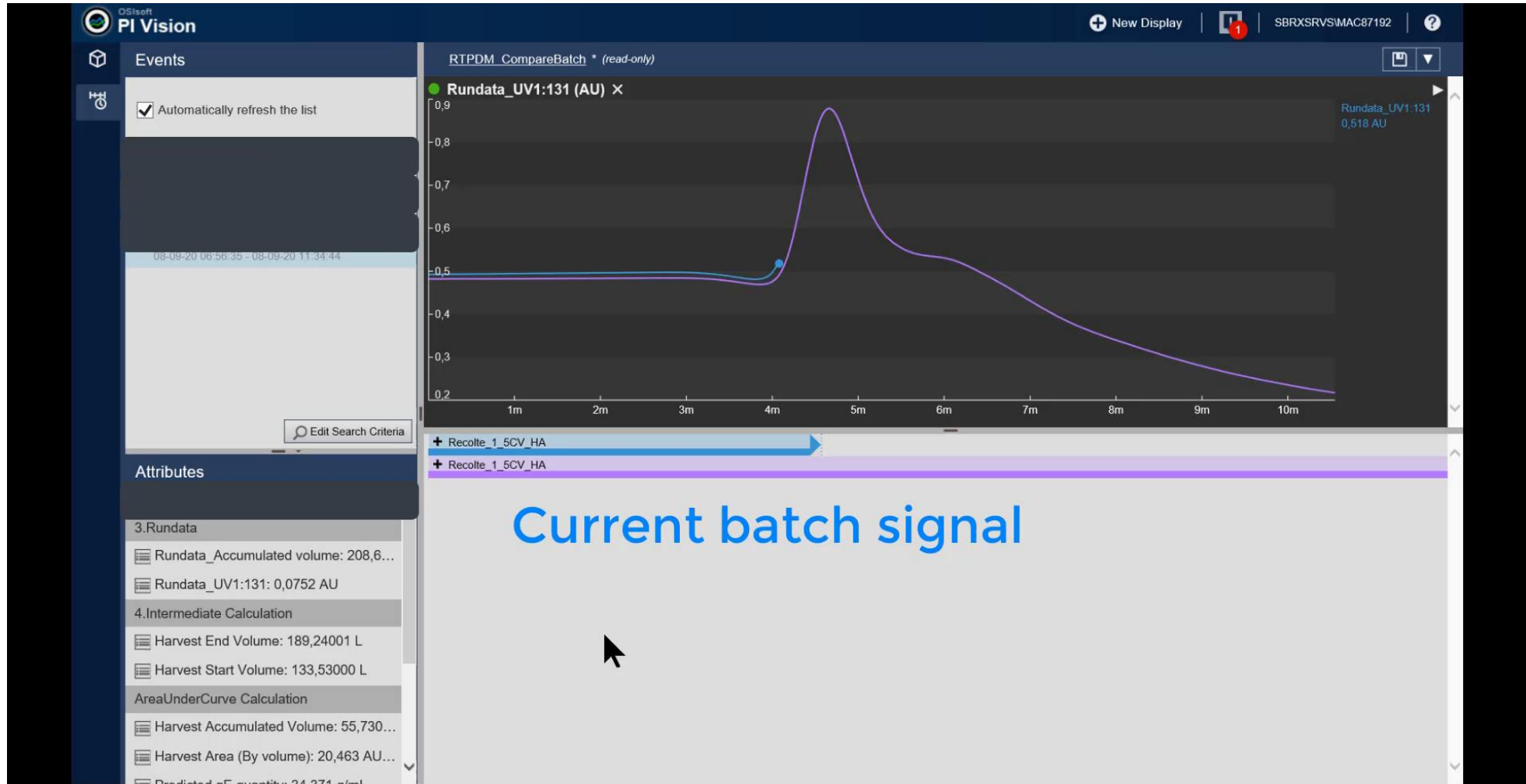


- Overlay of UV signal of three different batches
 - *Why is the peak shape so different?*

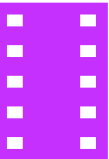
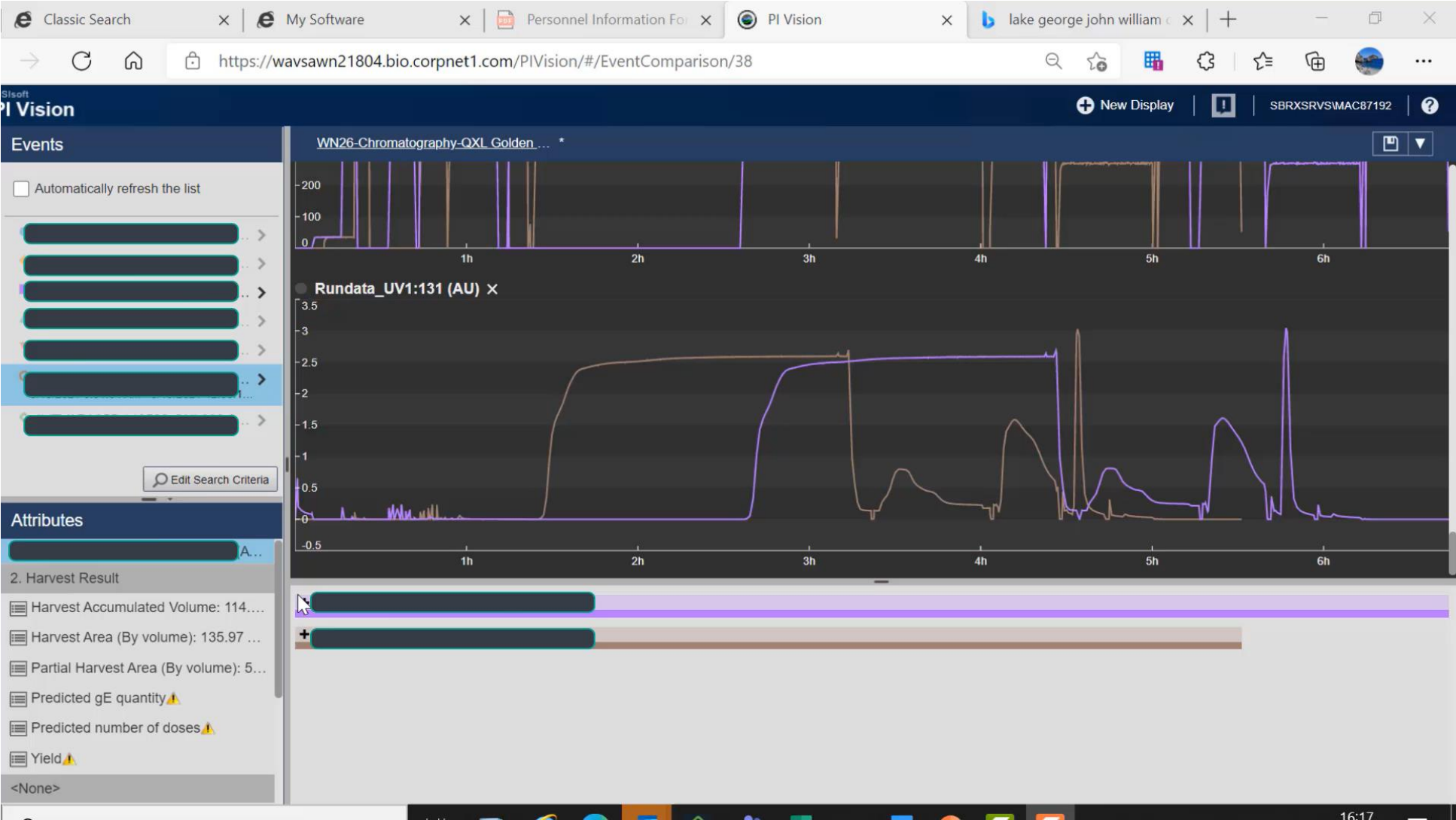


- Superposition of UV signal with pH
- *The pH was slightly lower by for the « abnormal » peak !*

AVEVA Application used : PI-Vision 2017R2 with Gantt chart (during the event)



AVEVA Application used : PI-Vision 2017R2 with Gantt chart (after the event)



Align & Zoom Feature in PI Vision 2017R2

What works well

- Allows to compare multiple events (event = one batch)
- Allows to “pin” or select a reference event
- Allows to zoom on child-event to align the signals that don’t occur at the exact same timestamp

Difficulty

- Alignment on PI Vision 2017R2 is done on the **child event number**
- Mis-alignment of signals when automation recipe has more events (unpredictable - not abnormal)

Excellent Customer Experience

- GSK challenge was shared with the AVEVA Customer Success Manager and a work-around was found by the Technical Product Manager of AVEVA while still using PI Vision 2017R2 (Search Criteria > Event Name : mimics the Align and Zoom feature)
- The User Feedback Page was updated by an excellent news : PI-Vision 2022 will allow alignment with the **child-event name**
- [Align Child Event Frames by Name as opposed to Sequence Number – User Feedback for OSIsoft \(now part of AVEVA\) Products and Services](#)

Impact & Savings

“Thanks to RTPDM and PI Vision, I was able to detect the atypical UV elution profile in SP chromatography on bulk production. This information obtained much easier and quicker than with the usual monitoring made on our batches has led to the immediate change of the batch of elution buffer which was incriminated in this deviation, thereby avoiding other deviations”

Philippe Charles “Product & Process Specialist, Wavre, Belgium”

Business case extract, expected benefits

The visualization on-line of Critical Process Parameters will

- Improve access to data from shop-floor ✓
- Pro-actively correct process deviations from shop-floor ✓
- Improve data integrity by removing data encoding ✗
- Increase the product knowledge and process understanding ✓
- Increase yield using golden batch comparison ✓
- Provide one of the foundation element to data analytics framework ✓
- Expected savings 10 M€ / year ✓


Our next steps


Real Time Process Data Monitoring using PI Vision “proof of concept” for GSK Vaccines in 2020 – 2021 and still in the learning curve

- Increase technical knowledge of the core teams in charge
- Roll-out RTPDM to Vaccines manufacturing sites from 2022
- Expand PI Vision usage to other users than process experts (maintenance, EHS,...)
 - Install PI System Data Infrastructure with PI Vision in all manufacturing sites
 - Move from a “sprint” mode to a “marathon” mode
 - Increase internal capabilities
 - Find out the right organization model to sustain digital transformation
- Use PI System as the primary production data source for other applications (MES, digital twin)
- Maintain the Excellent Customer Service from AVEVA 😊

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