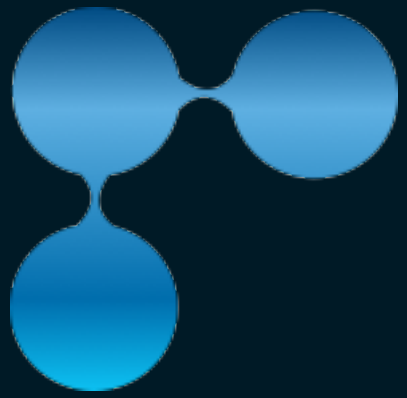


Seeq for Pharma: Analytics and AI Suite

Michelle Hart

Product Manager

Seeq

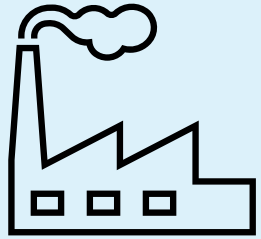
Paolo Braiuca

Pharma Industry Principal

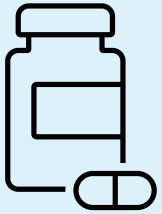
Seeq

Seeq’s early days

Time series data: biggest untapped potential in the process industry



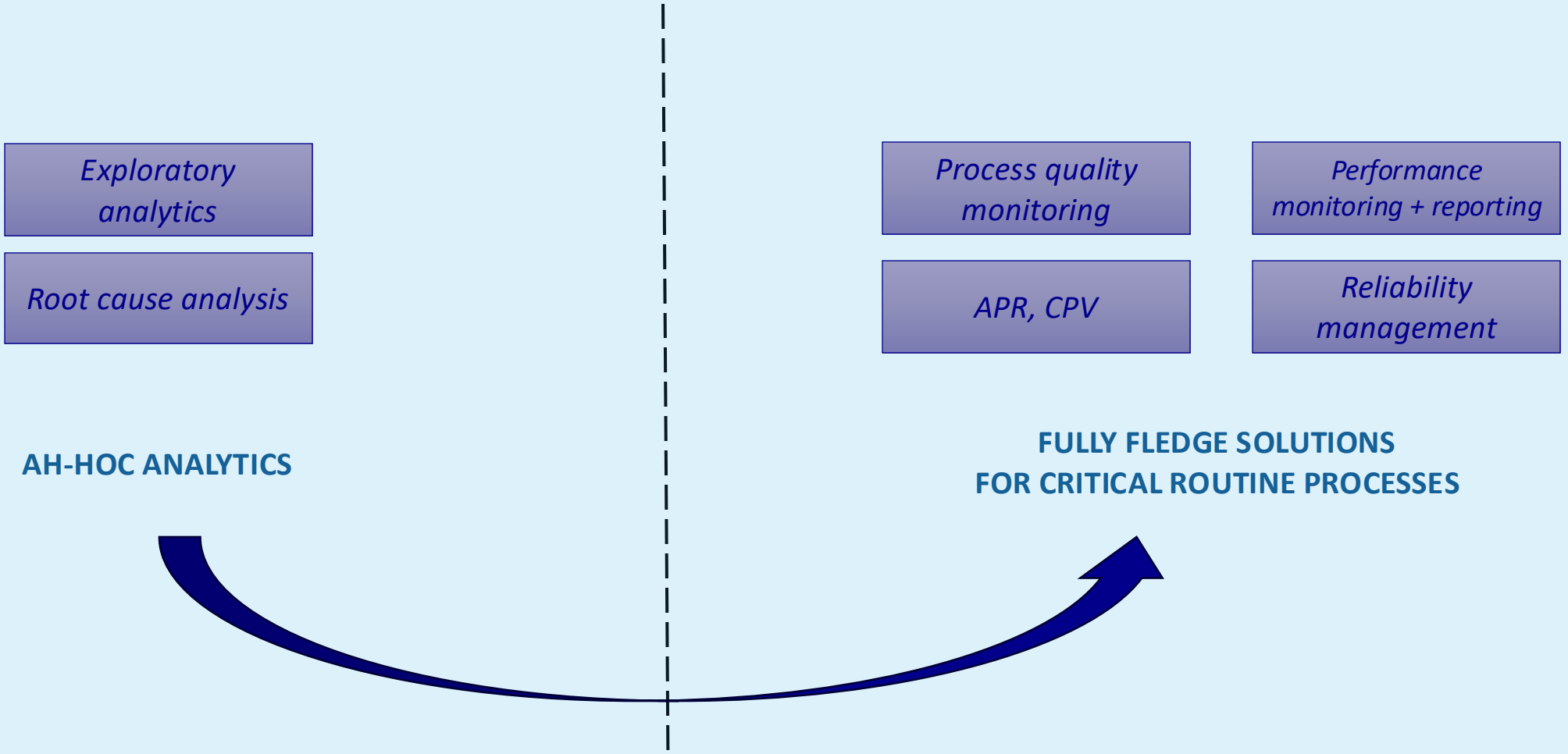
….and…



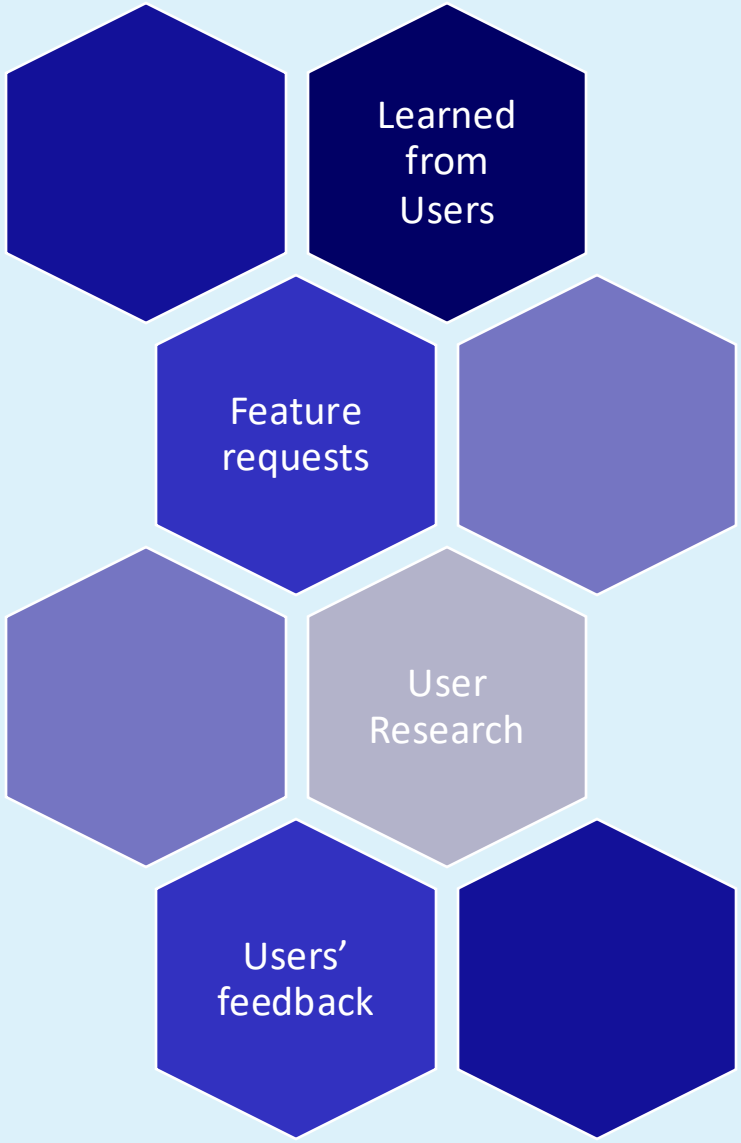
Welcome to the Pharmaceutical industry, where everything is 10 years behind and moves like molasses

INDUSTRY VETERAN
“Top 10 Pharma Company”
Seeq customer

Envisioning the Platform's Potential



Evolving into a Pharma-friendly Platform



Seeq becoming more and more suitable for application in pharmaceuticals development and manufacturing

What is Seeq applied to today?

Process Development

- CPP Identification
- Process Optimization
- Tech Transfer

R&D

Process Monitoring & Management

- Anomaly Detection And Root Cause Analysis
- Ensure Quality Compliance (CPV, APR, Batch Reporting)
- Predictive Modeling & Continuous Improvement Analytics

Drug Substance Manufacturing

Drug Product Manufacturing

Operational Efficiency & Supply Chain

- OEE – Continuous Improvement Analytics (Performance Metrics, Increase Equipment Availability)
- Data Insight Into Planning Scheduling

Drug Product Manufacturing

Drug Substance Manufacturing

Assets Monitoring & Management

- Anomaly Detection And Root Cause Analysis
- Predictive Maintenance
- Industrial Enterprise Monitoring

Engineering *(Facilities / Utilities / Maintenance)*

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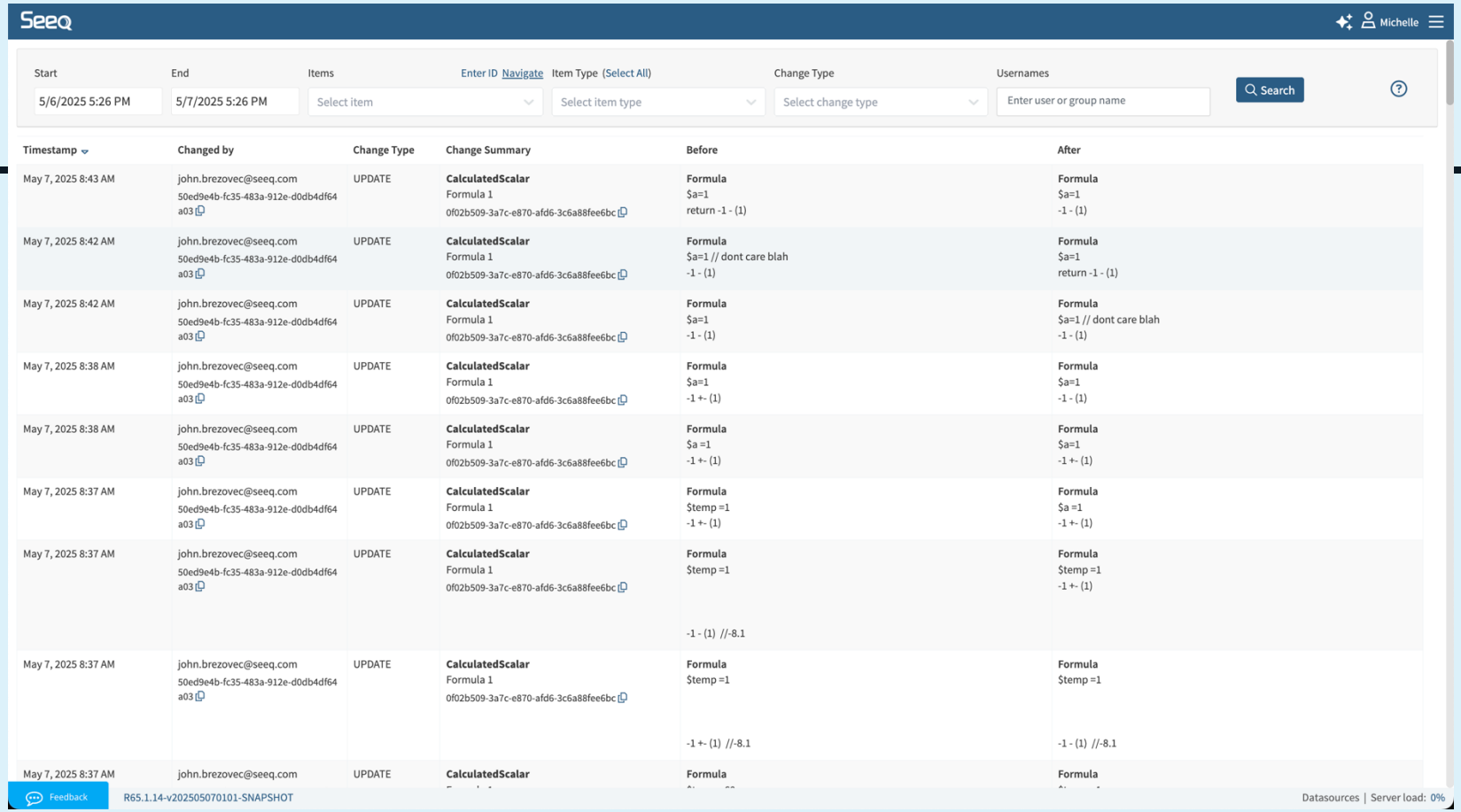
But what about validation?

- Customers started to validate early on!
- “Compliance features” the most requested since early days
- Most Pharmaceutical Customers have validated Seeq instances
- Long and successful audit history
- **Hearing it louder: “we want Seeq in GMP decision making!”**

Pharma Functionality in Seeq - History

2021

Audit Trail



Pharma Functionality in Seeq - History

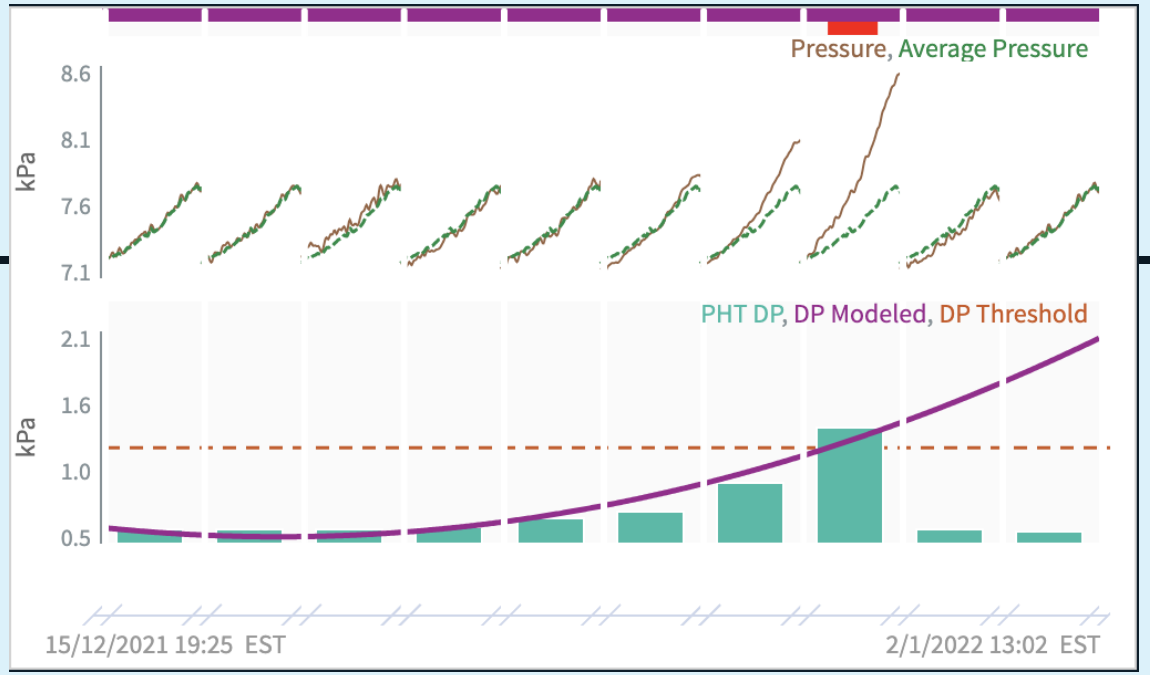
2021

2022

Audit Trail

Many features expanding use of Capsule Properties

Compare View



Pharma Functionality in Seeq - History

2021

Audit Trail

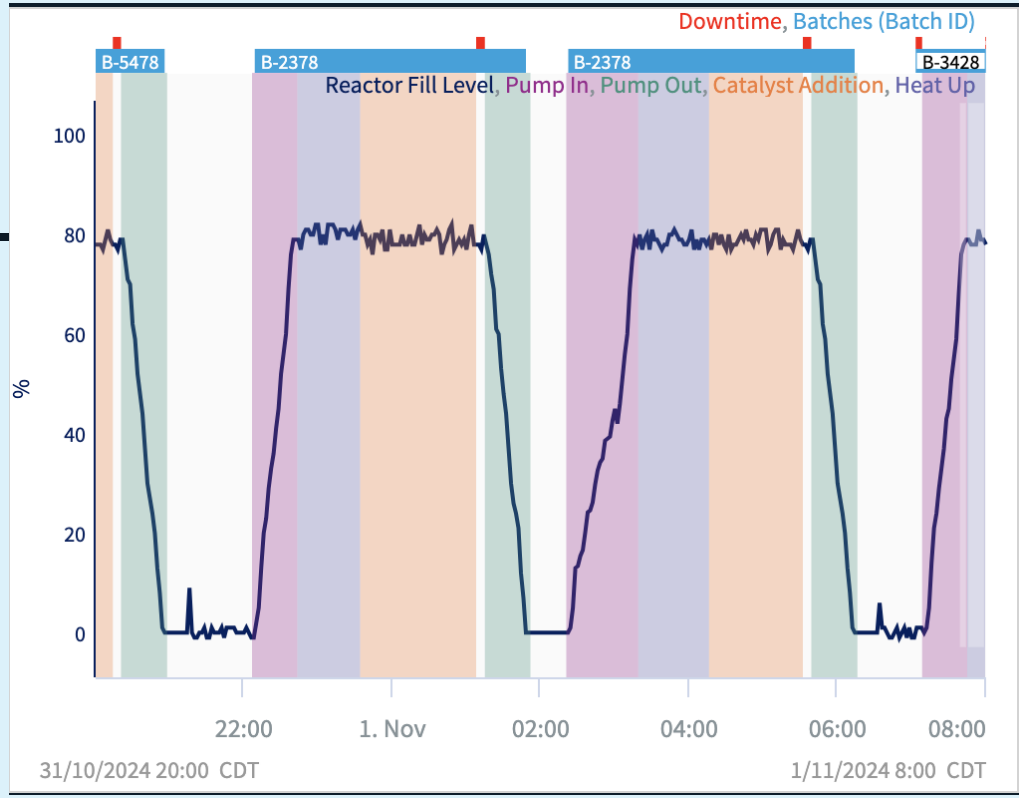
2022

Many features expanding use of Capsule Properties

Compare View

2023

Expanded functionality for Conditions on the trend



Pharma Functionality in Seeq - History

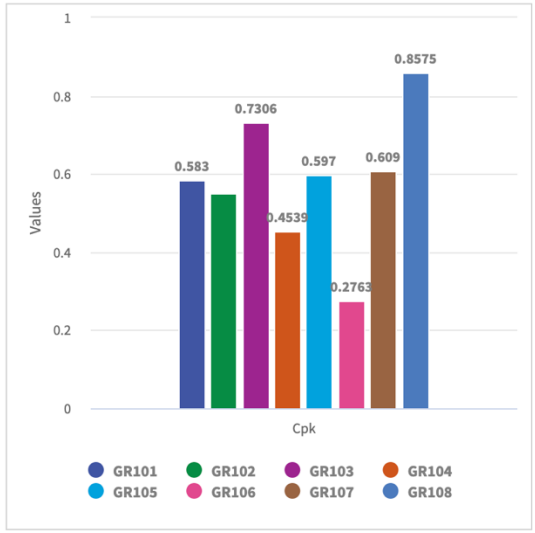
2021 | 2022 | 2023 | 2024

Quality Table

Grade Code

Group	Last: Start	Average: SSR	Average: USL	Average: LSL	Average: Flow	Average: Temp	Average: Total Samples
103 (5)	5 de jul. de 2024 7:30	92.693 %	1.21	0.99	0.0464 lb/h	304.26 °F	35.8
104 (3)	11 de jun. de 2024 7:30	79.724 %	0.825	0.675	0.029 lb/h	285.15 °F	32.333
105 (3)	14 de jun. de 2024 7:30	89.415 %	0.99	0.81	0.0424 lb/h	297.14 °F	42.667
106 (3)	18 de jun. de 2024 7:30	59.086 %	0.59	0.486	0.0288 lb/h	279.11 °F	45.667
107 (3)	22 de jun. de 2024 7:30	94.895 %	1.16	0.945	0.0438 lb/h	301.97 °F	45.333
108 (3)	26 de jun. de 2024 7:30	99.242 %	1.87	1.53	0.0469 lb/h	324.01 °F	22
101 (5)	7 de jul. de 2024 4:20	87.319 %	1.1	0.9	0.0459 lb/h	300.63 °F	42
102 (5)	10 de jul. de 2024 6:15	83.967 %	0.88	0.72	0.0336 lb/h	291.83 °F	46.4

Product Cpk



Improved Condition Tables and Charts

Administrator Capabilities can be granted separately

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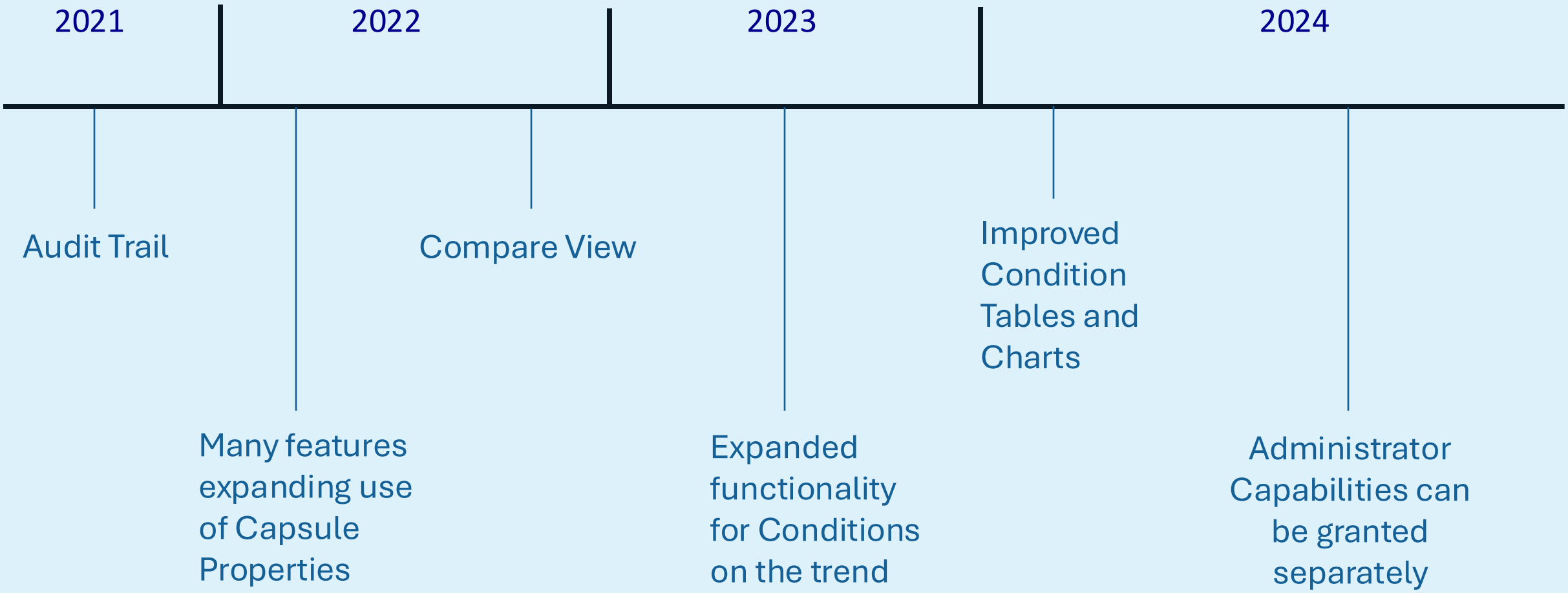
Pharma Functionality in Seeq - History



Why Seeq Pharma Suite?

Seeq FOR PHARMA ANALYTICS & AI SUITE

A product designed to respond to unique industry requirements

- **Easier for customers to validate** Seeq as a platform and the analytics solutions developed in Seeq
- **Enables GMP-decisions** use cases
  - Process-related and quality management solutions
  - Higher value
  - Business-critical
- **Fits customer journey** Pharma's Vendor Qualification needs

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What is Seeq Pharma Analytics & AI Suite?

Seeq FOR PHARMA | ANALYTICS & AI SUITE

Analytics Change Management

- Analysis Locking
- Analysis Versioning
- Readable Audit

Regulatory Compliant Support

- SaaS Update Coordination
- Seeq Additional Tenant
- Access to Pharma Trust Center
- Right to Audit

Pharma Specific Needs and Benefits

- Seeq Pharma Community of Practice

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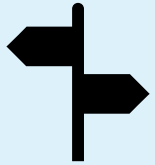
Analytics Change Management

Why?

- Makes it easier to use Seeq in validated environments
- Helps with enterprise rollouts and consistency across lines, sites, etc.

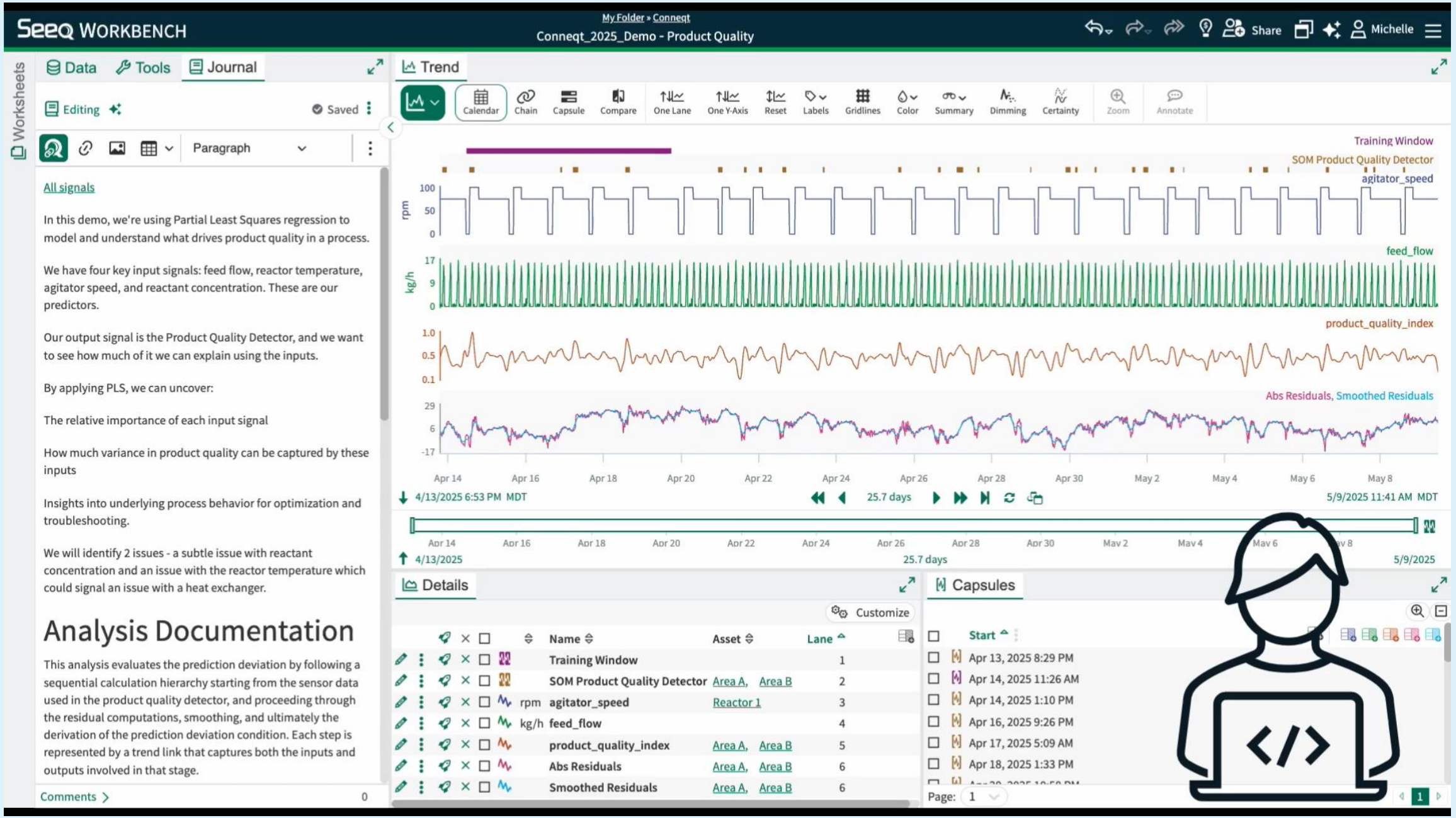
What?

- Ensures no one can make changes to an analysis when it is locked
- Allows versions to be linked together so updates can be made
- Changes to calculations are tracked

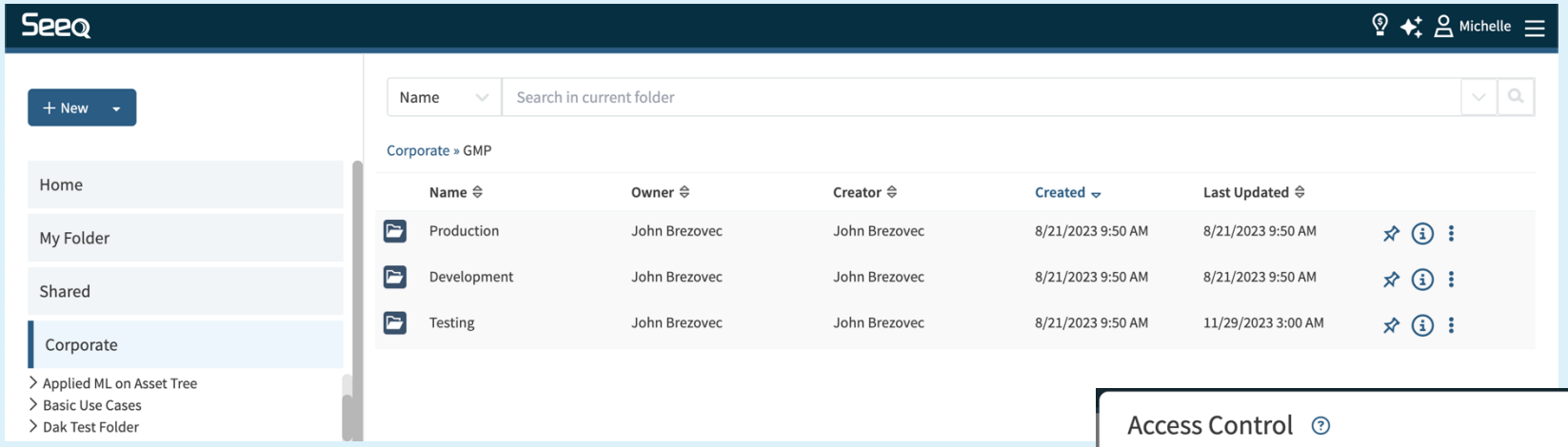


How?

- Workbench Analysis Locking
- Workbench Analysis Versioning
- Readable Audit Trail


Seeq WORKBENCH
My Folder » Conneqt
Conneqt_2025_Demo - Product Quality
Share
Michelle
Worksheets
Data
Tools
Journal
Editing
Saved
Paragraph
All signals
In this demo, we're using Partial Least Squares regression to model and understand what drives product quality in a process.
We have four key input signals: feed flow, reactor temperature, agitator speed, and reactant concentration. These are our predictors.
Our output signal is the Product Quality Detector, and we want to see how much of it we can explain using the inputs.
By applying PLS, we can uncover:
The relative importance of each input signal
How much variance in product quality can be captured by these inputs
Insights into underlying process behavior for optimization and troubleshooting.
We will identify 2 issues - a subtle issue with reactant concentration and an issue with the reactor temperature which could signal an issue with a heat exchanger.
Analysis Documentation
This analysis evaluates the prediction deviation by following a sequential calculation hierarchy starting from the sensor data used in the product quality detector, and proceeding through the residual computations, smoothing, and ultimately the derivation of the prediction deviation condition. Each step is represented by a trend link that captures both the inputs and outputs involved in that stage.
Comments
0
Trend
Calendar
Chain
Capsule
Compare
One Lane
One Y-Axis
Reset
Labels
Gridlines
Color
Summary
Dimming
Certainty
Zoom
Annotate
Training Window
SOM Product Quality Detector
agitator_speed
rpm
feed_flow
kg/h
product_quality_index
Abs Residuals, Smoothed Residuals
Apr 14
Apr 16
Apr 18
Apr 20
Apr 22
Apr 24
Apr 26
Apr 28
Apr 30
May 2
May 4
May 6
May 8
4/13/2025 6:53 PM MDT
25.7 days
5/9/2025 11:41 AM MDT
4/13/2025
25.7 days
5/9/2025
Details
Customize
Name
Asset
Lane
Training Window
SOM Product Quality Detector
Area A, Area B
agitator_speed
Reactor 1
feed_flow
product_quality_index
Abs Residuals
Smoothed Residuals
Capsules
Start
Apr 13, 2025 8:29 PM
Apr 14, 2025 11:26 AM
Apr 14, 2025 1:10 PM
Apr 16, 2025 9:26 PM
Apr 17, 2025 5:09 AM
Apr 18, 2025 1:33 PM
Page: 1

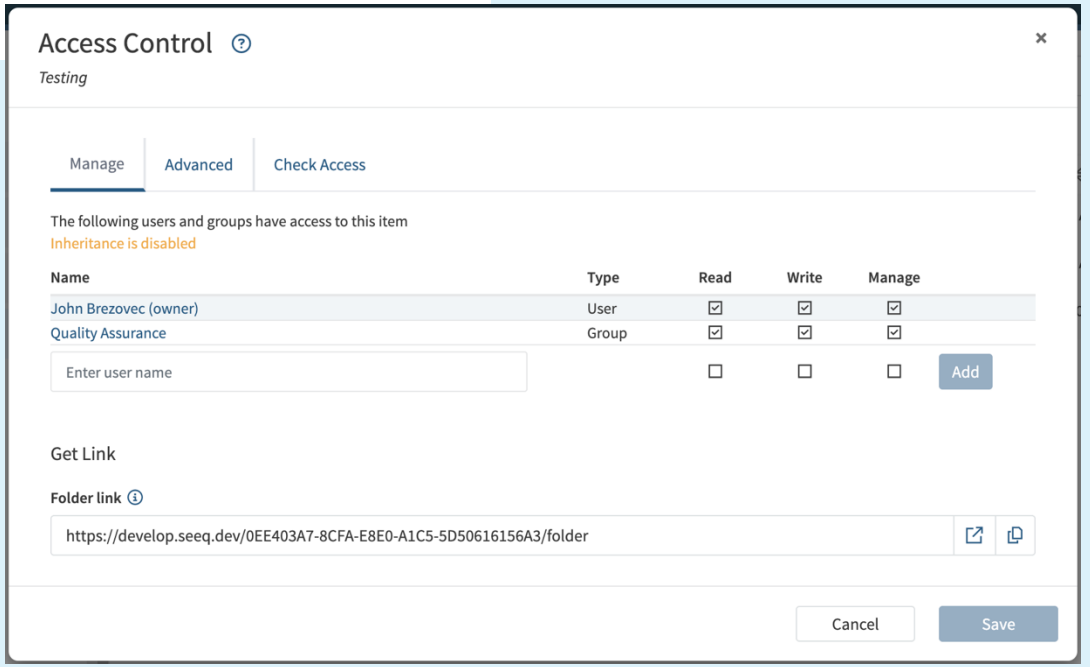
Recommended setup for Validation



Use folders in the Corporate drive for each stage in the approval process

Use Access Control on the folders to control who can make changes at each step in the process

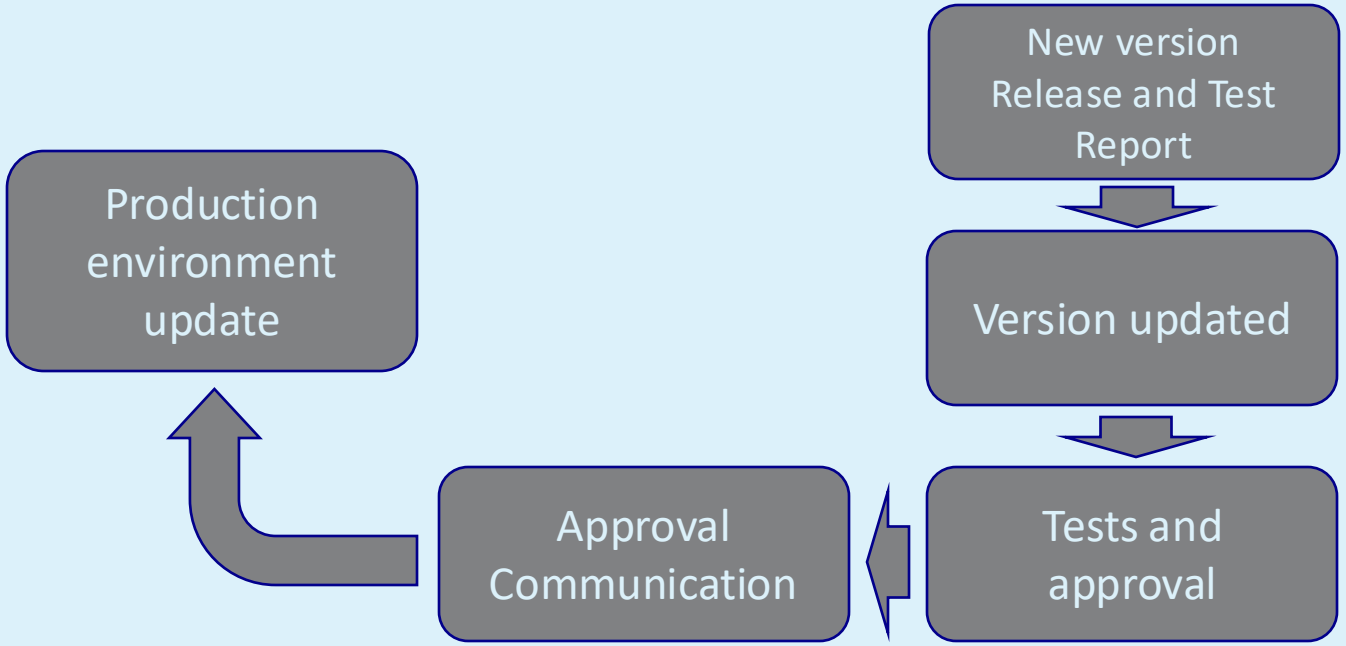
Lock Analyses once changes should no longer be made



Regulatory Compliant Upgrades

PRODUCTION SERVER
Validated

TEST SERVER
“Additional tenant”



Default update cycle time: **Quarterly**

Flexibility to accommodate customers’ requirements

SLA language defines Update Coordination mechanism

Controlled update mechanisms – fits industry standards

Lower risk of unnoticed bugs and faster fixes

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Right to Audit

- Documentation and resources for the initial quality audit
- Periodic follow-up audits

Access to Pharma area of the Trust Center

- Dedicated portal for Pharma documentation
- Documentation to assist validation processes
- Quarterly Regulatory Release Notes and Testing

Pharma Community of Practice

- Ability to network with other Seeq users in the industry
- Access to virtual and in-person events
- Early visibility of new features and opportunity to participate in user research
- Private forum area on seeq.org