



ThermoFisher
S C I E N T I F I C

Secrets for SuCCcess – Compliance, Cloud and CDS

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Secrets to Success

- What does success in the laboratory look like?
- Being compliant and passing audits
- Achieving cost savings through
 - Leveraging advances in IT
 - Improving productivity/throughput
 - Reducing errors
- Going home at 5pm and not having to worry!





● Making Compliance Easier

● Leveraging Advances in IT

● Improving Productivity

● Reducing Errors

“If you think compliance is expensive – try non-compliance.”

Former U.S. Deputy Attorney General Paul McNulty

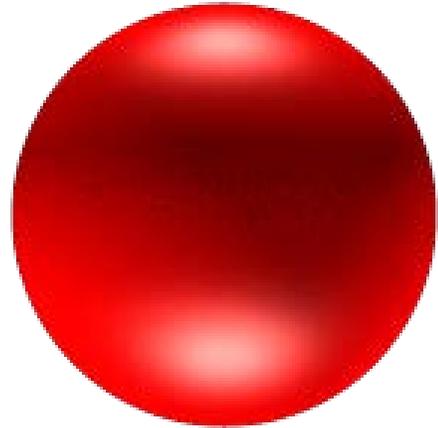
COMPLIANCE



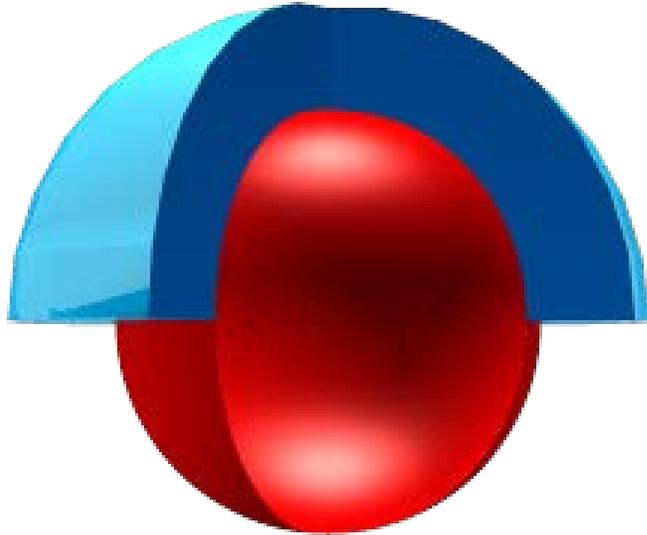
- Easy implementation of technical controls
- Easy monitoring of adherence
- Easy demonstration of compliance

It takes less time
to do things right
than to explain why
you did it wrong.

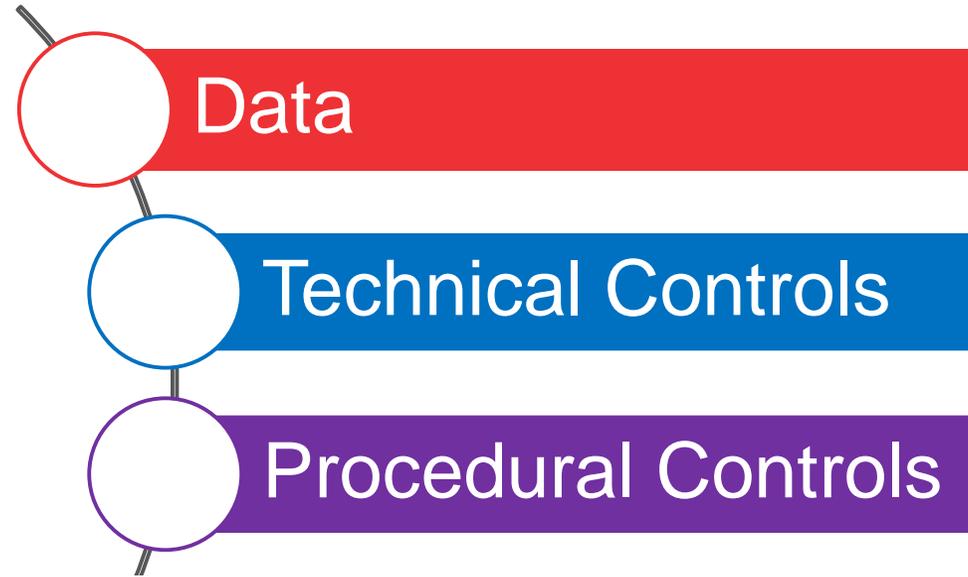
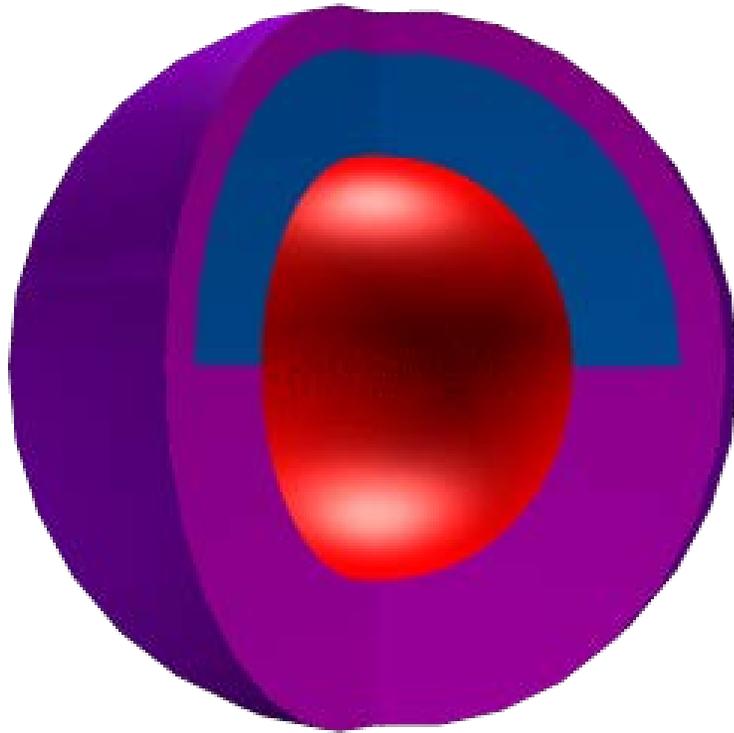
~Henry Wadsworth Longfellow



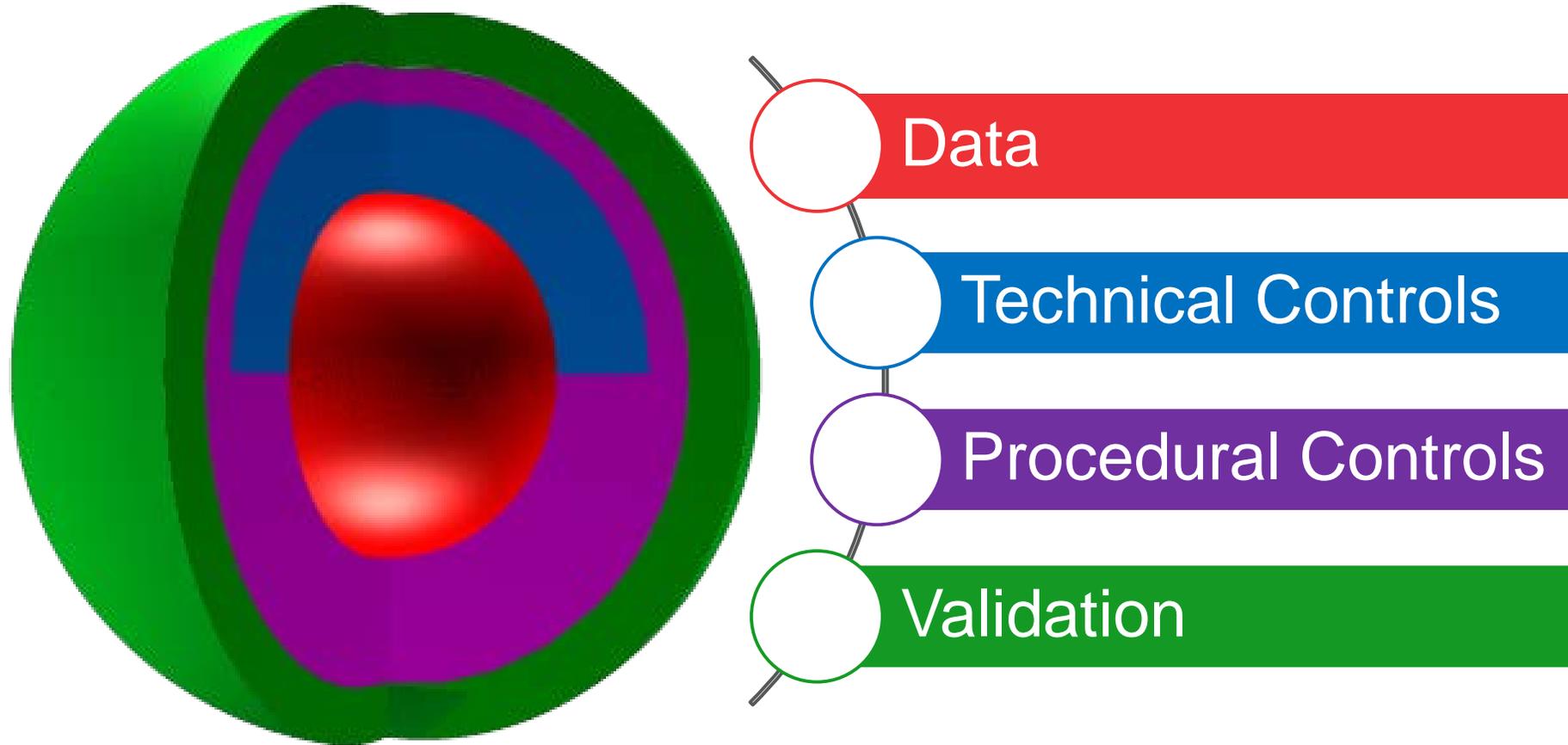
Compliance Technical Controls – Data Integrity Layers



Compliance Technical Controls – Data Integrity Layers

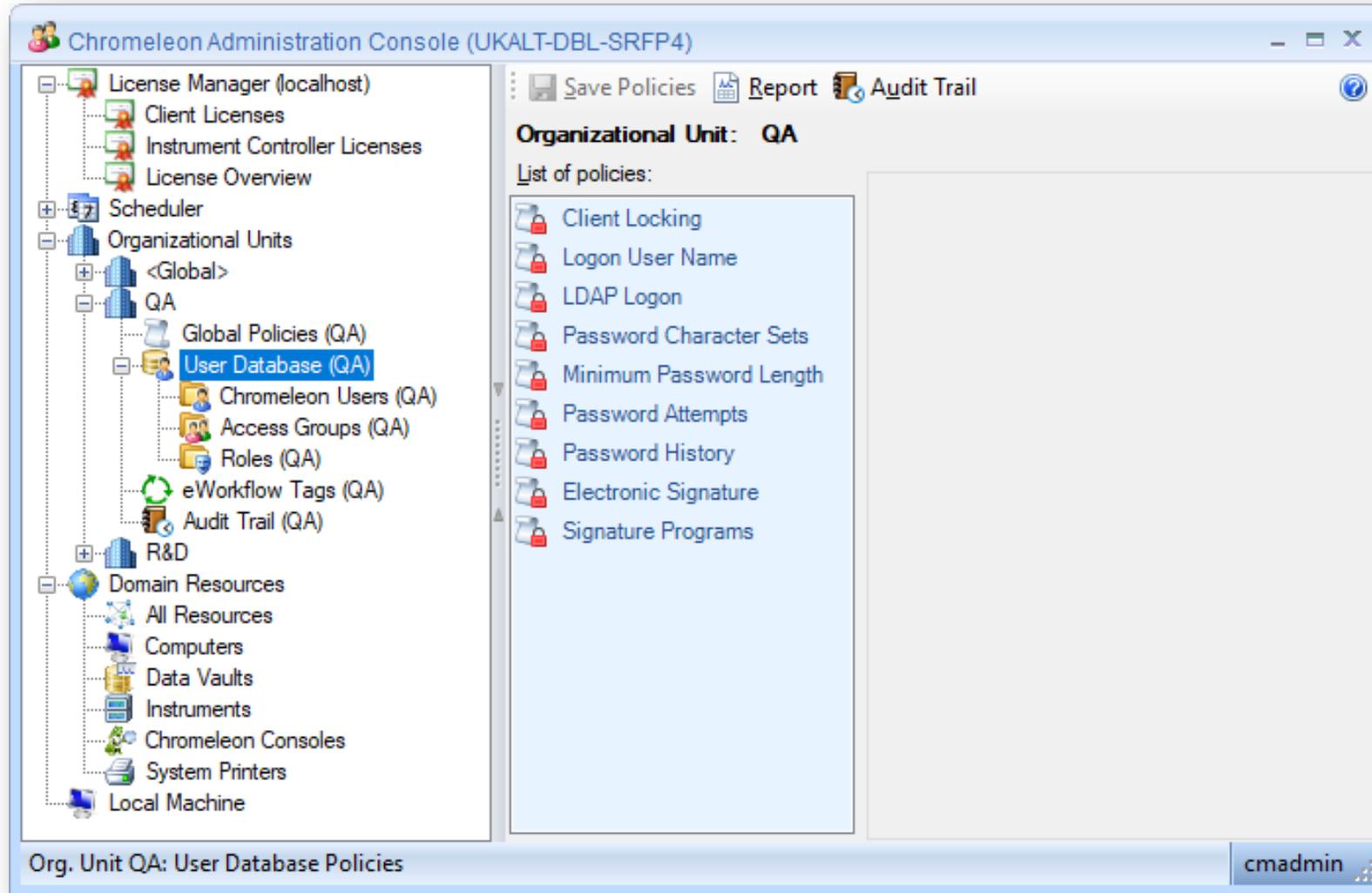


Compliance Technical Controls – Data Integrity Layers



Easy Implementation of Compliance Controls

- Centralized Administration Console



Easy Implementation of Compliance Controls

- Centralized Administration Console
- Comprehensive set of Audit Trails:
 - Data, injection, instrument, user management
 - Domain Resources, Data Vault Manager, eWorkflow™ Tags
 - Station, Global Policies, Organizational Units
- Extensive user management with privileged actions & full auditing of actions
- Access groups to control user access to software elements
- Versioning of data objects with industry-leading comparison and roll back
- Industry-leading network failure protection and data transport protocols
- Relational database at the heart of everything (Oracle or SQL Server)
- Integrated System Suitability Tests (SST)



Thermo Scientific™ Chromeleon™ 7 CDS has passed many FDA audits without any 483 observations
White papers and technical notes covering compliance, 21 CFR Part 11 and Data Integrity are available at

www.thermofisher.com/chromeleon

Easy Implementation of Compliance Controls – Privileged Actions

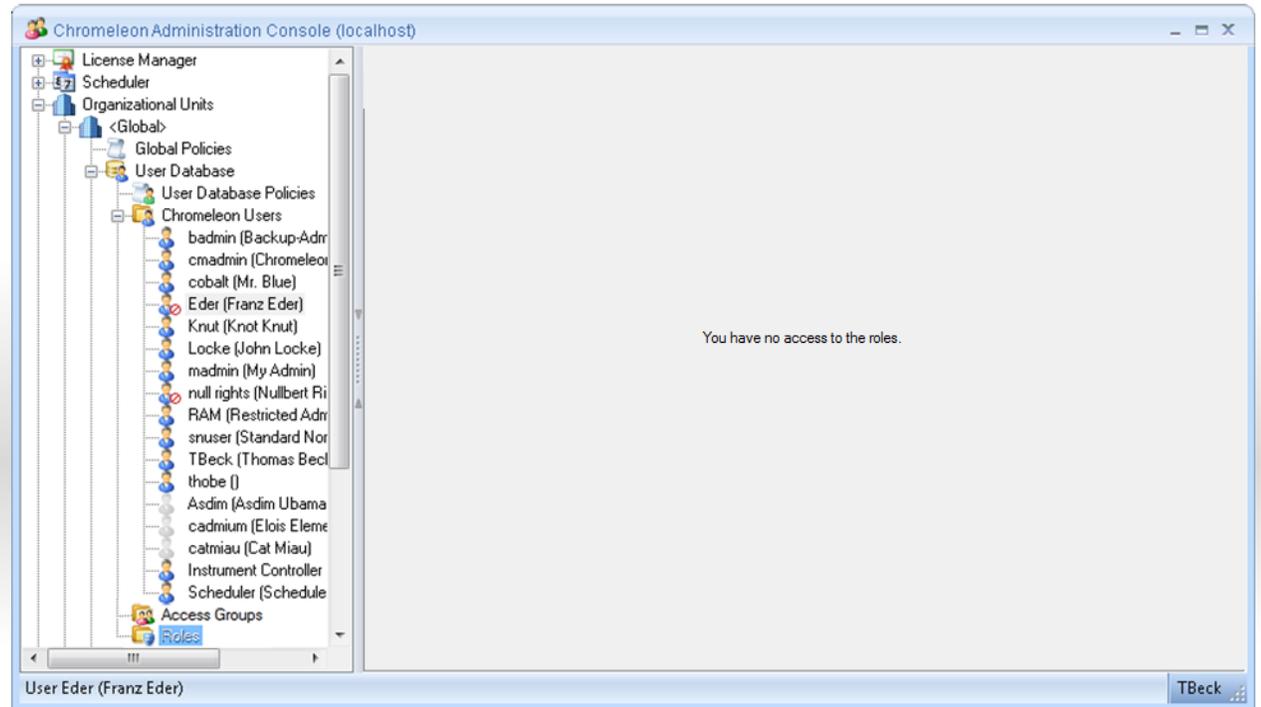
- Purpose: Require further authentication and/or comments for users performing operations
- Privileged Actions can be configured against any action to confirm who performs that action
- A comment can be captured, which can be freeform or available as a drop-down picklist

The screenshot displays a software interface with a left-hand navigation pane and a main table. The navigation pane includes items like 'Instrument Audit Trails', 'Detection Algorithm Version', 'User Templates Location', 'Watermark', 'UI Customizations', 'Privileged Actions' (highlighted), 'Email Configuration', 'Station Audit', and 'Raw Data'. The main table lists various actions with columns for 'Requires Authorization', 'Requires Comment', and 'Default Comment'. A 'Verify Password' dialog box is overlaid on the right, titled 'Verify Password - System Man...'. It contains a signature icon, the text 'Exercise Requires Signature', and input fields for 'Username' (containing 'SYSTEM'), 'Password', and 'Comment'. Below the fields is a note: 'Completion of this form carries the same meaning and weight as a written signature.' and 'Ok' and 'Cancel' buttons.

Action	Requires Authorization	Requires Comment	Default Comment
+ Instrument Configuration	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Instrument Method	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Instrument Audit Trail	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Data Vault	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Folder	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Query	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Sequence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Injection	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
+ Manual Data Processing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
- eWorkflow	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Create	<input type="checkbox"/>	<input checked="" type="checkbox"/>	created eWorkflow
Modify	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Rename	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Delete	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

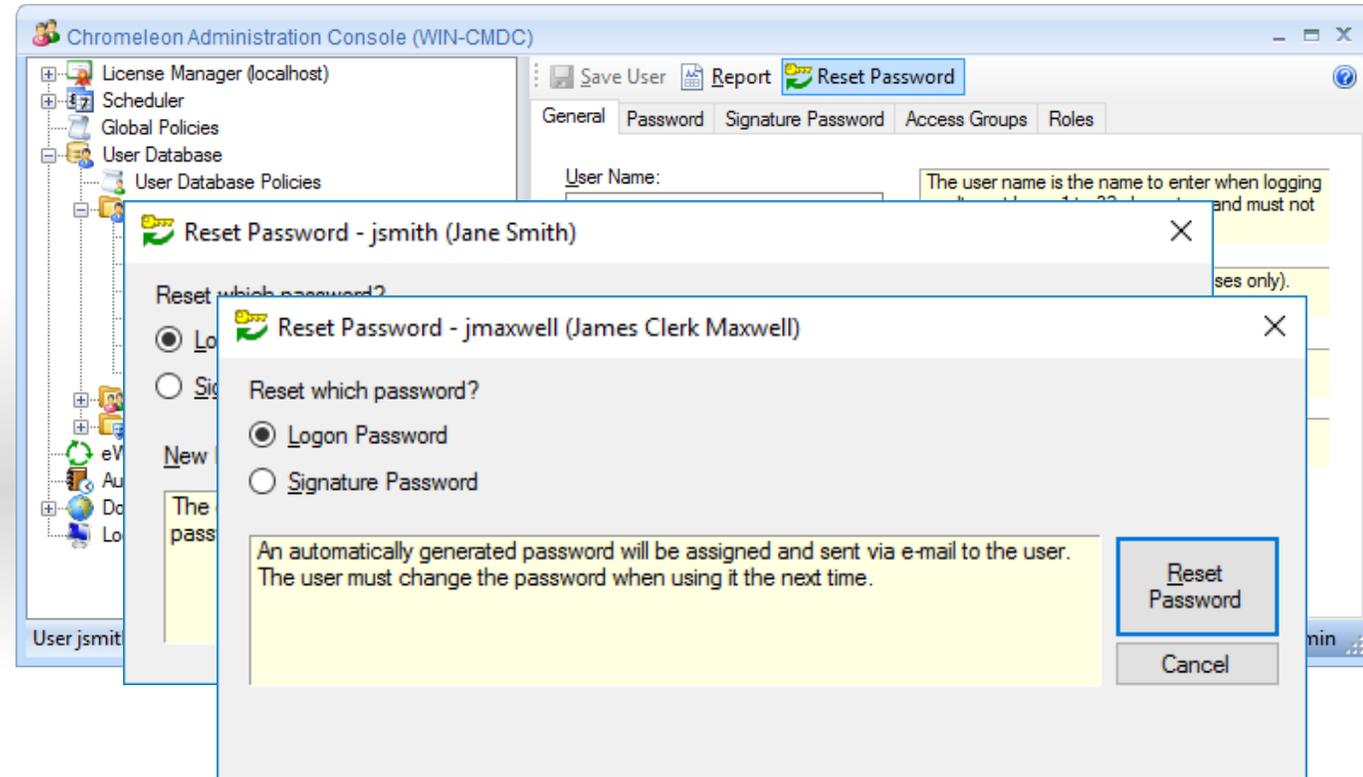
Easy Implementation of Compliance Controls – Managing Users

- Introducing more fine-granular control of user management
- Introduces the ability to define “reduced-admins”
 - Cannot modify User Management Policies
 - Prevent changes to roles or access groups
 - Only reset passwords
- Reduced-admins actions can be controlled so that they cannot grant themselves higher privileges
- Ability to only allow reduced-admins to create users with the same or less privileges and access



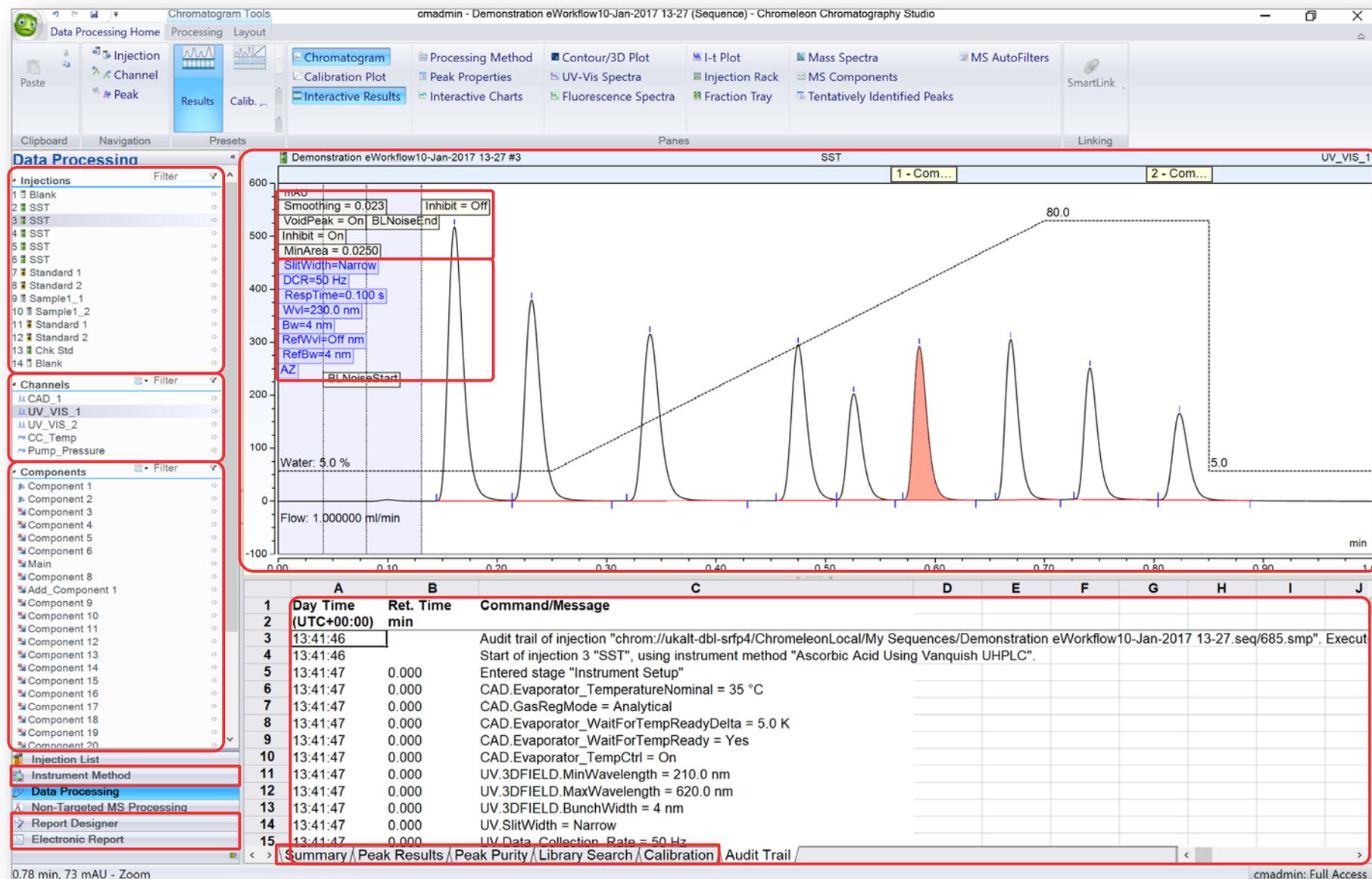
Easy Implementation of Compliance Controls – Reset Password

- If administrator has the reset password policy they can assign new passwords to all users
- To ensure a reduced-admin cannot take-over a full admin's account, so long as the full admin has an associated email address, the new password is not visible and will only be disclosed in the email to the full admin user



Easy Monitoring of Adherence

- Easy review of data via Chromatography Studio
 - Injections
 - Channels
 - Components
 - Chromatogram
 - Detection Parameters
 - Instr. Method Parameters
 - Interactive Results
 - Injection Audit Trail
 - Report & eReport



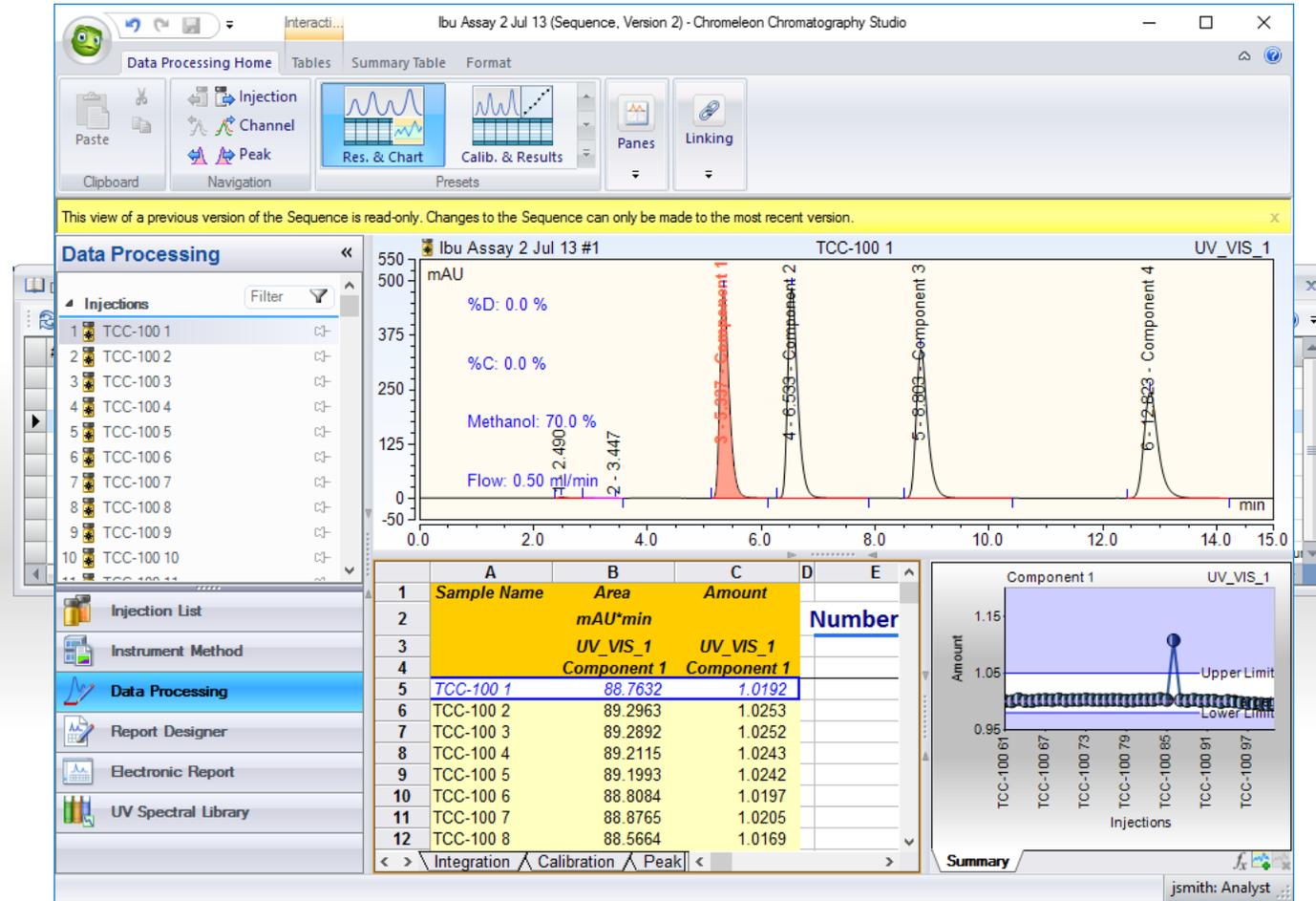
Easy Monitoring of Adherence - Example

- Summary of version numbers giving reviewers clear indication of where to focus

No.	Injection Name	Injection Version Number	Chromatogram Version Number	InstrumentMethod	Instrument Method Version Number	Processing method Name	Processing Method Version Number
1	Equilibration Blank	2	1	sps5060 assay lc50	1	sps5060 assay	2
2	Blank	2	1	sps5060 assay lc50	1	sps5060 assay	2
3	Blank	2	1	sps5060 assay lc50	1	sps5060 assay	2
4	SST	2	1	sps5060 assay lc50	1	sps5060 assay	2
5	STD 1-A	2	1	sps5060 assay lc50	1	sps5060 assay	2
6	STD 1-B - 1	2	1	sps5060 assay lc50	1	sps5060 assay	2
7	STD 1-B - 2	2	1	sps5060 assay lc50	1	sps5060 assay	2
8	STD 1-B - 3	2	1	sps5060 assay lc50	1	sps5060 assay	2
9	STD 1-C	2	1	sps5060 assay lc50	1	sps5060 assay	2
10	STD 2-B - 1	2	1	sps5060 assay lc50	1	sps5060 assay	2
11	800317350 a	4	1	sps5060 assay lc50	1	sps5060 assay	2
12	800317350 b	4	1	sps5060 assay lc50	1	sps5060 assay	2
13	800317940 a	4	1	sps5060 assay lc50	1	sps5060 assay	2
14	800317940 b	4	1	sps5060 assay lc50	1	sps5060 assay	2
15	800317950 a	4	1	sps5060 assay lc50	1	sps5060 assay	2
16	800317950 b	4	1	sps5060 assay lc50	1	sps5060 assay	2
17	STD 2-B - 2	3	1	sps5060 assay lc50	1	sps5060 assay	2
18	800317960 a	4	1	sps5060 assay lc50	1	sps5060 assay	2
19	800317960 b	4	1	sps5060 assay lc50	1	sps5060 assay	2
20	800317970 a	4	1	sps5060 assay lc50	1	sps5060 assay	2
21	800317970 b	4	1	sps5060 assay lc50	1	sps5060 assay	2
22	STD 2-B - 3	3	1	sps5060 assay lc50	1	sps5060 assay	2
23	Shutdown	3	1	shutdown lc50	1	sps5060 assay	2
Max version Number:		4	1	n.a.	1	n.a.	2

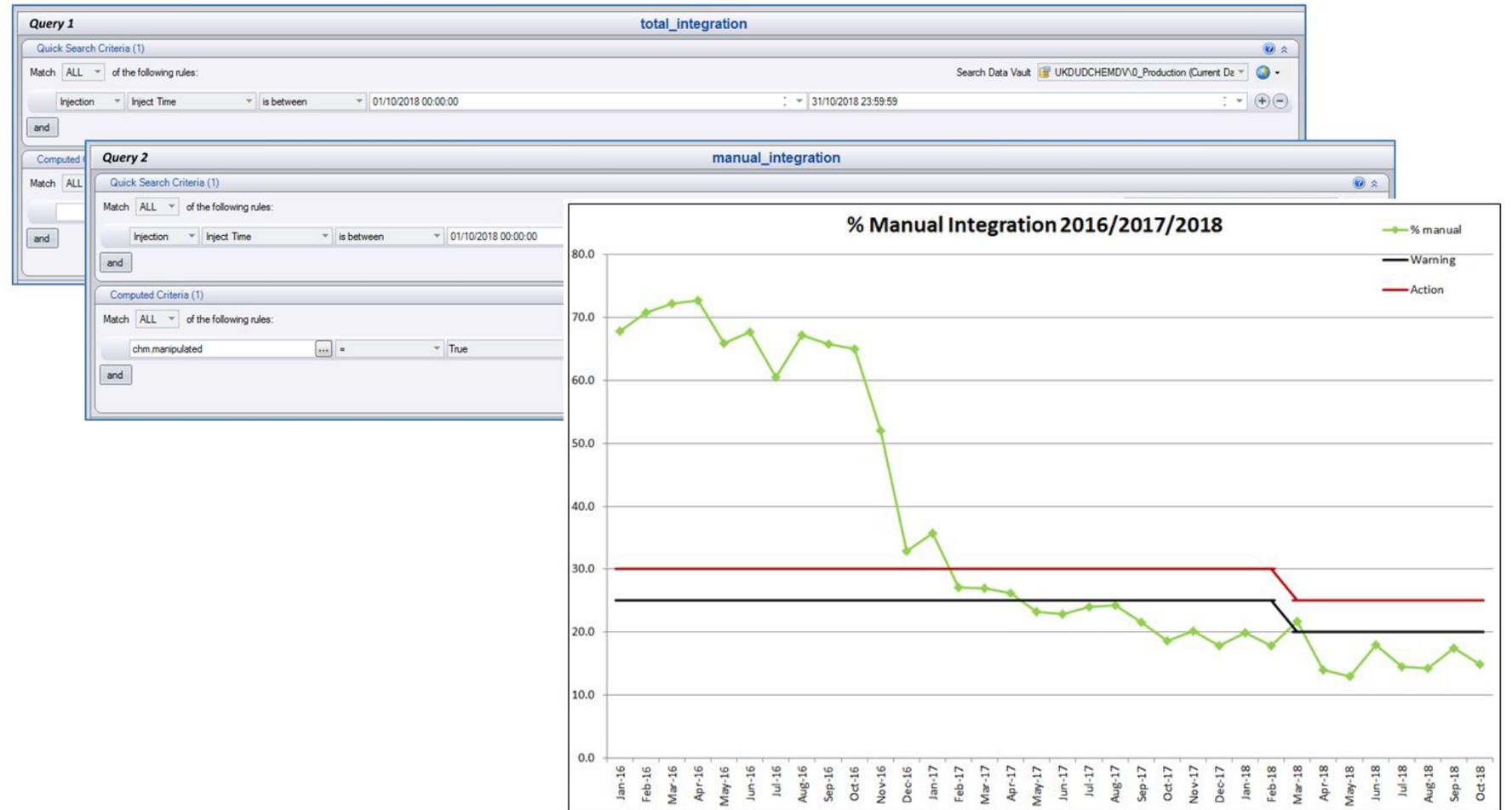
Easy Demonstration of Compliance – Studio Version Comparison

- Studio button is now available in Data Audit Trail Viewer
- Selecting a previous version to the current open the sequence in the Studio as read-only
- Several Studios can be opened with different versions



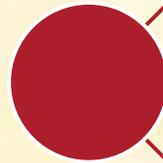
Easy Demonstration of Adherence - Example

- Monitoring use of manual integration
- Run Query
- Open report template





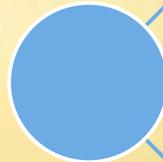
Making Compliance Easier



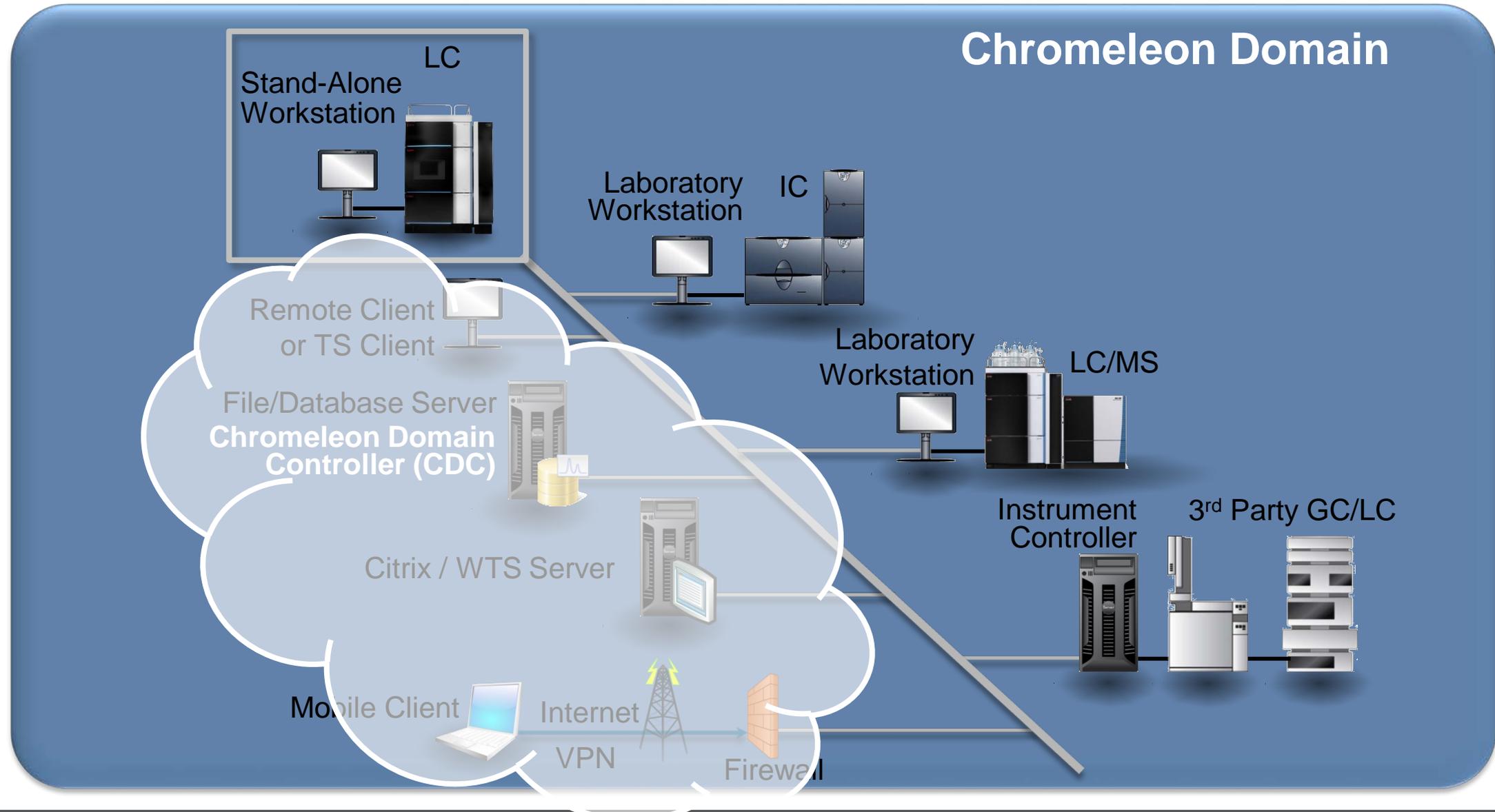
Leveraging Advances in IT



Improving Productivity



Reducing Errors

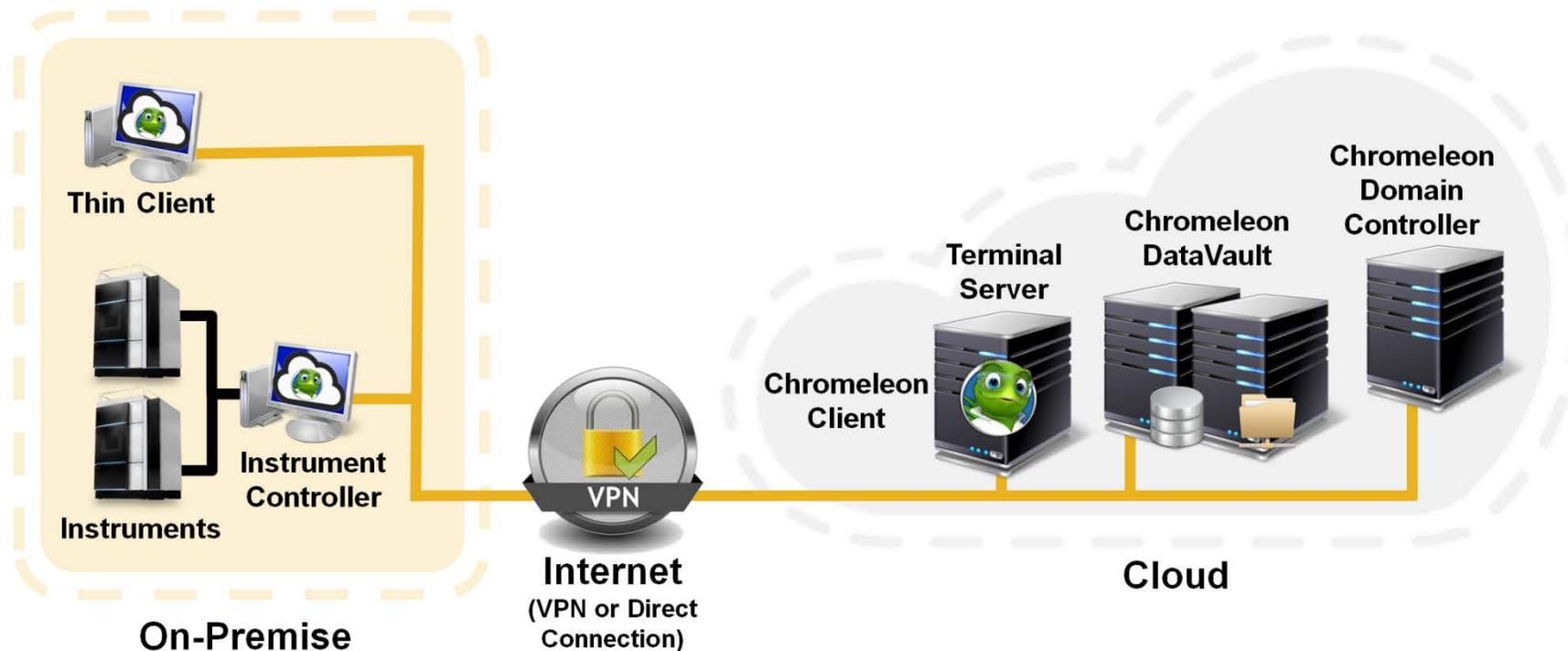


Leveraging Advances in IT – Cloud Benefits and Challenges

- Reduced Operating Costs
 - Switch CapEx to OpEx
 - Only pay for what you use → total cost of ownership (TCO) plunges
- Flexibility and Scalability
 - Fast deployment → rapidly scale resources up or down at peak or quiet times
- Reliability
 - 24/7/365 and >99.95% availability
 - Fast failover and easy backup/restore
- Control
 - Minimal control over cloud resources
- Security
 - Degree of uncertainty about how security at all levels can be achieved
 - Data isolation in a multi-tenancy environment
- Reliability
 - Outages and other technical issues (internet down)

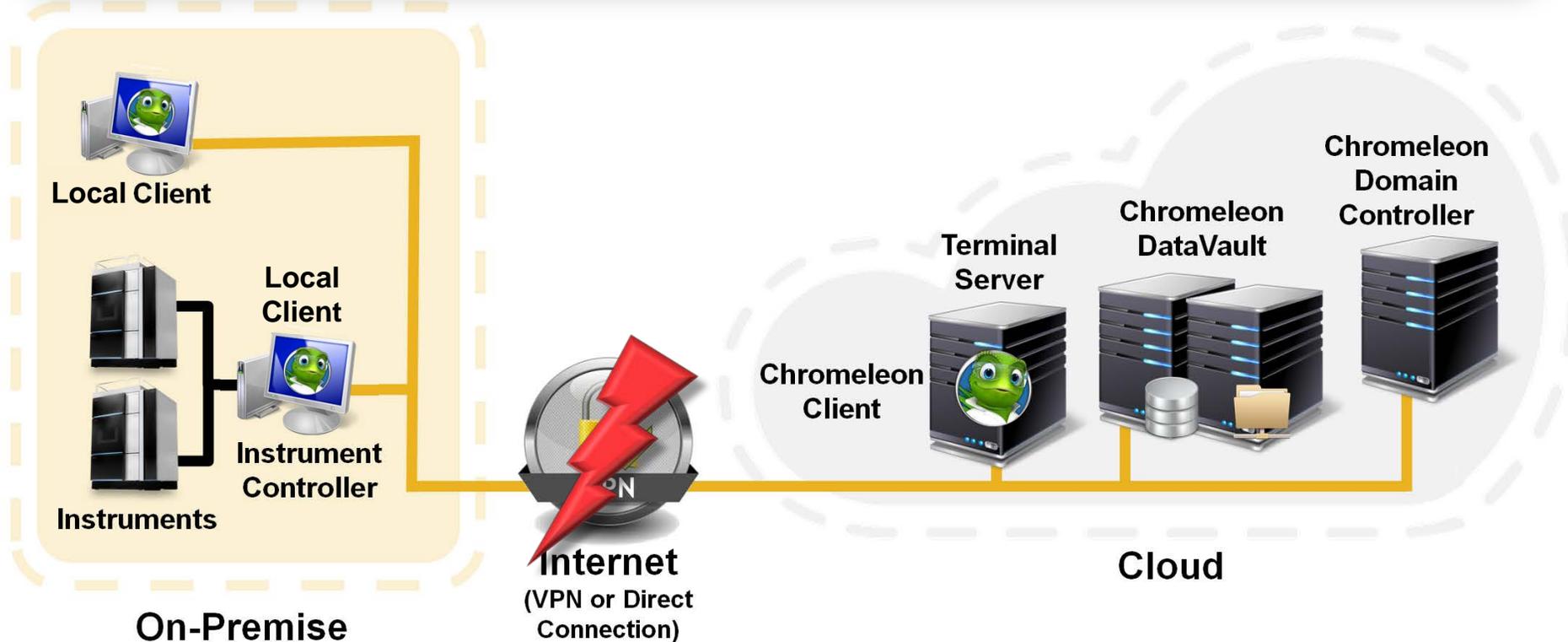
Leveraging Advances in IT – Chromeleon CDS Cloud

- Lift and shift central resources and Chromeleon Client to cloud
 - Reduced costs on servers and IT infrastructure
 - Easy scalability of server resources
 - Elasticity of Client computing resources
- Significant performance improvements possible



Leveraging Advances in IT – Cloud Network Failure Protection

- ✓ On-premise users can continue working with Local Clients
- ✓ Software license available on Instrument Controller
- ✓ Users can log on using Local Client
- ✓ No loss of data being generated during internet connection failure





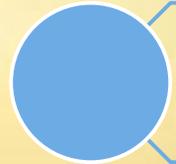
Making Compliance Easier



Leveraging Advances in IT



Improving Productivity



Reducing Errors

Chromeleon CDS increases your lab productivity

- ✓ Operational Simplicity delivers ease-of-use saving time, effort, and training costs
- ✓ Suite of intelligent tools work together ensuring more right the first time analyses saving time and cost
- ✓ True 24/7 laboratory uptime with outage protection for maximum utilization of resources and faster return on investment



Chromeleon CDS simplifies your lab workflows

- ✓ eWorkflow™ procedures deliver operational simplicity, reproducibility, and easy method distribution
- ✓ Parameter-free integration with instant reporting gives ease of use saving time and effort
- ✓ Unique integration of MS can reduce number of tests, simplify workflows and give faster return on investment





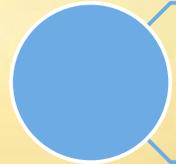
Making Compliance Easier



Leveraging Advances in IT



Improving Productivity



Reducing Errors

Boosting Lab Productivity – Getting It Right The First Time

Getting analysis right first time automatically gives:

- ✓ High quality of and confidence in results
- ✓ Lower cost of analysis
- ✓ Improved lab efficiency
- ✓ Faster release to market and return on investment



Predictive Performance

- ✓ Analysis more likely to complete first time



ICH Method Validation Templates

- ✓ Robust method more likely to run first time



eWorkflows

- ✓ Create correct sequence first time, every time



Sequence Ready Check

- ✓ Confirms sequence will run to completion



Smart Startup

- ✓ Ensures first injection is always good



System Suitability Tests

- ✓ Gives highest confidence in results



Intelligent Run Control

- ✓ Get right results, no out of spec investigations



Report Templates with Report Check

- ✓ Correct calculations give high confidence in results

Streamline your Laboratory

Ensure Compliance



Achieve, maintain & demonstrate compliance

- Easy, centralized setup
- Simple monitoring of adherence
- Tools to help demonstrate compliance

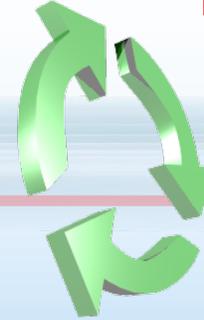
Maximize Your Lab Productivity



Up to 30% efficiency gain

- Time savings of 6-60 minutes are routinely obtained using smart processing tools
- Get more 'right first time' analyses
- Network-independent data acquisition for 24/7 uptime

Simplify Your Lab Workflows



Faster, simpler workflows

- Roll-out methods faster with eWorkflow procedures
- Simplify method development with parameter-less integration
- Faster results with instant reporting

Lower Your Cost of Ownership



Scalable deployment with easy maintenance

- Single software for all instruments
- Leverage advances in IT (Cloud)
- Simplified administration
- Link to existing software systems for seamless data flow

Chromeleon CDS delivers compliance, productivity, ease of use, and lower CoO

For more information on Chromeleon CDS software visit:

thermofisher.com/OneCDS

Like Charlie Chromeleon on Facebook to follow his travels and get important updates on chromatography software!



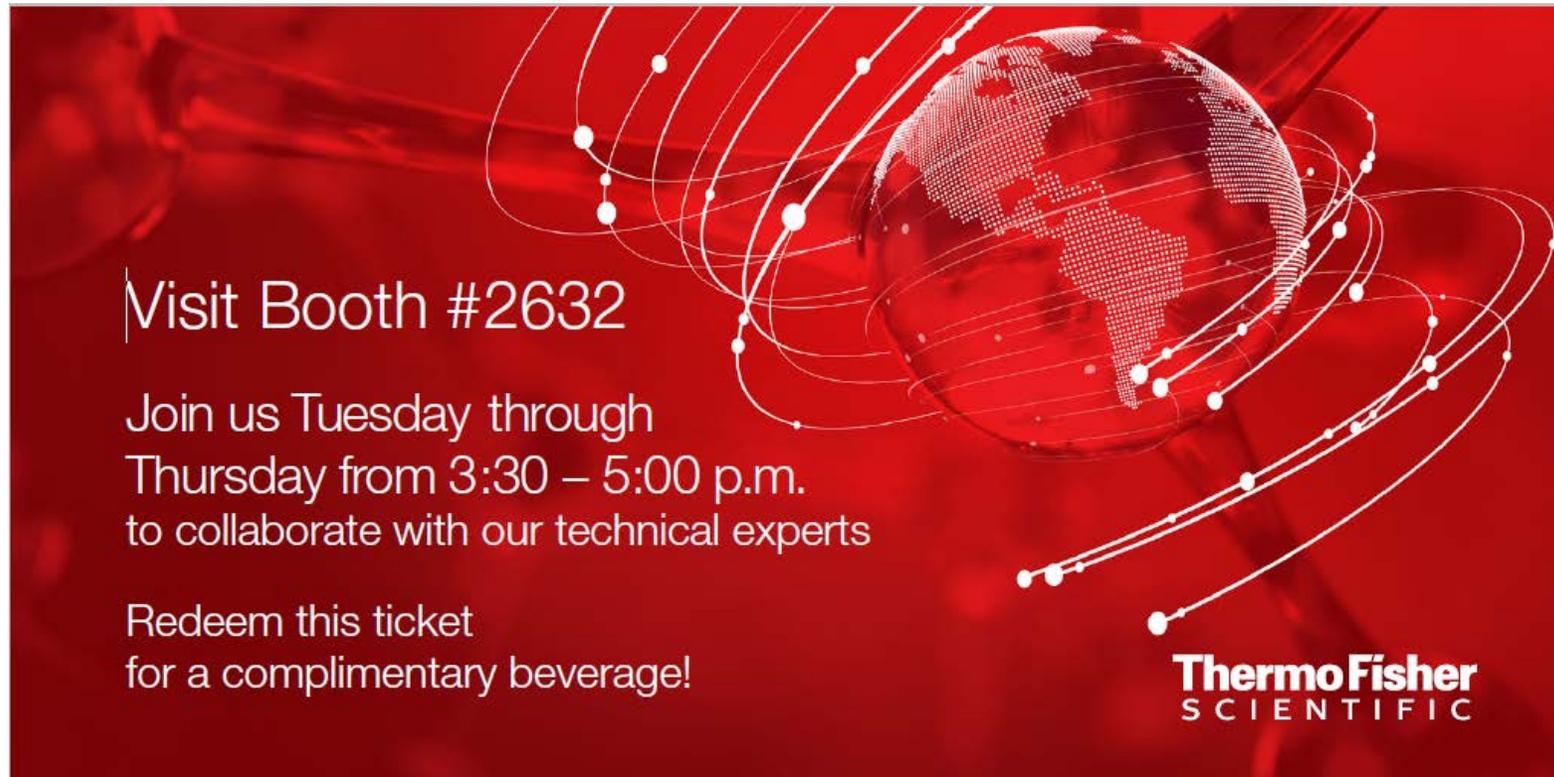
Join the LinkedIn customer forum – Chromeleon User Group – to discuss Chromeleon CDS with us and your industry peers.



Spasibo Gracias ۱ شکر
Obrigado Spasibo Dank U
Grazie
Eυχαριστώ
Danke
Merci
Dank U
Ngiyabonga
Diolch
Thank You
Obrigado
Merci
Eυχαριστώ
Dziękuję
Danke
Grazie
Merci
Dank U
Diolch
Ngiyabonga
Tack
Terima Kasih
U
Diolch
Grazie
Tack
Dank U
Danke
Merci
Eυχαριστώ
Tack

Thank You

Please return our survey to receive a drink ticket for our daily networking event where you can continue discussions with our experts!



Visit Booth #2632

Join us Tuesday through
Thursday from 3:30 – 5:00 p.m.
to collaborate with our technical experts

Redeem this ticket
for a complimentary beverage!

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