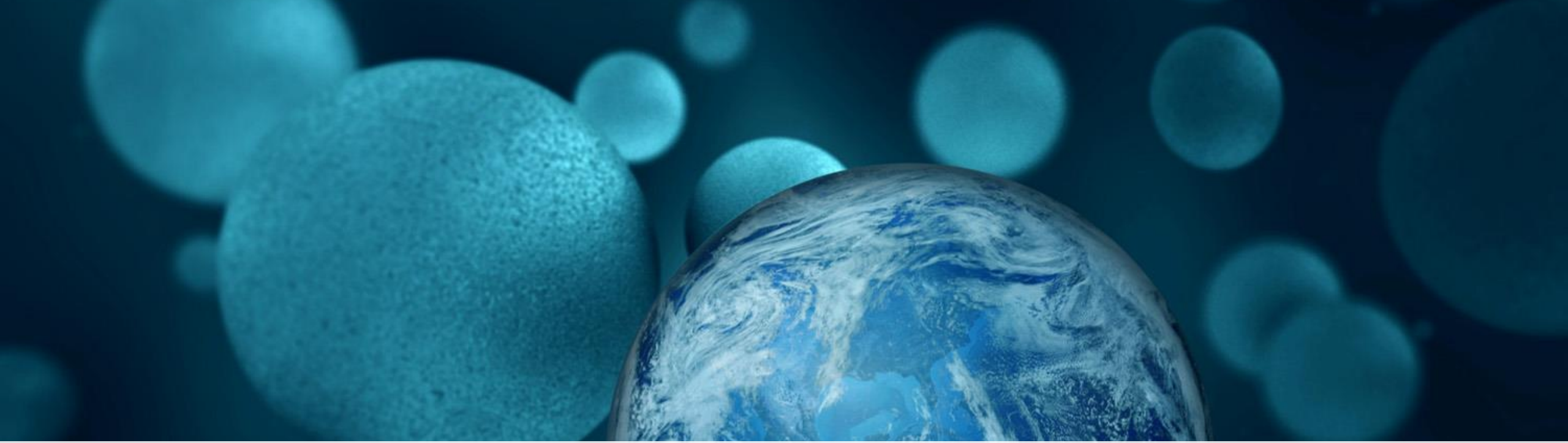


ThermoFisher SCIENTIFIC

Chromeleon Enterprise Chromatography Data System

Dr Simon Dunne
Nov 2019 – ACM2 Ltd, Sofia, Bulgaria

Chromeleon 7 CDS Streamlines Chromatography

ThermoFisher SCIENTIFIC

Introducing Chromeleon 7 Chromatography Data System

- New-generation Thermo Scientific™ Chromeleon™ Chromatography Data System

- Core design principle **“Simply Intelligent”** delivering…
  - **Intelligent Functionality** - it does everything you need!
  - **Operational Simplicity™** - everything you need to do is fast and easy!

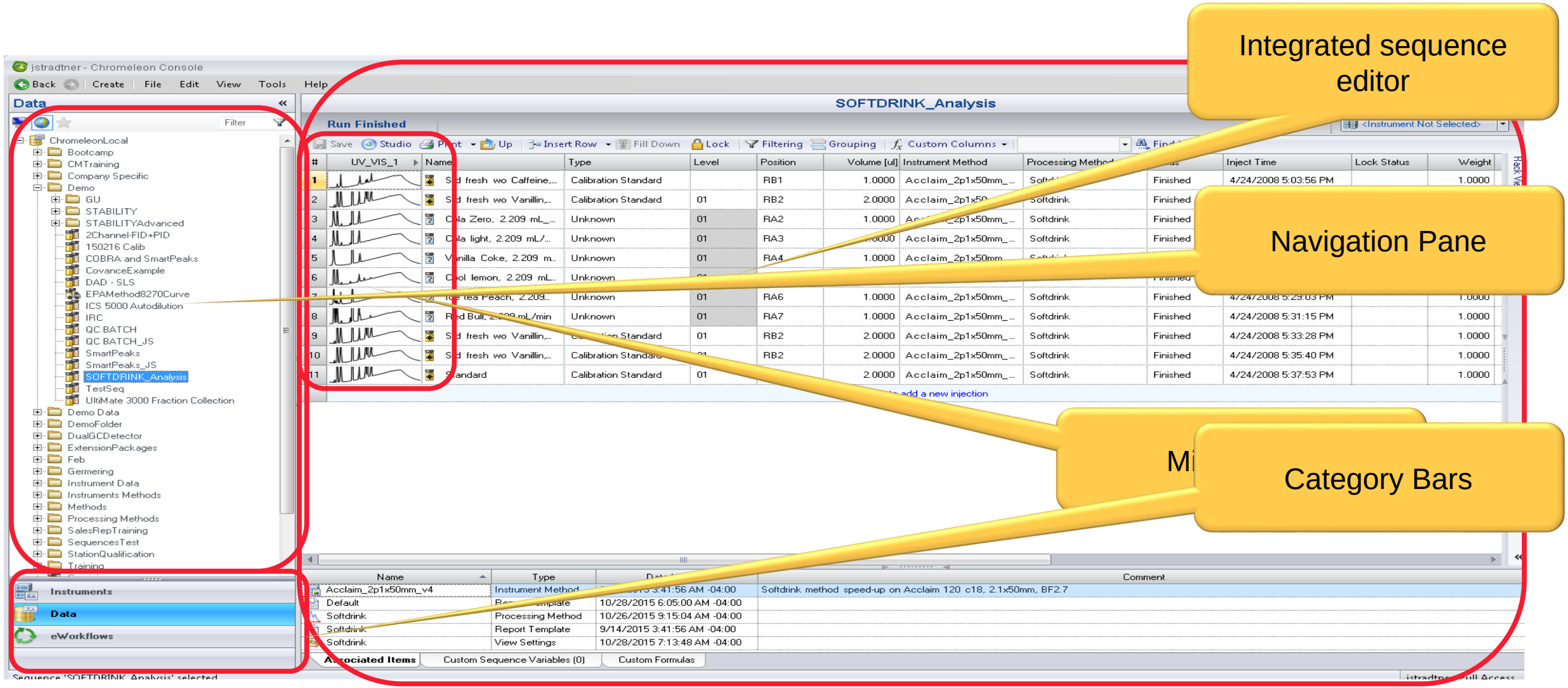
- Major design rules:
  - Minimize number of steps needed to perform any task
  - Make all steps easy to understand and easy to use
  - Minimize time needed to perform any task

Universal Instrument Control

- Bi-directional instrument control for over 525 different modules from 20 different manufacturers including:
  - Thermo Scientific (LC, IC, GC, MS, Sample Prep)
  - Agilent (LC, GC)
  - Waters (LC)
  - Shimadzu (LC, GC)
- LIMS can incorporate data from non-chromatographic (AA, ICP, UV, FTIR, MS, etc.) & ‘simple’ instruments (balance, pH meter, etc.)

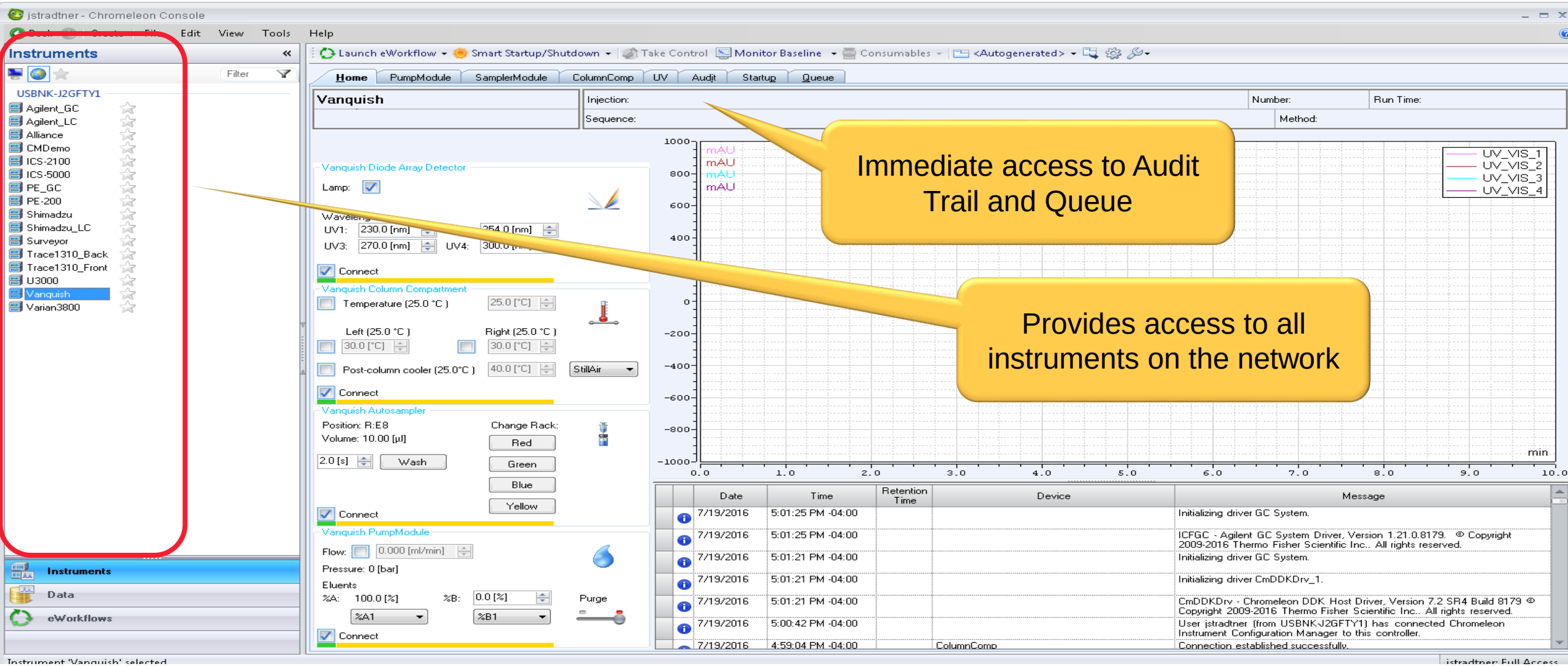
ThermoFisher SCIENTIFIC

Console – Easy Access to Data



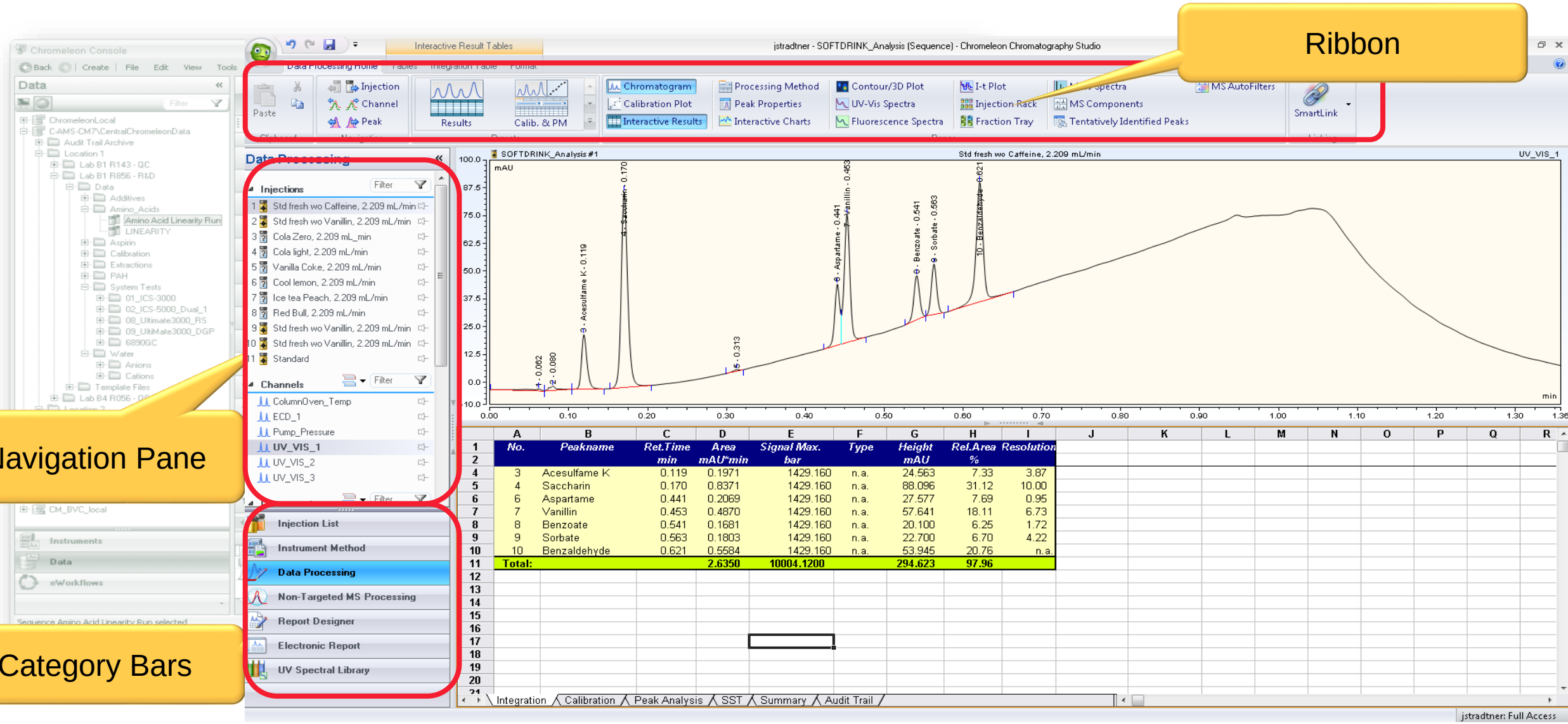
ThermoFisher SCIENTIFIC

Console – Easy Access to Instruments via ePanels



ThermoFisher SCIENTIFIC

User Interface – Studio – Data Processing and Reporting

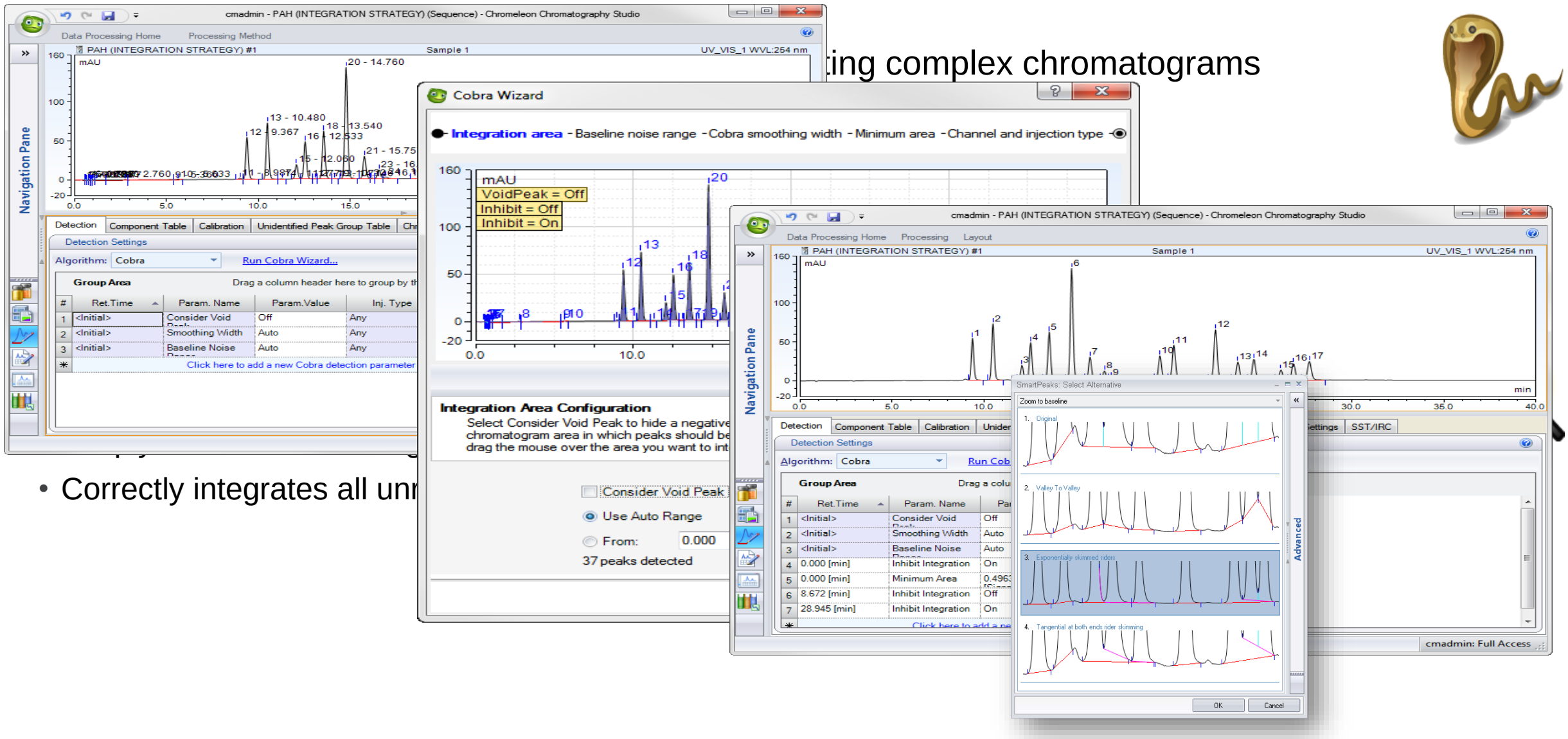


No.	Peakname	Ret.Time min	Area mAU*min	Signal Max. bar	Type	Height mAU	Rel.Area %	Resolution
3	Acesulfame K	0.119	0.1971	1429.160	n.a.	24.563	7.33	3.87
4	Saccharin	0.170	0.8371	1429.160	n.a.	88.096	31.12	10.00
6	Aspartame	0.441	0.2069	1429.160	n.a.	27.577	7.69	0.95
7	Vanillin	0.453	0.4870	1429.160	n.a.	57.641	18.11	6.73
8	Benzoate	0.541	0.1681	1429.160	n.a.	20.100	6.25	1.72
9	Sorbate	0.563	0.1803	1429.160	n.a.	22.700	6.70	4.22
10	Benzaldehyde	0.621	0.5584	1429.160	n.a.	53.945	20.76	n.a.
Total:			**2.6350**	**10004.1200**		**294.623**	**97.96**	

Improved Integration – Simplifying Data Processing and Review

ting complex chromatograms

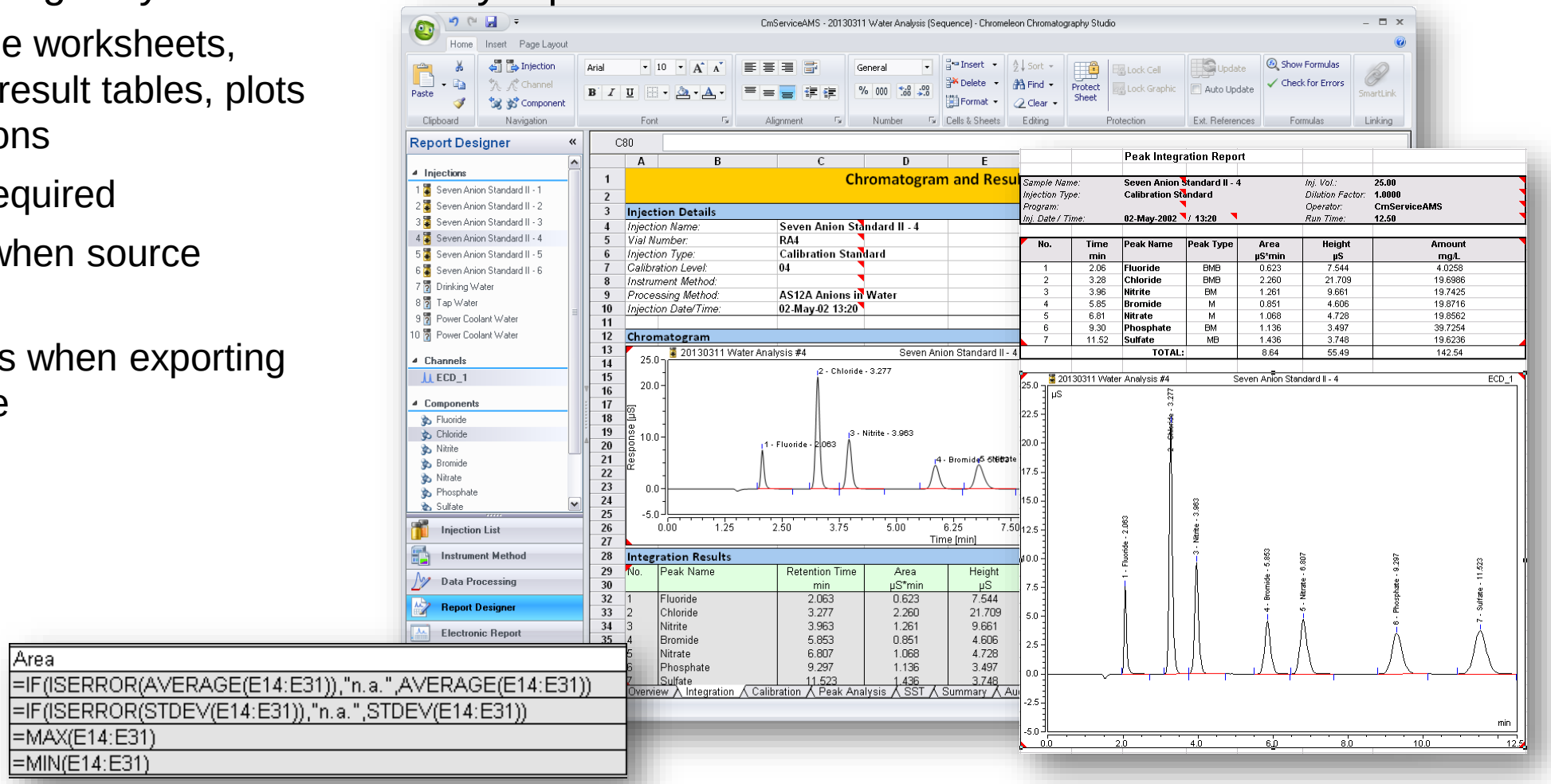
- Correctly integrates all unr



ThermoFisher SCIENTIFIC

Data Reporting – Flexible Report Designer

- With the Report Designer you can create any report
  - Can contain multiple worksheets, test and variables, result tables, plots and custom equations
  - Instant results as required
  - Automatic update when source data changes
  - No validation issues when exporting to external software



ThermoFisher SCIENTIFIC

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

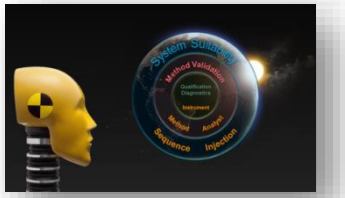
✓ Robust method more likely to run first time

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

eWorkflow Procedures

✓ Create correct sequence first time, every time

ThermoFisher SCIENTIFIC

Simplifying Lab Workflows – eWorkflow Procedures

eWorkflow procedures contain:

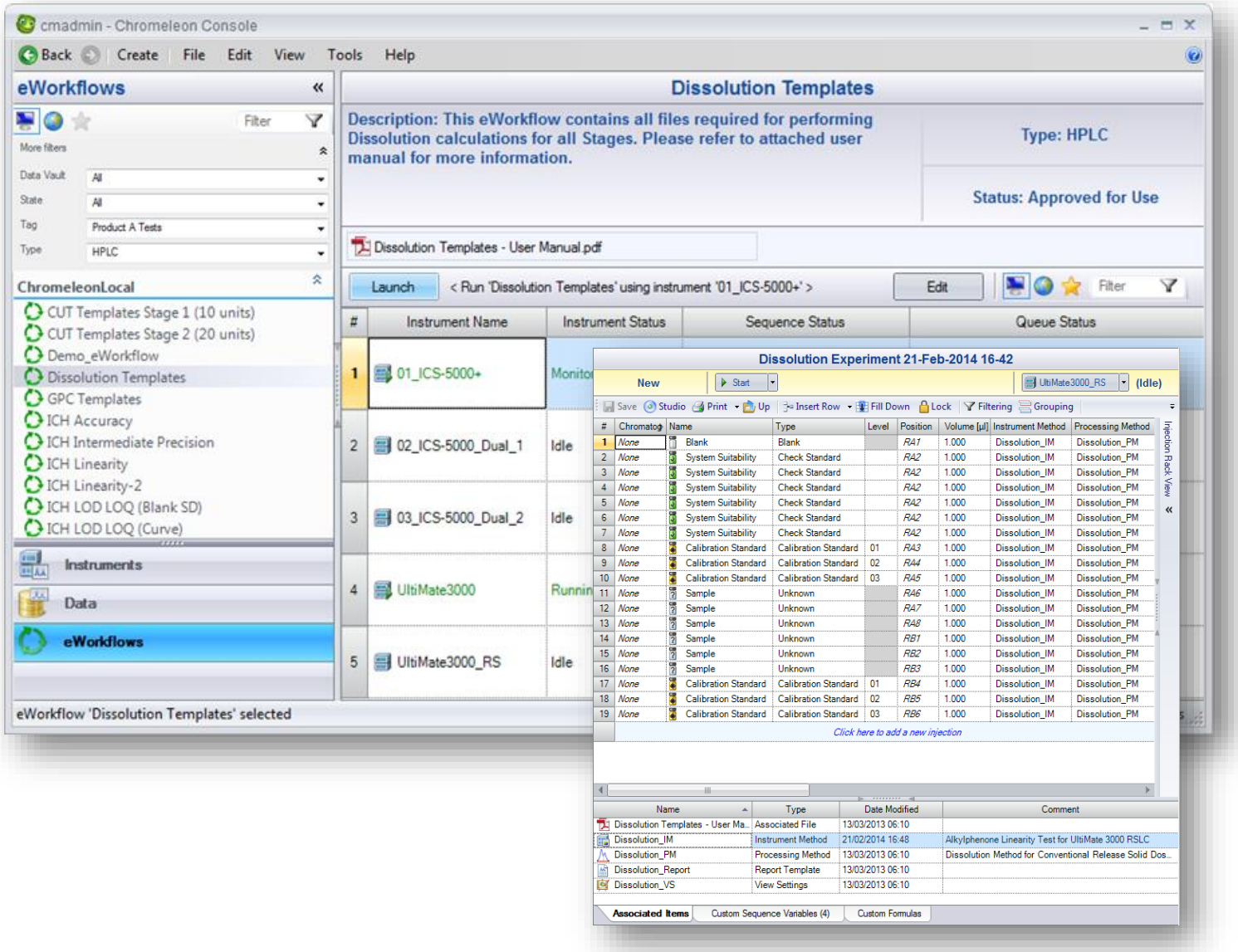
- Instruments on which the analysis can be run
- All associated methods and files including reports and external documents like SOPs

✓ Ensure your SOP is followed

✓ Reduce errors and produce reliable results faster

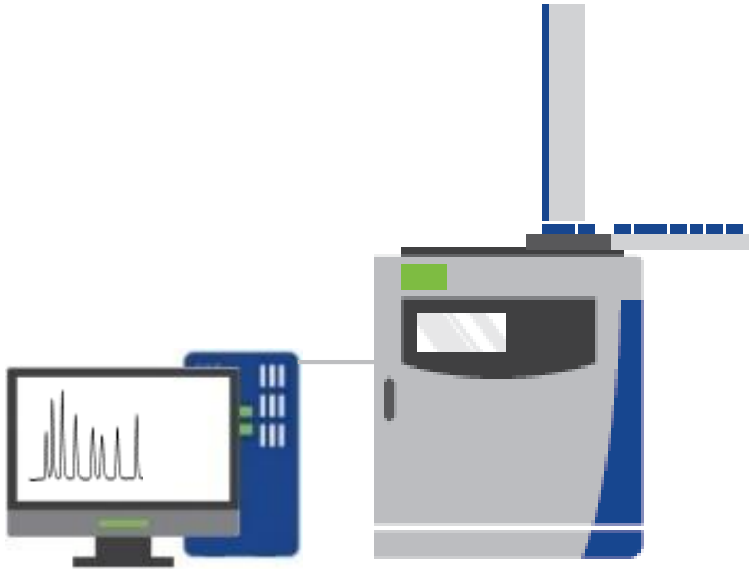
✓ Fully customizable for any application in any laboratory

✓ Minimize amount of training required

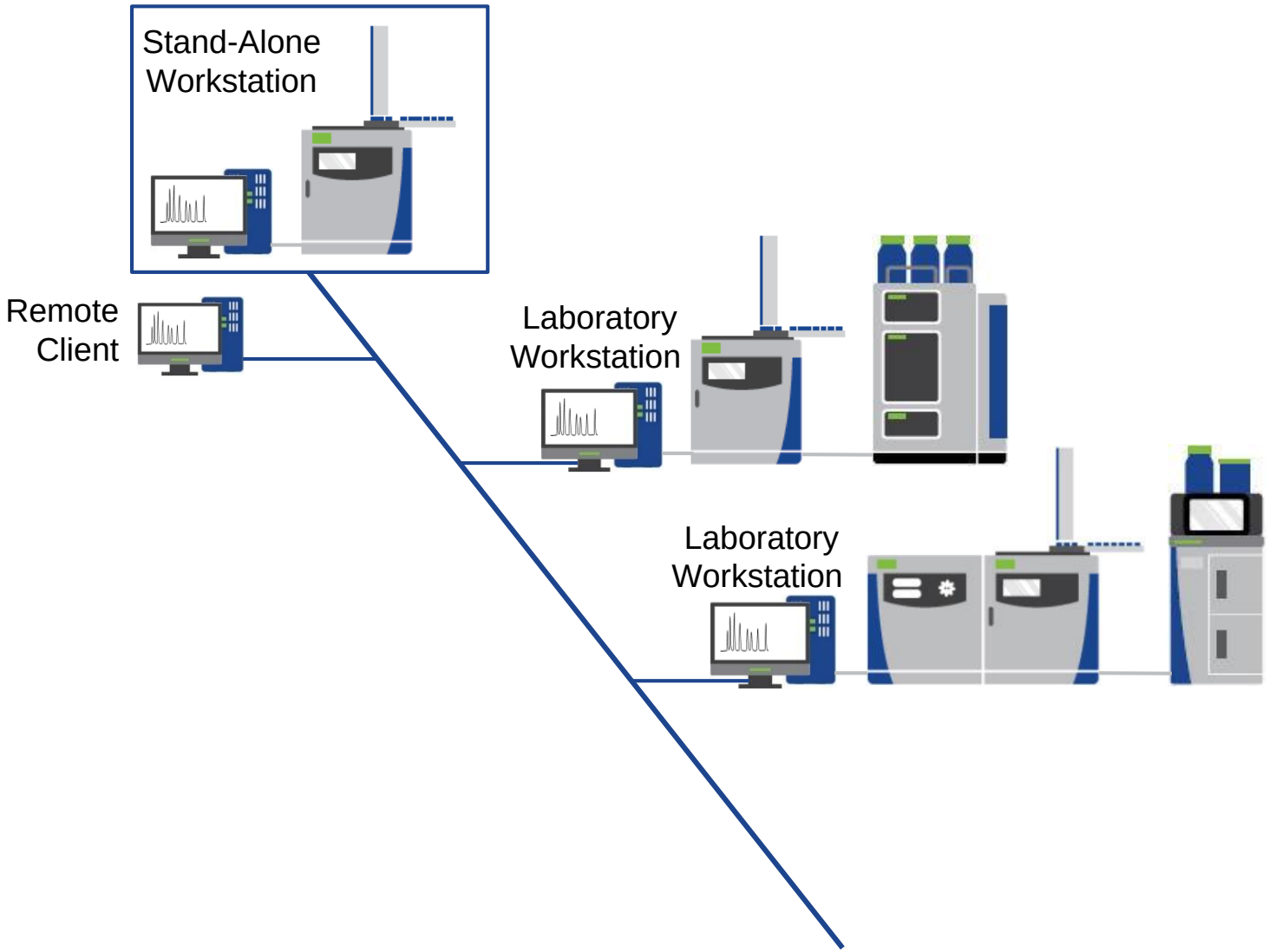


ThermoFisher SCIENTIFIC

Centralized Software Solution – From Stand-Alone Workstation…

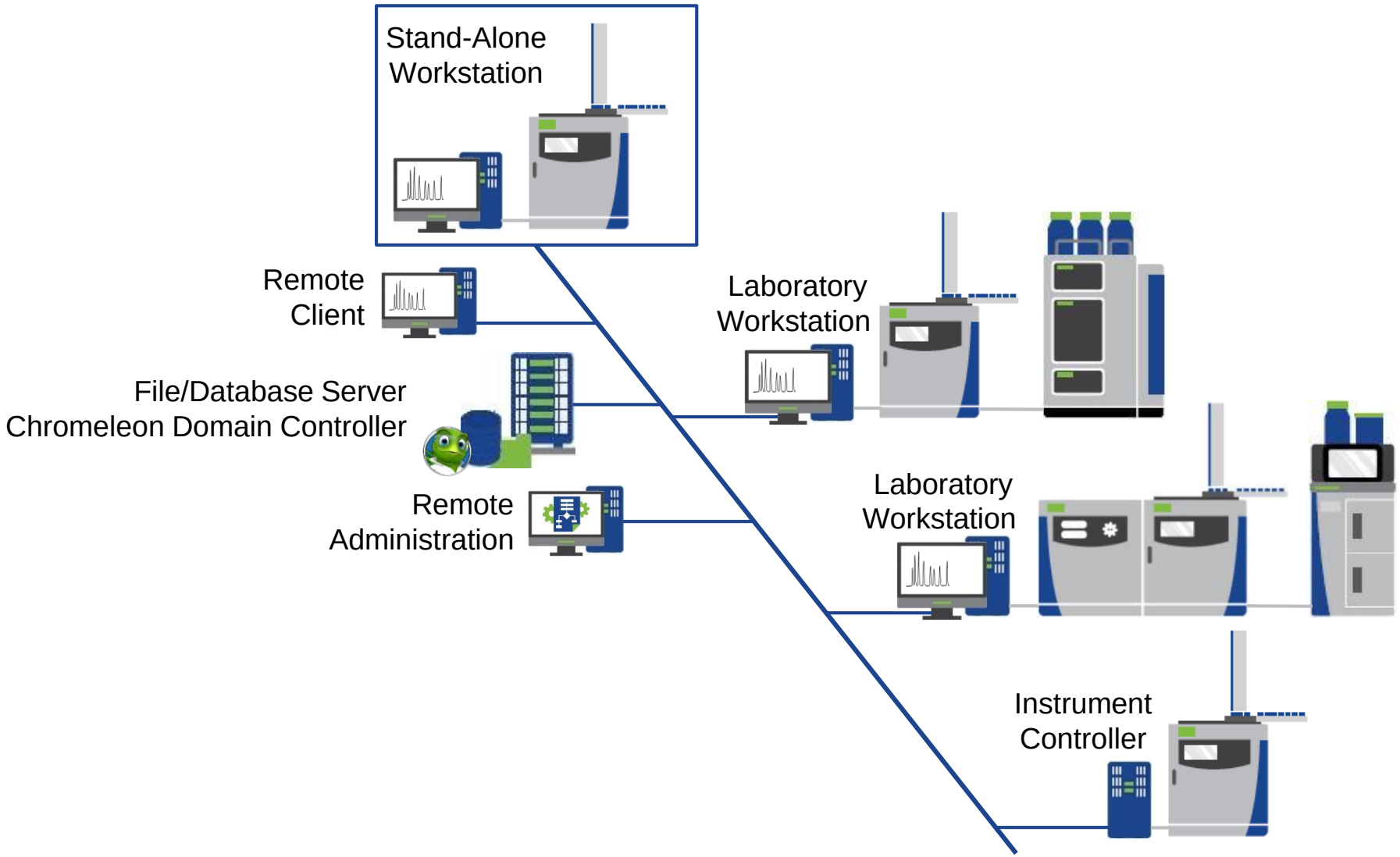


Centralized Software Solution – …or a Workgroup…



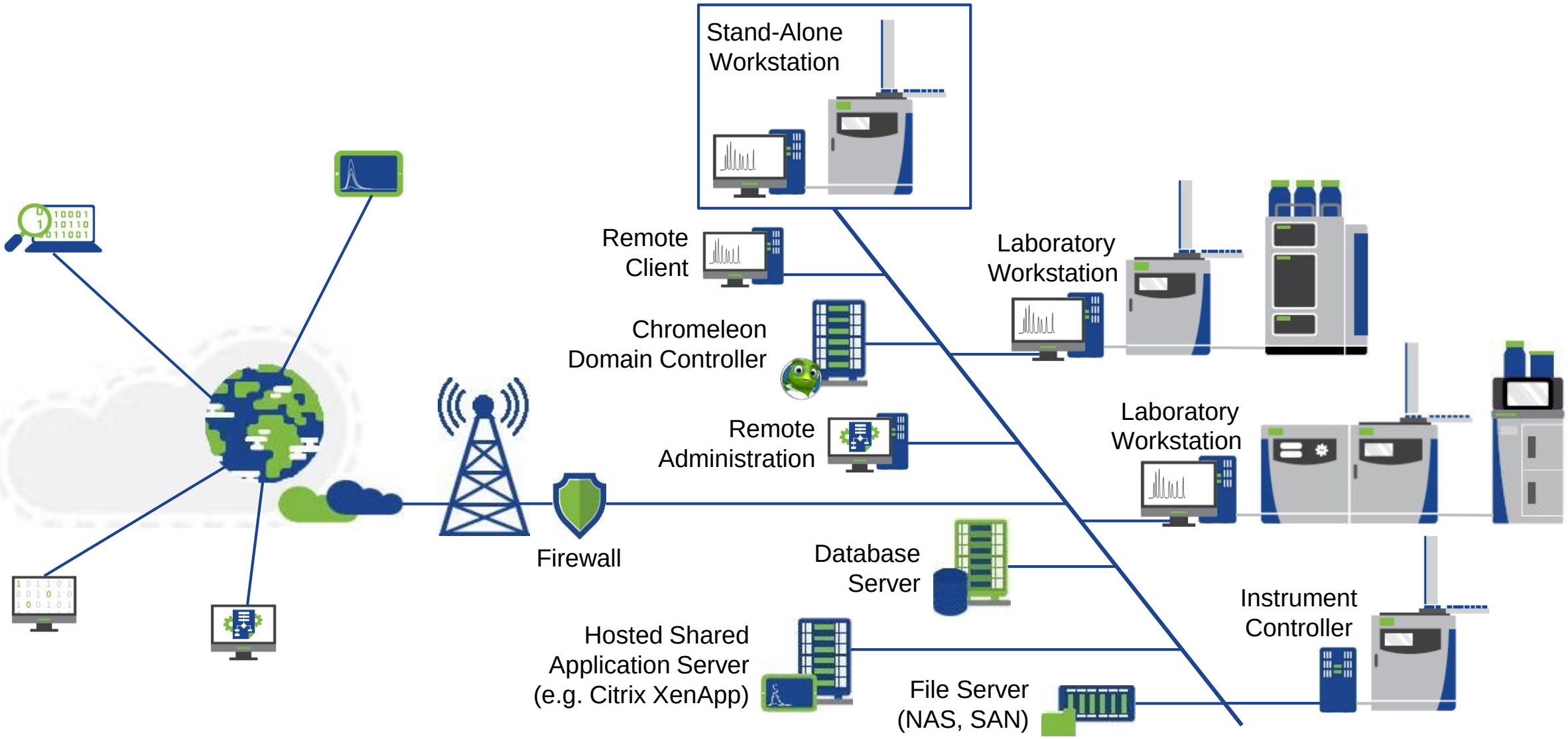
ThermoFisher SCIENTIFIC

Centralized Software Solution – …to a Small Network…



ThermoFisher SCIENTIFIC

Centralized Software Solution – …or a Global Wide Area Network



ThermoFisher SCIENTIFIC

Operational Efficiency – Standardized and Centralized Software Solution

- One software to control all chromatography instruments in the lab
  - Including Thermo Scientific™ Mass Spectrometry (MS) instruments
  - Remote instrument control

- Centralized software solution
  - Scalable from workstation to global enterprise and anything in between
  - Manage and maintain one software
  - Centralized storage and data access

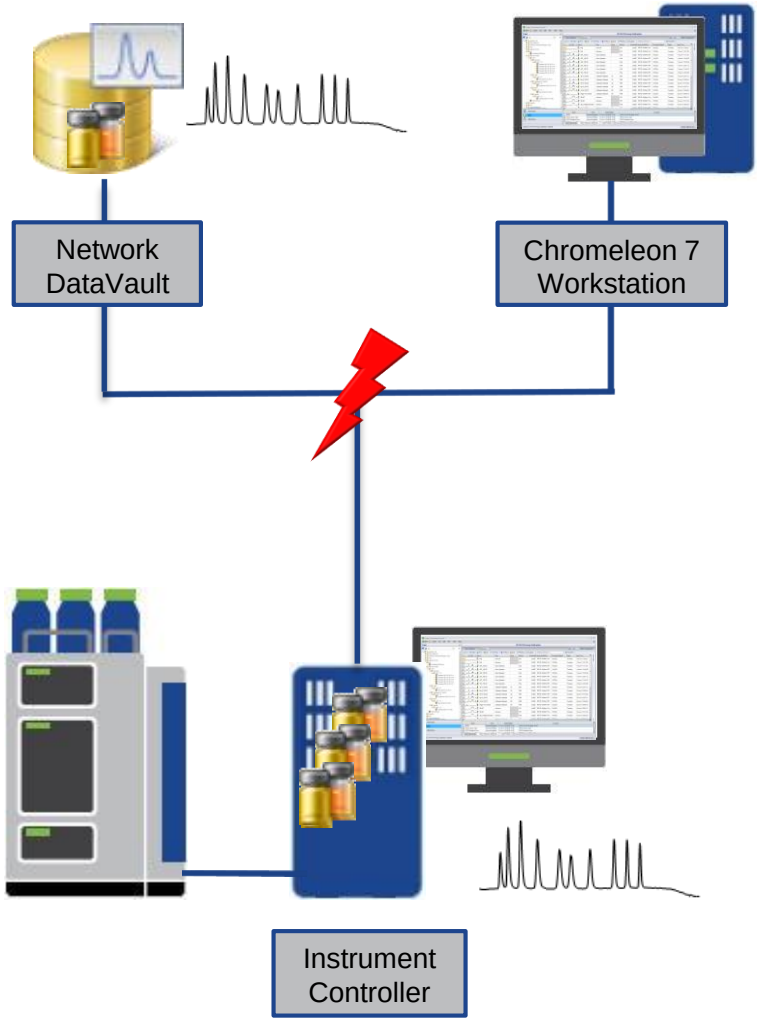
- Decreased cost of operation
  - Reduced learning – lower training cost
  - License only one software – concurrent user licenses
  - Use one, existing infrastructure
  - Adaptable from walk-up user to system administrator

Chromeleon Enterprise Advantages…

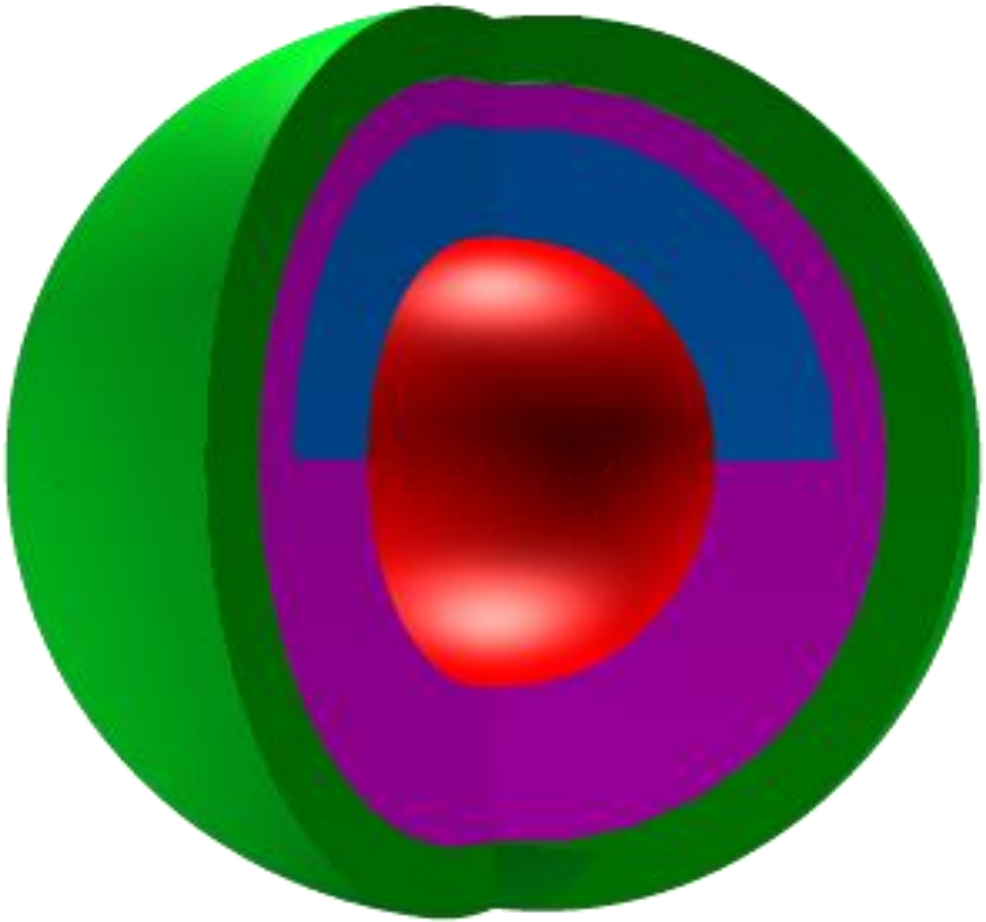
- Free license upgrades
- Access to 24/7 dedicated Chromeleon support team
- Easily scale-up for the addition of resources (users, instruments, servers)
- Centralised secure data storage in relational DB on server
- Central and automated administration of Instrument Maintenance windows, Chromeleon/Windows update rollout; System printers
- Network Failure Protection
- Easier backup and archive of data
- Share methods/reports simply across whole lab
- Data Trending for comprehensive data interrogation
- Standardise processes across labs
- Lower IT overhead
- Lower administrative overhead
- eSignatures
- Email notification of completed sequences/user lockout
- Auto-reporting
- LIMS integration
- Data more secure in full SQL database
- Maximise running time of expensive instruments
- Time stamps consistent across lab
- Scalable on the IT, admin and instrument/user levels
- Failover options for the servers
- Virtualisation and cloud options
- Discovery enables easy enterprise role-out

Ensure 24/7 Laboratory Uptime - Unique Network Failure Protection Function (NFP)

- License and User Management information is cached locally
  - License is always available
  - Users can always logon
  - Users can continue to work
- XVault technology ensures continuous operation
  - NFP mode is automatically enabled at network failure
  - Continued data acquisition
  - After network recovery, data is automatically uploaded to the central server
  - User can log on to the instrument controller to view and edit the running queue, submit new analyses, process and report data
  - User management is active to ensure data security
  - All information and actions are audited and traceable

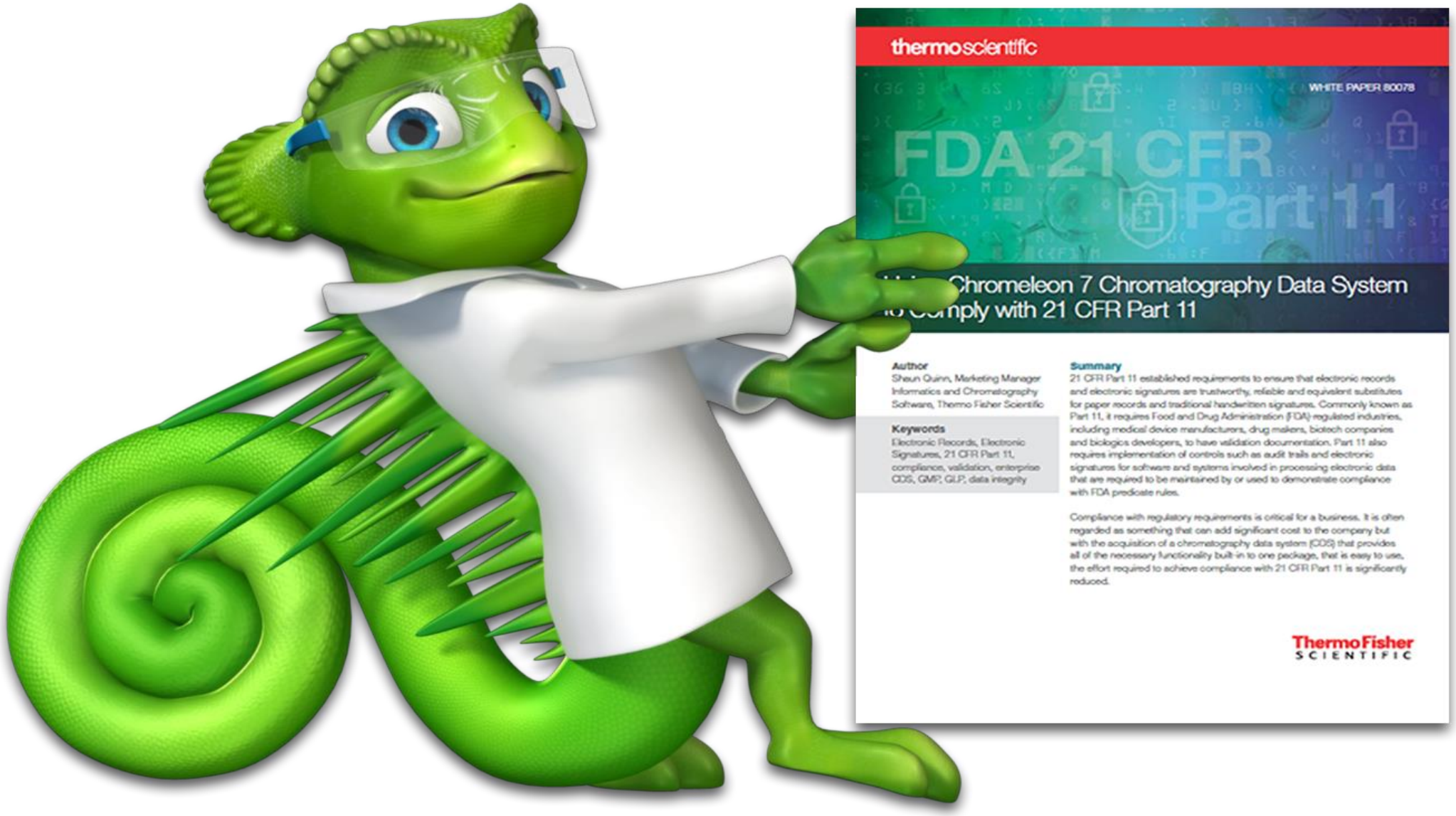


Compliance & Data Integrity



- Data
- Technical Controls
- Procedural Controls
- Validation

Compliance Guide



Audit Trails in Chromeleon CDS

- Audit Trails are a critical requirement of electronic record regulations that:
  - Enable detection of non-desirable activity by users
  - Provide management with a tool that influences users' behaviour
  - Ensure data integrity

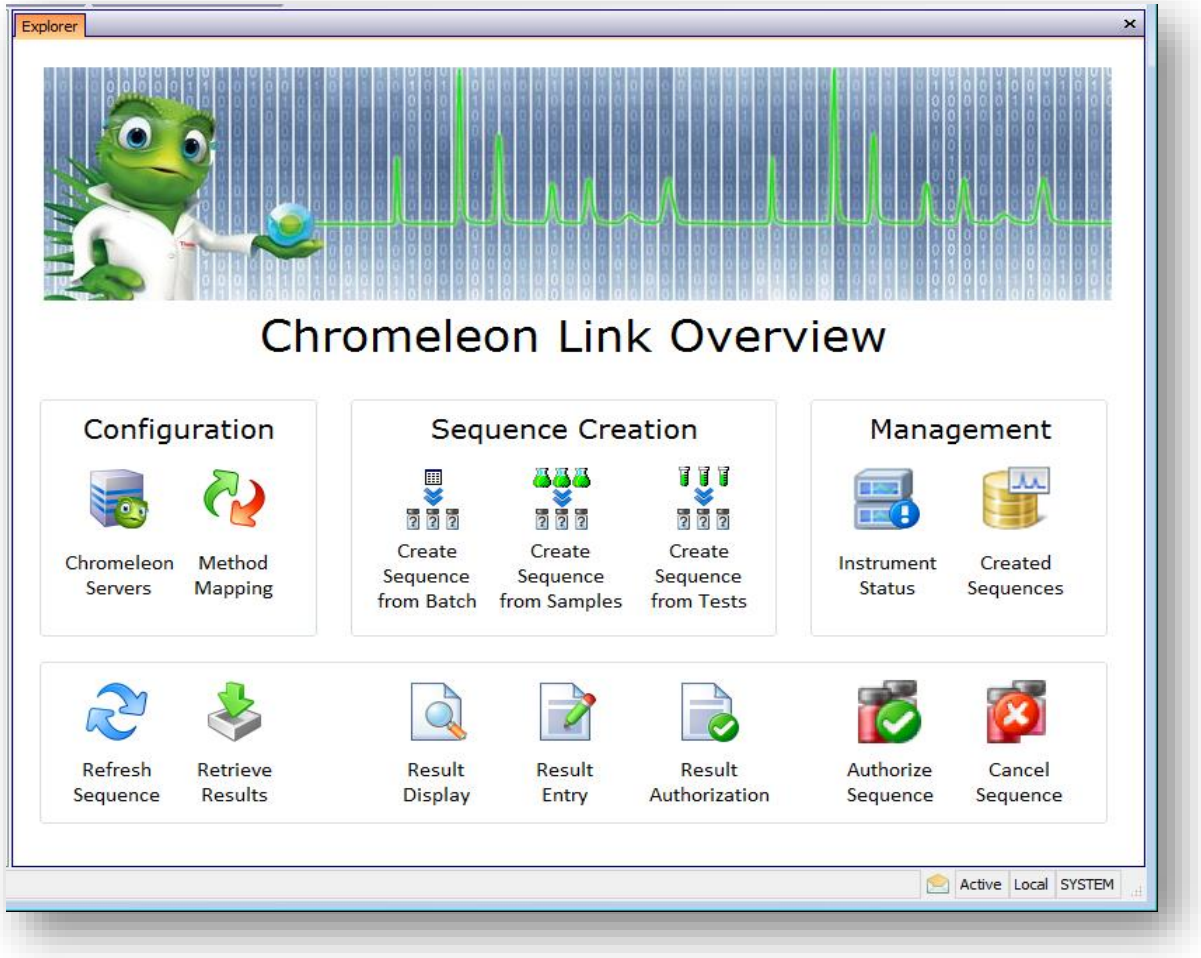
- Chromeleon CDS provides Audit Trails in all locations
  - Data Audit Trail – Changes to all objects in the Data Vault
    - Enables version comparison of objects and results
  - Injection Audit Trail - All information that was recorded in the Instrument Audit Trail for a specific injection
  - User Management Audit Trail – Log of changes to user management, Captures logon, logoff and failures
  - Administrative Audit Trail – Domain Resources, Data Vault Manager, eWorkflow Tags, Station, Global Policies, Organizational Units
    - Track actions at the record or system level (such as attempts to access the system or rename or delete a file).

Connectivity – Seamless Data Flow

Chromeleon CDS to SampleManager LIMS link

This link gives users ability to:

- See real time information like instrument status & queue in LIMS
- Select samples in LIMS & use eWorkflows to create sequence
- Pull LIMS samples into existing sequence from Chromeleon CDS
- Show Chromeleon CDS results directly in LIMS



Thermo Scientific Chromeleon 7 enterprise CDS

… Increase productivity

- Industry-leading Operational Simplicity™ and throughput with eWorkflows™
- Faster data processing, visualization, and reporting with dynamic updating and Intelligent Functionality built-in

… Control all your instrumentation

- Thermo Scientific LC/IC/GC/(quant)MS plus >300 third-party modules
- Customizable instrument ePanels for consistent look and feel

… Achieve regulatory compliance

- Flexible to support research and compliant laboratories
- Comprehensive user management and eSignatures

… Simplify administration

- Centralized or distributed data storage
- Scales from workstation to large global networks

… Connect your laboratory

- Easily interface with other laboratory software (e.g. LIMS)
- Download ready-to-run applications from AppsLab Library

Thank You!