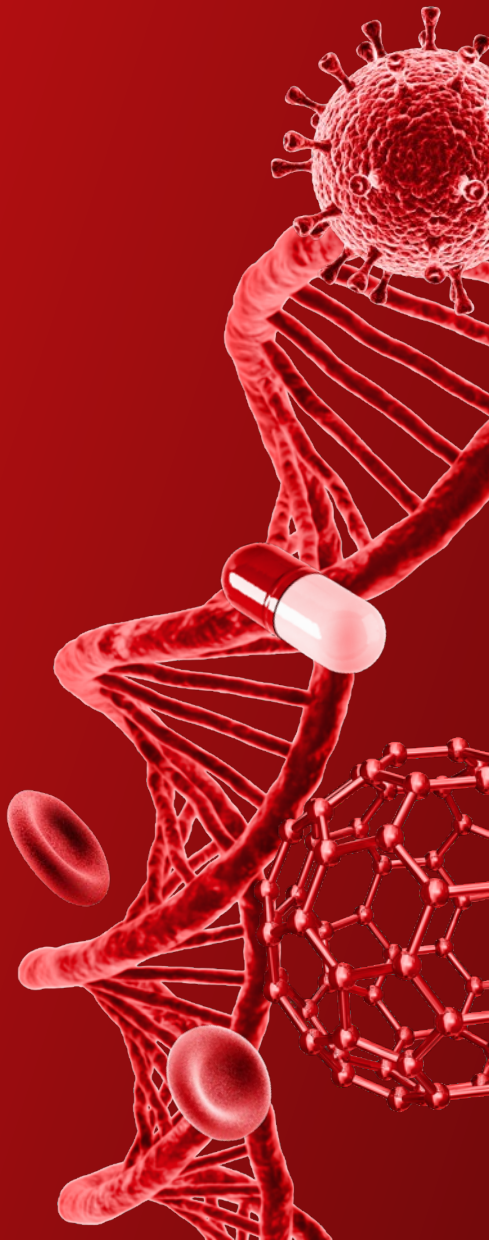
Welcome



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Validation for compliance & data integrity. Why do you need it & how do you do it?

eCDS Marketing

The world leader in serving science

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Validation for compliance & data integrity

- When working in GxP regulated environments, customers must
  - Assess **all risks** around their day to day work
  - Check their **whole organization** achieves minimum expectations of regulatory bodies or similar
- They look to CDS vendors like Thermo Fisher Scientific to provide solutions to help them to comply with agencies' mandatory requirements

Validation for compliance & data integrity

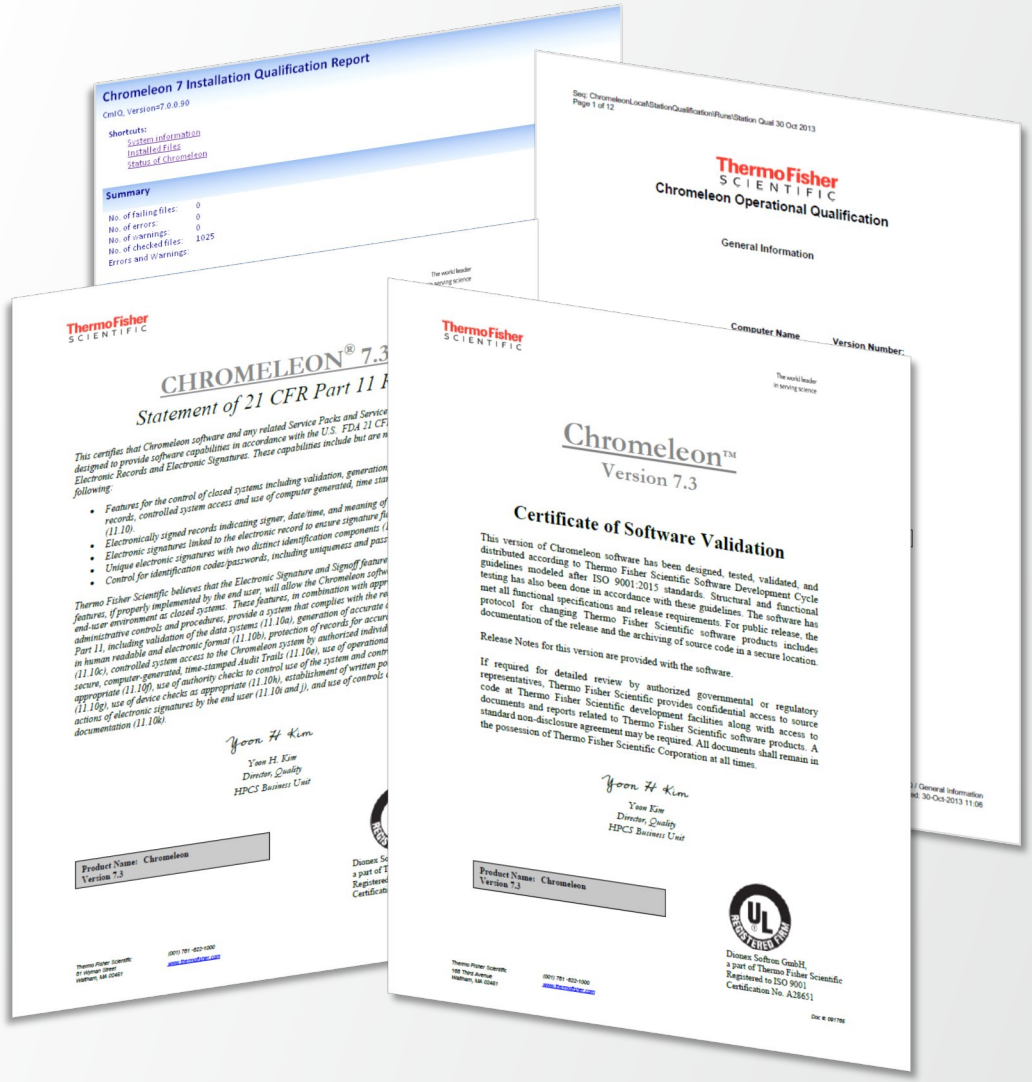
- Qualification vs. Validation
  - Qualification – prove and document that systems are properly installed, work correctly, and comply with specified requirements
    - Directly related to **instruments, computers or software**
  - Validation – documented evidence that assures a process will consistently produce results within specifications
    - Directly related to the **process**
  - **Qualification is part of Validation**
    - Regulatory agencies take view that end-users of the Chromatography Data System (CDS) are responsible for its qualification and validation

Validation for compliance & data integrity

- Common statement from Thermo Fisher sales and service people:

"But by default we provide software IQ/OQ, and validation and 21 CFR Part 11 readiness certificates - that should be ***more than enough*** *for our customers"*

Oh no, it isn't!



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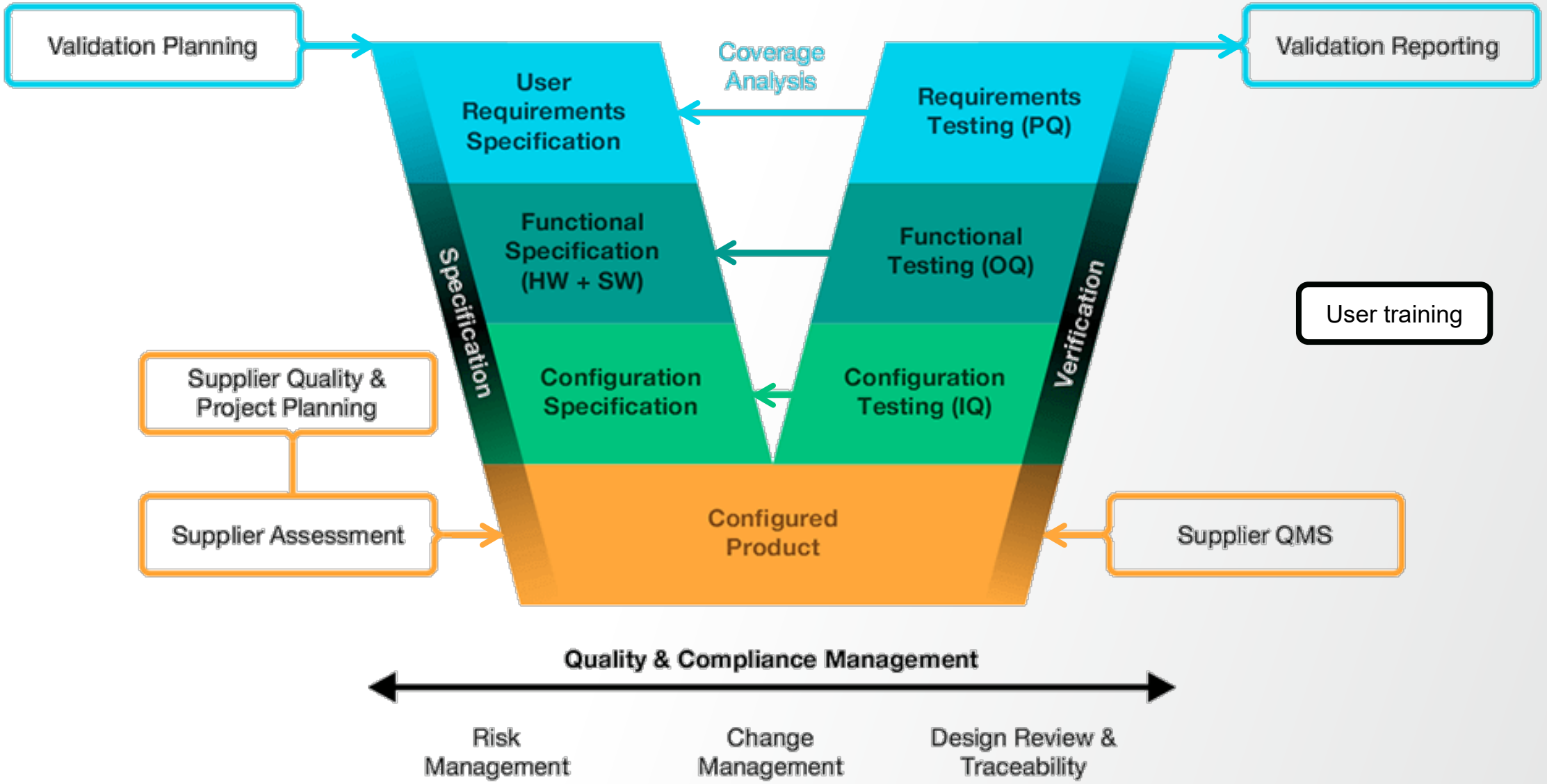
Validation for compliance & data integrity

- Must document validation of **entire software system**:
  - User Requirements Specification (URS) / specifications / risk assessment / trace matrix
  - Computerized System Validation (CSV)
  - Qualification (IQ/OQ/PQ for instruments & software)
  - Disaster Recovery Plan (DRP) & Business Continuity Plan
  - Certification (software, vendor staff, training, etc.)

- Need to **document** all validation processes including:
  - Software installed by qualified people in a validated environment
  - Appropriate settings - configured and applied
  - Documentation for all processes, i.e. certified training by qualified people with relevant training documents
  - Backup and archive - tested, validated and documented

Validation V-model



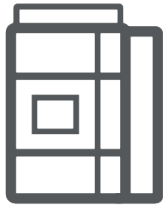
Validation for compliance & data integrity

CDS supplier expected responsibility | *CDS supplier support possible*

VALIDATION

QUALIFICATION

Instruments

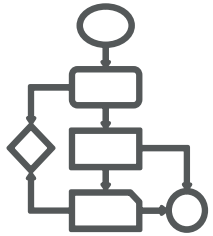


Software

Computers

- ✓ IQ plan, test scripts, report
- ✓ OQ plan, test scripts (i.e. validation kit), report
- ✓ PQ plan, tests, report

Process



- ✓ Functional Requirement Specifications
- ✓ System Configuration Document
- ✓ Project Plan
- ✓ User Requirement Specification
- ✓ Traceability Matrix
- ✓ Validation Plan
- ✓ Validation Report

Supplier assessment

- Customers must risk assess, and be able to demonstrate that they have validated and have full control of every aspect of all processes
  - Question: How to prove that Thermo Scientific™ Chromeleon™ CDS is correctly reporting retention time, peak area or specific component amount?

- To avoid (re)validating every calculation in Chromeleon CDS, customers will use the fact that Thermo Fisher validates it and offers a validation certificate
  - Question: Is that sufficient?
  - No it isn't. Anyone can 'create' a certificate!

- Customer needs to assess that Thermo Fisher has and uses a quality system that meets or exceeds the level of their own QA expectations

- They need to validate Thermo Fisher as supplier – two options:
  - On-site audit (if they have well-trained internal team or an external consultant)
  - Paper audit (sufficient for auditors)

Excellent! We audited Thermo Fisher and have a validation certificate. That's sufficient right?… No, it isn't !

Computer system validation (CSV)

- Thermo Fisher provides Chromeleon CDS as an off-the-shelf software
- In order to be compliant, customer must **configure** Chromeleon software correctly
  - Global policies
  - Audit trails
  - Users, roles and privileges
  - Access controls
  - Privileged Actions
  - e-Signatures
  - Etc.

- All these need to be checked, tested, validated and reported as part of the **computer system validation**
- Also must check and report that:
  - Every process within Chromeleon CDS is documented accordingly
  - All users have been properly trained in accordance with their requirements
  - Everything is under control

FDA

- US Food & Drug Administration (FDA) 21 Code of Federal Regulations (CFR), Annex 820.70(i) specifies:

  - (i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall **validate computer software** for its intended use according to an established protocol. **All software changes shall be validated** before approval and issuance. These validation activities and results shall be documented.

Computer Software Validation

Change Control

How can Thermo Fisher help you?

Subtitle of section

How can Thermo Fisher help?

- What do we provide with an enterprise CDS quote that supports compliance?
  - Complete solution that makes it easier for customers to achieve compliance
- Includes:
  - Licenses
  - Mandatory Software Maintenance Agreement (SMA)
  - Services
    - Project management with enterprise documentation
    - Deployment of at least 2 different environments (Test & Production)
    - Configuration
    - Training
    - Consultation
  - CSV guidance through experienced eCDS specialists

How can Thermo Fisher help?

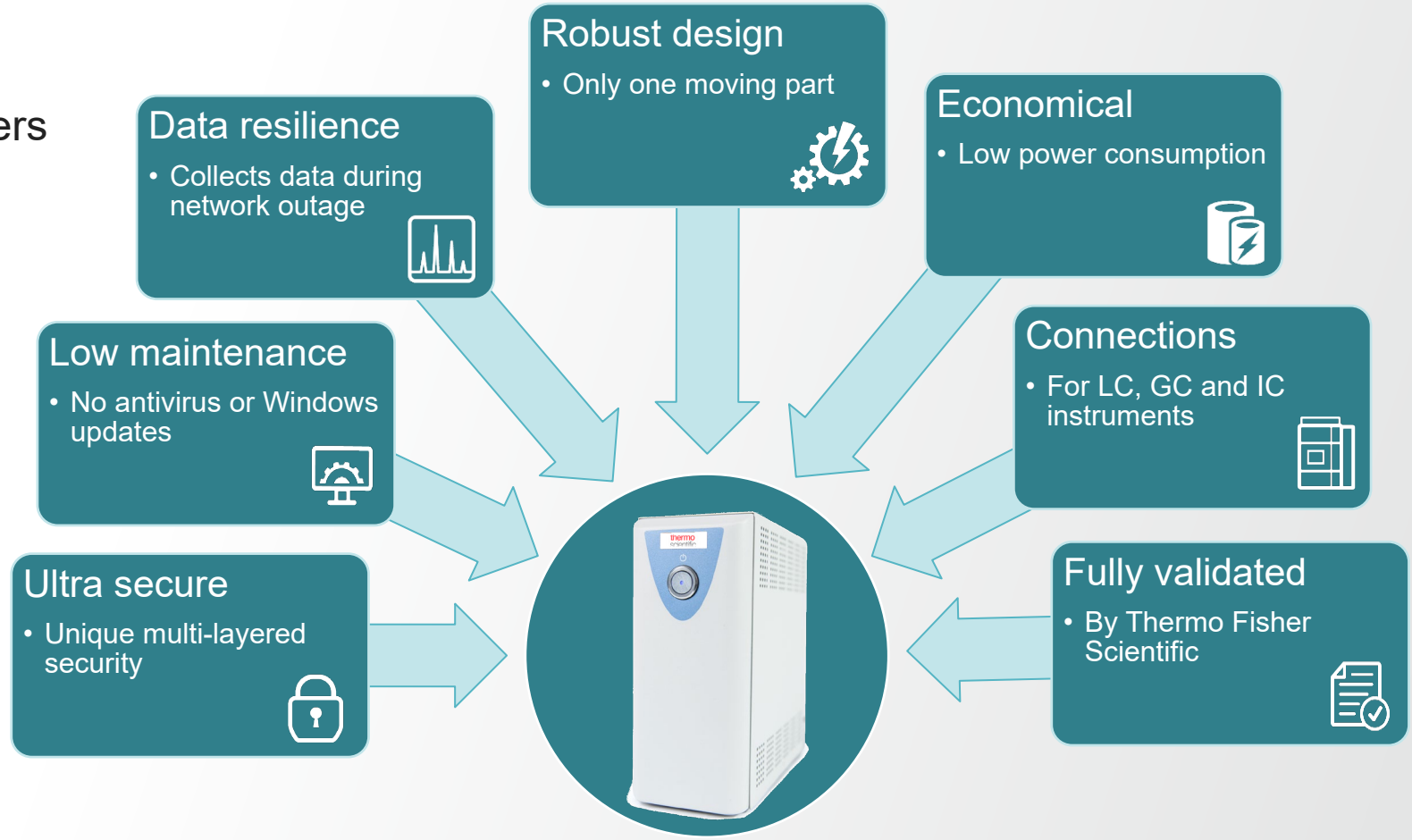
- Quote details
  - Mandatory SMA
    - In Pharma industry it's mandatory to only use **supported software** (Windows, CDS, etc.)
    - FDA 21 CFR, Annex 11, Chapter 16 requires a Business Continuity Plan (BCP) – SMA is an **integral part of successful BCP**
  - Training
    - In GMP guide, both Part 1 (final products) & Part 2 (API), Chapter 2, it talks about personnel, i.e. USERS
      - Every user must be properly trained for tasks they need to perform – both for Chromeleon CDS and for instruments
    - Train the trainer approach often results in incomplete knowledge transfer
      - Standard quote has 3 workshops for key users in addition to initial 4 days of training for everyone
    - *Don't forget – poorly trained users will open more support tickets!*

How can Thermo Fisher help?

- Quote details cont…
  - Environments
    - Test/‘sand box’, production, validation, archive
    - Standard quote usually has two environments:
      1. Test/‘sand box’ – non GxP, allows key users to test, evaluate and configure everything with total freedom
      2. Production – based on tested ‘sand box’ solution
    - Validation environment
      - Sometimes labs only use one environment to do Test and Validation
        - Customer may be reluctant to add more virtual machines (VMs) and pay for additional days for installation with documentation
      - To mimic final environment as requested by Annex 15, Thermo Fisher adds instruments to Instrument PC (IPC) with help from Field Service Engineers and adds support days from our implementation team

How can Thermo Fisher help?

- Why 247 Instrument Controller (247 IC) instead of IPC?
  - 247 IC specifically designed for controlling instruments in enterprise Chromeleon CDS
  - ROI in typically 3 years or less
  - Connects to local network with on premise, virtual or cloud-based servers
  - Installed and managed inside Chromeleon Administration Console



Summary

Chromeleon CDS

Built for **Compliance**

Built for **Data Integrity**

Built for **the Lab**

Built for **IT**

Built for **Users**

Built for **Quality Assurance**

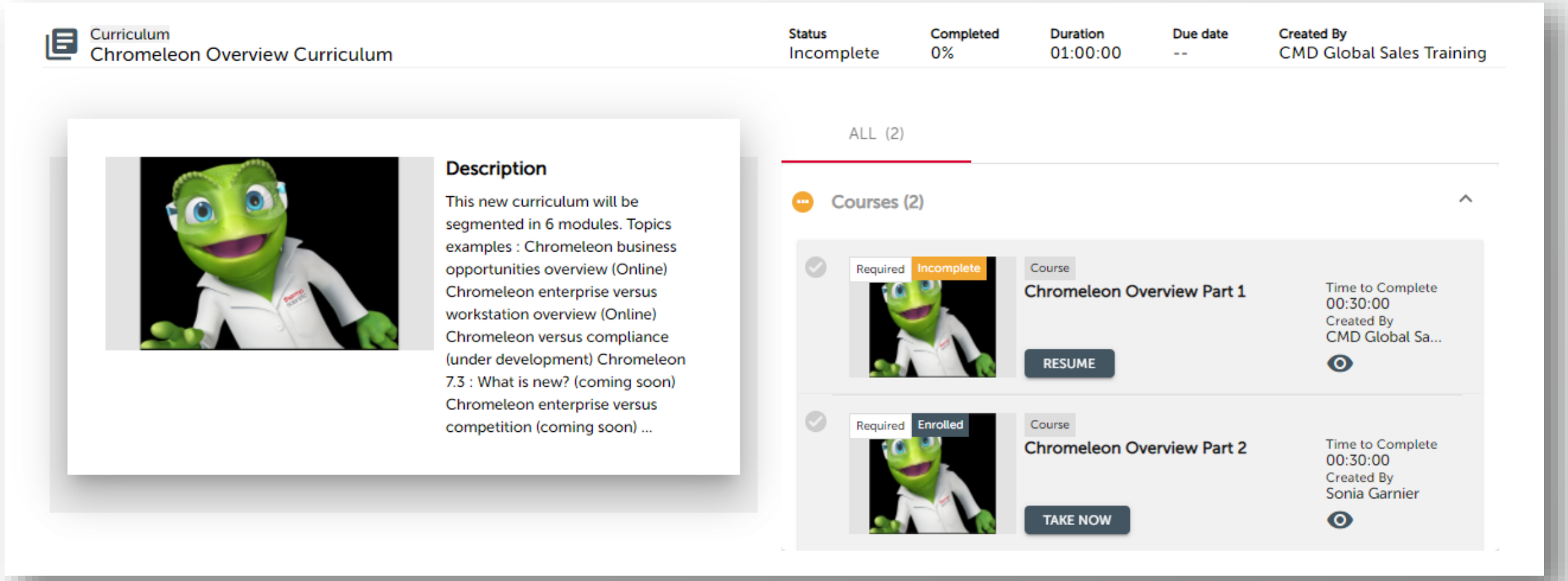
Built for **global companies**

Without compromise

eCDS etraining

Brainshark eCDS training available now

- Part 1: Chromeleon business opportunities overview
- Part 2: Chromeleon Workstation Versus Enterprise Features



For more information on Chromeleon CDS

thermofisher.com/chromeleon

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

facebook.com/CharlieLovesChromatography

Join our LinkedIn customer forum to discuss Chromeleon CDS with us and your industry peers.

Chromeleon CDS User Group

Thank you