How a Global Pharma Achieved

Streamlined Compliance with LabX

Data integrity underpins every step of pharmaceutical operations, particularly when complex SOPs and stringent regulations are involved. In this detailed case study, a global pharma company shows how METTLER TOLEDO's SevenExcellenceTM meters and LabXTM software enabled them to convert manual protocols into automated workflows—minimizing transcription errors and bolstering compliance. Learn how their shift to a digital data ecosystem simplified multi-step procedures and improved overall consistency, delivering tangible value for both quality assurance and day-to-day lab efficiency.



SevenExcellence with LabX: Secure and Optimized Workflow

Looking for top-tier accuracy in pH, ion concentration, redox potential, and dissolved oxygen? SevenExcellence™ by METTLER TOLEDO delivers uncompromising precision. This bench instrument measures up to three parameters simultaneously and connects with LabX™ software, enabling data security and 21 CFR Part 11

compliance. Streamline calibration, reporting, and LIMS/ERP integration for a holistic approach to measurement workflows.

Our focus here is a major pharmaceutical organization that supplies generic medicines and biosimilars worldwide. With expertise spanning prescription drugs, OTC medicines, and antibiotic production, the company has a strong

research-and-development track record—especially in the field of oncology support therapies. However, their existing instruments and manual data procedures weren't keeping pace with evolving compliance demands, particularly around pH and conductivity measurements based on USP <645>.

Challenges

• Outdated Data Capture:

Creating workflows and maintaining digital records that align with data integrity requirements was cumbersome on older devices.

- Complex Sample IDs: Managing up to 20–30 samples daily overwhelmed manual entry processes, raising the risk of transcription errors.
- Multi-Step SOPs: Reliance on memory for intricate test sequences exposed the lab to out-of-spec results and potential regulatory flags.



• Inefficient Monitoring:

Without centralized oversight, investigating deviations was tedious—any slip in SOP adherence could trigger a lengthy internal probe.

 Paper Journals: Old-fashioned logging introduced further transcription hazards, which didn't meet modern standards for data reliability.

Solutions: SevenExcellence + LabX

To overcome these issues, the company chose **SevenExcellence meters** paired with **LabXTM software** for data management and workflow integration.

Seamless Data Acquisition

With LabX coordinating every step in the background, operators can calibrate the pH meter, record results, and generate compliant reports without juggling separate programs. This alignment with USP <645> ensures measurement



Figure 1: Optimized conductivity measurement: SevenExcellence meter combined with LabX software streamlines the process and reduces error margin.

uniformity while drastically reducing manual burdens.

Automation Yields Efficiency

Ultrapure water analysis under USP <645> involves multiple stages—each prone to user fatigue if done by hand. LabX solves this by letting labs design **customized workflows**, turning those multi-step SOPs into guided prompts that minimize error risk.

Reliable, Accurate Results

Every action taken at the instrument terminal or PC is logged automatically, ensuring a clear audit trail. Different user-access levels help guard against out-of-spec results, guaranteeing no unauthorized changes.

Pre-checks in LabX force operators to calibrate sensors within valid ranges—cutting down on questionable data and re-runs.

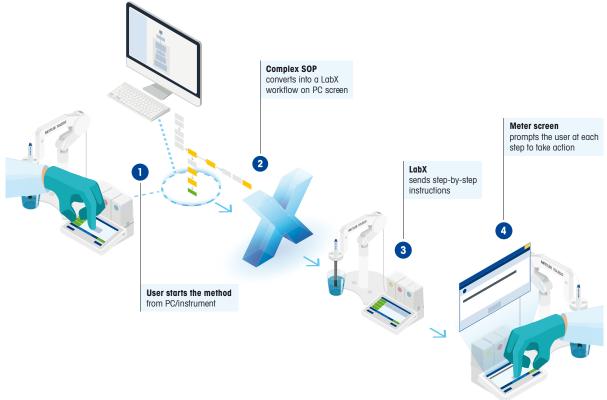


Figure 2. Improved efficiency: Converting complex SOPs into simplified and efficient workflows.

Noteworthy Outcomes

- Better Compliance: LabX software with SevenExcellence fosters data integrity—meeting or regulatory standards.
- Single Source of Truth:
 Converting SOPs into LabX work-flows ensures universal guidance at the instrument terminal, removing guesswork.
- Greater Flexibility: Users can operate from the meter or PC,

- with automatic data storage in the background.
- Reduced Errors: Digitizing the entire process lessens transcription issues, helps standardize procedures, and keeps the lab audit-ready.

Conclusion and Impact

By uniting SevenExcellence meters with LabX software, this global pharma site overcame outdated manual workflows—cutting down

on error-prone data entry and ensuring consistent, validated steps for each measurement. Thanks to integrated prompts, robust audit trails, and real-time data capture, their lab is now set up for greater efficiency and unwavering compliance with USP <645> and beyond.

- www.mt.com/ph
- www.mt.com/labx



A Closer Look at SevenExcellence™ and LabX™ in Action

See how the SevenExcellence[™] pH Meter integrates with LabX[™] software for precise, multichannel measurement of pH, conductivity, and more. This demonstration highlights automated workflows, secure data handling, and swift calibration with InMotion[™] autosamplers. Discover how these features streamline compliance (e.g., 21 CFR Part 11) and boost efficiency in your lab.

> Link to the video



On-Demand Webinar: pH Measurement and Compliance

Ensure your pH measurements stand up to industry regulations and deliver consistent product quality. This concise webinar covers segment-specific guidelines (Pharma, Food & Beverage, Chemicals), essential instrument specs, and expert tips on accurate, repeatable, and reliable pH testing. Join us to learn how compliance pitfalls can be avoided, how best practices boost measurement confidence, and why the right instrumentation is key.

> Watch on demand now





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Parul Chhaparia is a Content and Marketing Communications Specialist at METTLER TOLEDO, where she crafts impactful campaigns that bridge scientific expertise with engaging storytelling.

With a background in business journalism and extensive experience in creating content that simplifies complex scientific topics, Parul combines analytical precision with creative flair. Beyond her work at METTLER TOLEDO, she enjoys traveling to uncover stories about people, cultures, and places, fueling her passion for discovery and connection.



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