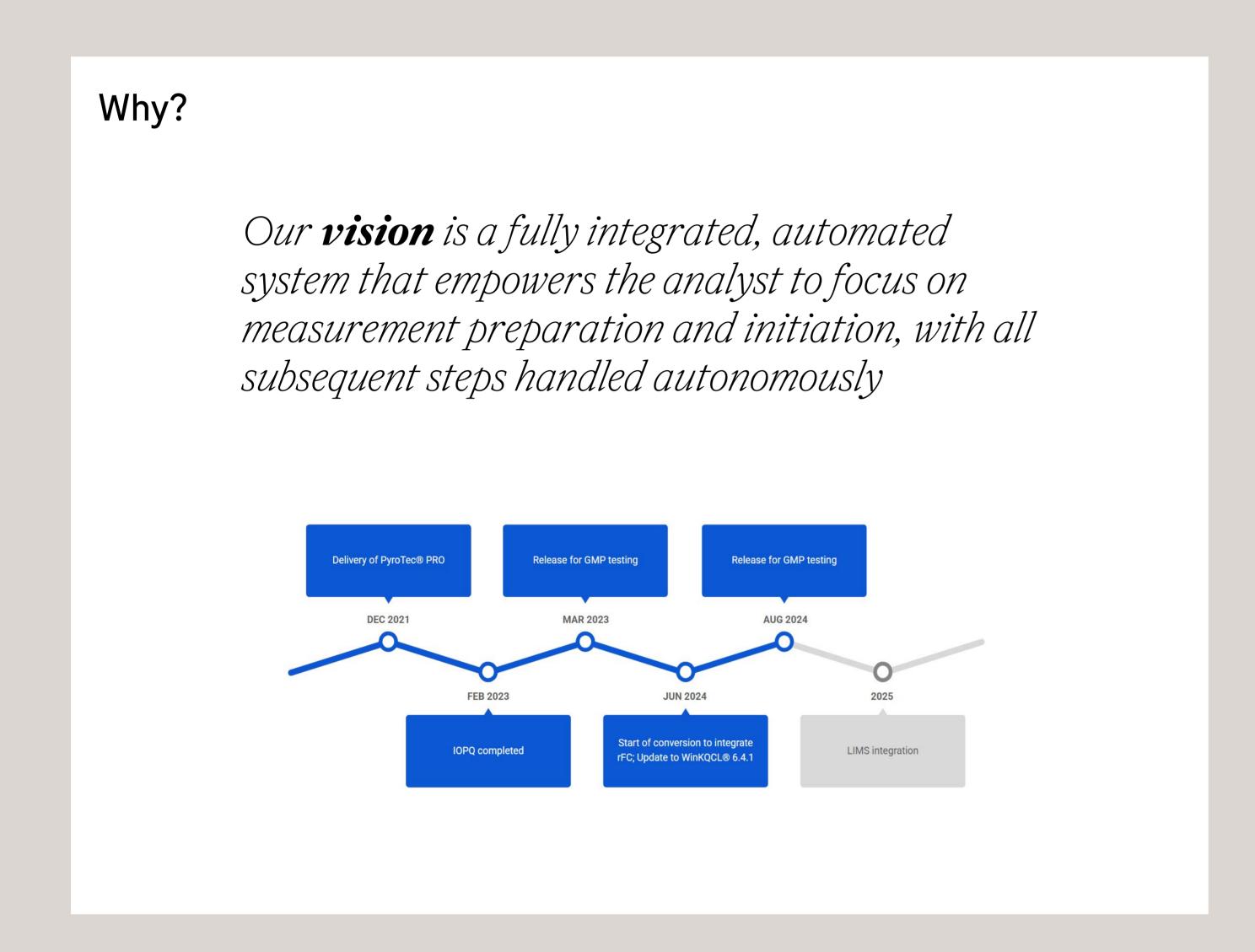
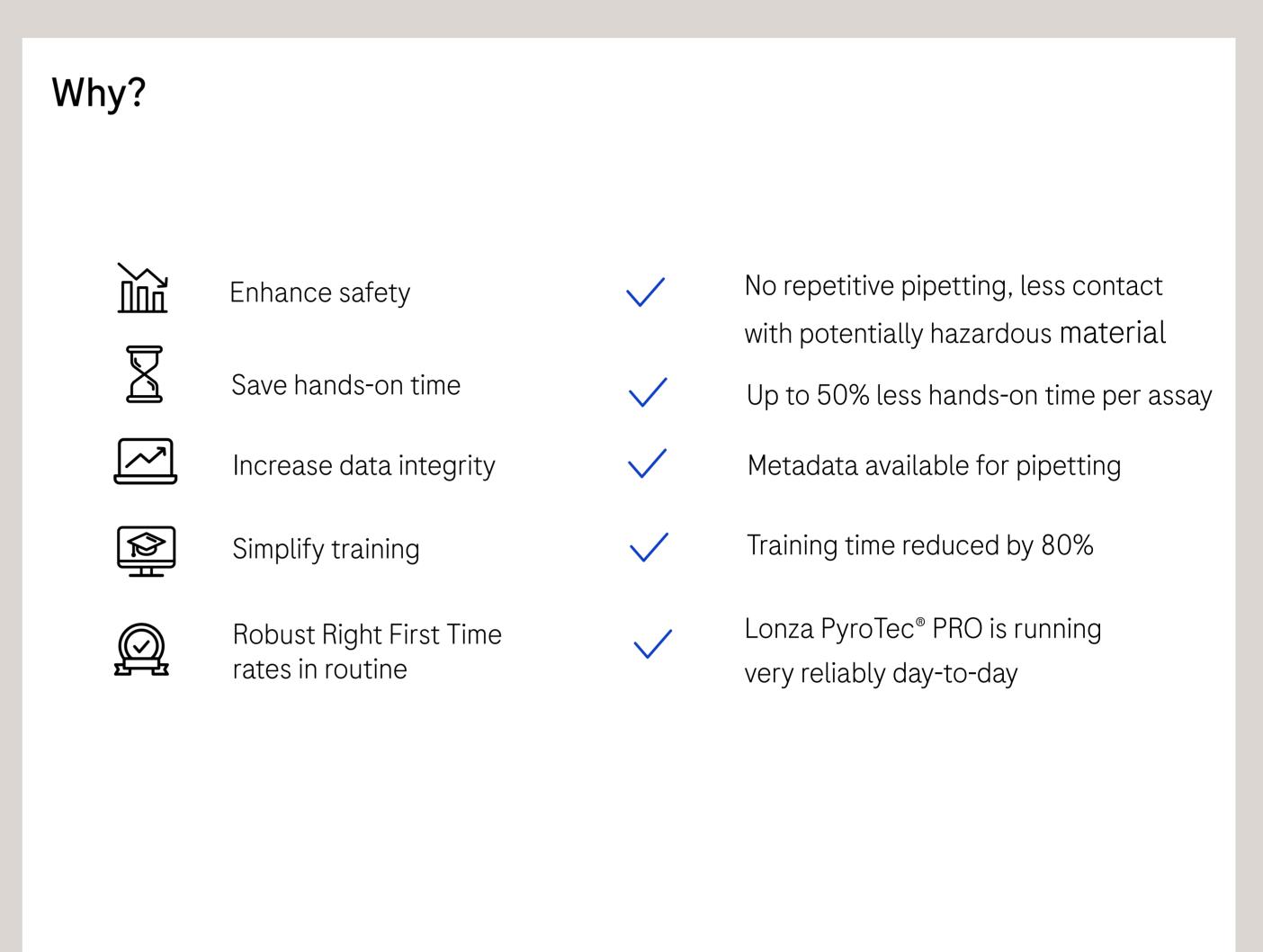
Implementing Automated Endotoxin Testing in a GMP Environment

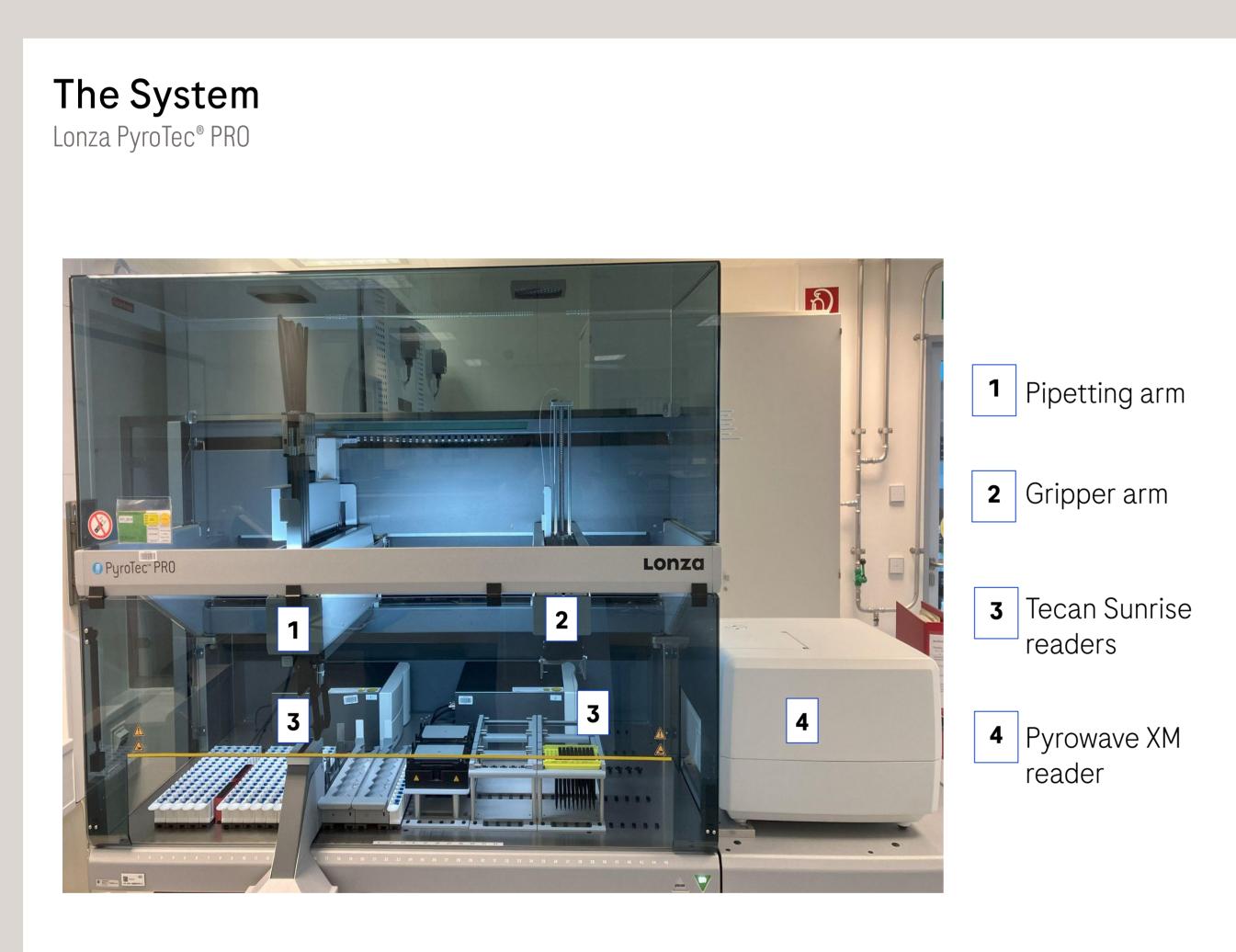


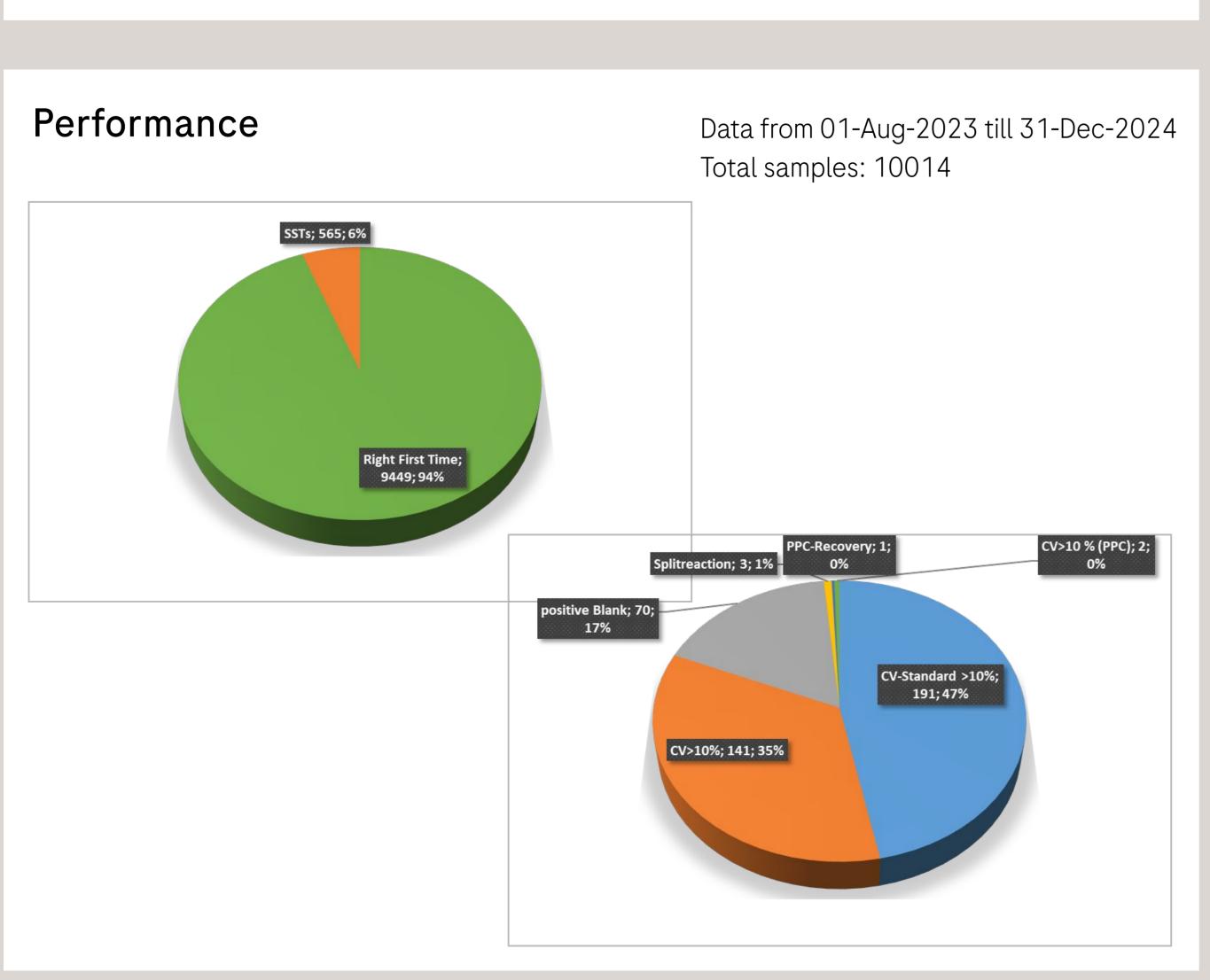
Katharina Stoib

Roche Diagnostics GmbH Penzberg, Germany









Workflow

- 1. Create Template (WinKQCL®)
- 2. Open Automation Module and select template
- 3. Load Deck
- 4. Start measurement
- 5. Review Results & Document

Activity	Duration	Notes
System Warm-up & Setup	10 min	Daily initialization
Reagent & Sample Prep	10-15 min	
Automated Pipetting Run	40 min	Includes 10 min incubation time
Result Review & Documentation	< 5 min	
Total Hands-On Time	20-30 min	Focus remains on preparation and review

From Initial Challenges to Demonstrated Value

Initial Performance Issues: We encountered system instability and lower-than-expected acceptance from lab personnel in the first few months

Resolution: Extensive troubleshooting was required, in close partnership with the vendor. Hardware Limitation: Currently restricted to only one rFC reader (no Nebula® multimode reader compatibility)

Methodology Constraint: Intermediate dilutions cannot be processed, unsuitable for Method Suitability Testing

Positive User Feedback: PyroTec® PRO has high acceptance and is strongly favored by lab personnel

Net Benefit: The overall advantages realized from automation significantly justify the

investment and effort

Next-Level Integration: Connecting to LIMS will unlock substantial new efficiency

benefits