
Smarter Labs,
Sustainable
Future:
Redefining Compliance
with AI and Automation

Revolutionizing Regulated Labs: AI and Automation for Compliance and Sustainability

Enhancing Lab Efficiency with Smart Technology and Eco-Friendly Practices

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Revolutionizing
Regulated Labs

The Global Focus on Sustainable Development

Vision and Sustainability Goals

Health and Well-being

Labs are vital to healthcare and pharmaceutical progress.

Industry, Innovation, and Infrastructure

Adoption of AI and automation in labs fosters innovation and strengthens scientific infrastructure.

Responsible Consumption and Production

Reducing waste and using resources efficiently are key in sustainable labs.

Climate Action

Sustainable labs help fight climate change and protect the environment.

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Challenges & Opportunities

Current Landscape & Regulatory Challenges

Regulatory Frameworks Impact

Strict regulations like GMP impose rigorous standards make automation appear risky and complex in pharma.

Key Compliance Concerns

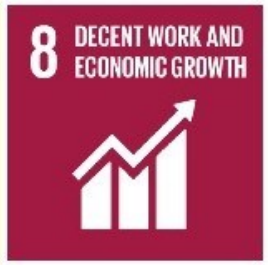
Pharmaceutical automation & AI adoption lags behind other sectors.

Data integrity, validation, and audit readiness are primary challenges obstructing progress.

Strategic Alignment

Addressing regulatory challenges enables pharma to safely unlock benefits and maintain quality.

Financial Impact and Business Resilience



Strategic Imperative for Pharmaceuticals

Investing in automation strengthens financial health and prepares companies for future market challenges.

Hidden Cost Savings Through Automation

Automation reduces training needs and laboratory error, leading to significant cost savings and optimized workflows.

Return on Investment Analysis

Assessing ROI highlights automation's long-term financial efficiencies and strategic value for companies.

Creating Sustainable Culture

Streamlined Training

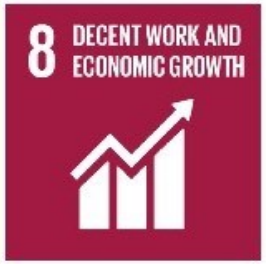
Automation & AI reduces training time enabling new team members to onboard faster and begin making meaningful contributions earlier in their roles.

Engagement & Retention

Automation and AI reduce the time spent on mundane repetitive work, allowing Analysts to utilize expertise in meaningful ways, improving engagement & retention.

Creating Clarity

Automation and AI can standardize processes, workflows and communication without adding additional workload to team members, creating clarity within individual teams and across the organization.



Environmental Benefits

Reduced Energy Consumption

Automation & AI can streamline or eliminate processes reducing the demand on energy.

Waste Reduction

Automation and AI reduces waste generation through miniaturization, employing modelling and reducing rework.

Chemical Consumption

Automation & AI can support reduced chemical consumption, reducing the impact of laboratories to aquatic environments and life on land.

The 2020 Challenge

The 2020 Challenge...

E-PREP

The 2020 Challenge

- Support a minimum of 7% increase in Laboratory Analysis
- Reduce laboratory operational costs by 10%

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Selection of Technology

ePrep ONE

- ePrep ONE automates sample preparation for laboratory analysis

ClickUp

- All-in-one, cloud based work management and productivity platform with features including automation & AI

Design Objectives

Optimize Laboratory Efficiency

Streamline laboratory workflows to reduce time spent on manual tasks and enhance overall productivity.

Ensure Regulatory Compliance

Integrate tools and processes that help maintain rigorous documentation, traceability, and audit readiness.

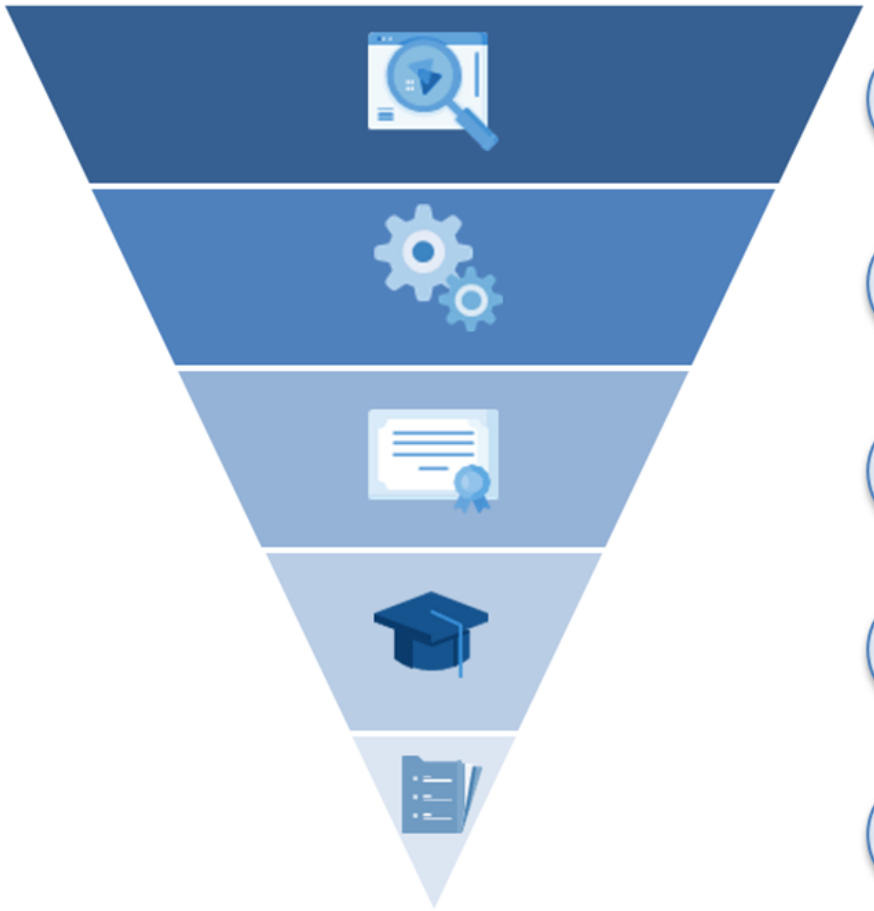
Promote Sustainability

Adopt resource-efficient processes to minimize waste and environmental impact while upholding scientific accuracy and quality.

Maximize Return on Investment

Maximize ROI by building multipurpose solutions and minimizing use of customization.

Application Development @ Ego – Risk Based Approach



1. Information & Risk Identification
2. Application Methodology
3. Determination of Transfer Approach
4. Validation or Verification
5. Data Evaluation & Report

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Equivalency - Not Replication

Pharmaceutical Guidelines

Pharmaceutical guidelines emphasize that automation must demonstrate *performance equivalence* not replicate manual conditions.

All-of-Process vs Part-of-Process

Automation can encompass the *entire workflow* or only *critical segments*.

Bespoke vs Off-the-Shelf

Both must deliver *equivalent performance*, not identical steps.

Process Efficiency Considerations

Automation must enhance *sustainability, throughput, consistency,* and *resource use* while maintaining *equivalent quality and compliance* to manual processes.

Maximizing Return on Investment Through Flexiblity

- HPLC / UHPLC / LC-MS
- GC / GC-MS
- UV-Vis Spectroscopy
- FTIR
- Standard Preparation

- Titration
- Wet Chemistry
- Swab Extraction
- Thin Layer Chromatography
- Liquid-Liquid Extraction

Automation of Sample Preparation

At Ego, there are over 500 potential targets for automation of sample preparation.

That we currently know about...

On average there are 20 unique New Raw Materials & 5 to 10 Unique New Formulations or Reformulations added per year.

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Project Management - ClickUp

Single Source of Truth

Centralized platform for managing all laboratory projects, tasks, and milestones.

Task Management

Clear assignment of responsibilities, setting deadlines, and monitoring progress in real time.

Organized Documentation

By maintaining all project documentation within ClickUp, the lab ensures that compliance records are organized, easily retrievable, and always up-to-date.

Improved Collaboration

This system fosters better team communication and enhances accountability at every stage, locally or globally.

Application Development @ Ego Agile Based Structure

Target Selection

Project Approved

- Project Plan
- Kickoff Meeting

Block 1

- Discovery
- Initial Workflow Design
- Optimization

Block 2

- Finalize Workflow
- Validation Protocol
- Training Identification

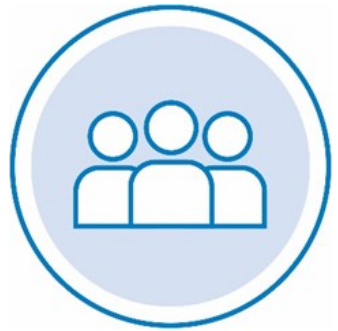
Block 3

- Validation
- Validation Report
- Document Instructions

Block 4

- Review & Approval
- Operator Training
- Project Retrospective

Release for Routine Use



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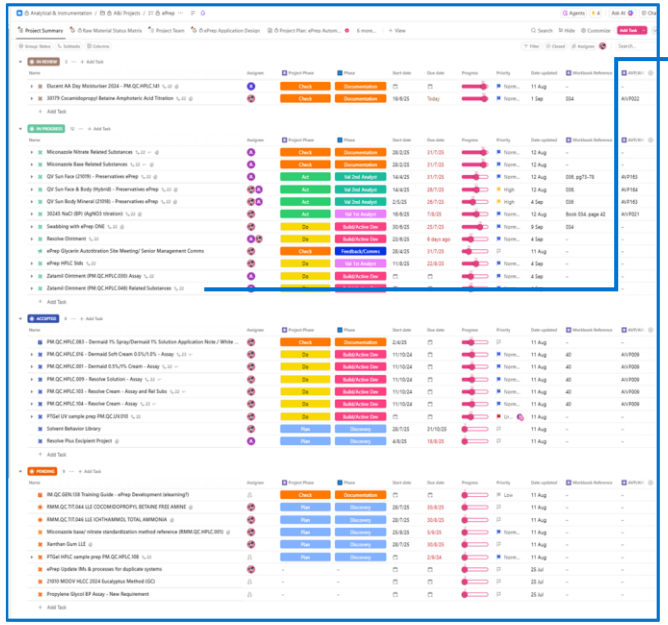
Application Development @ Ego Connected Information



Development tasks are automatically added to selected targets

Subtasks 0/22

Name	Assignee	Priority	Due date
Discovery/Literature Check			
Initial Workflow Development			
Finalise Workflow			
Stakeholder Meeting - Pre AVP development			
Draft AIVP			
Author Collation & Issue AVP for Review & Authori...			
Complete Analyst 1 AVP testing			
Complete Analyst 2 AVP testing			
Complete AVP write up			
AVP Review			
AVP Approval			
Cost Analysis			
Stakeholder Meeting - Pre release			
User Release Date Communication			
Method Update			
Lab Report Draft to CL			
Update Status Matrix			
Post release meeting (15 min)			
Site Meeting/ Senior Management Comms			
Schedule End User Retrospective			
End User Retrospective			
Application Note / White Paper			

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ClickUp Automation

Project Requests

eForms collect information required to inform project proposals, ROI calculation and prioritize opportunities.

Automated Workflow

Automated workflows seamlessly direct projects by predesignated criteria, and assigning work to the appropriate team member.

Project Templates

Tasks required for project completion are added on specific triggers, creating focus on only the work required.

Documentation

Document templates linked to project stages ensure standardized language and information.

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ClickUp Brain

Workflow Management & Task Coordination

ClickUp Brain is a powerful AI tool that supports task coordination and manages workflows.

Prioritization & Efficiency

ClickUp Brain prioritizes tasks, flags bottlenecks, and suggests ways to boost efficiency.

Locate Information

Natural language processing lets team members quickly get updates, and insights from ClickUp Brain, fully searchable information makes work more efficient.

Real Time Reporting

ClickUp Brain will create standup or summary reports as required.
Customizable dashboards can be configured to display status at a glance

Case Study

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Glycerin

- Glycerin[1], is a colourless sweet-tasting, viscous liquid derived from plant and animal sources.
- It is commonly utilized in pharmaceutical formulations as a humectant.
- The global Glycerin Market for 2024 is estimated at $2.95 billion USD, projected to increase to $4.37 billion by 2032.

[1] British Pharmacopeia, [1] United States Pharmacopeia

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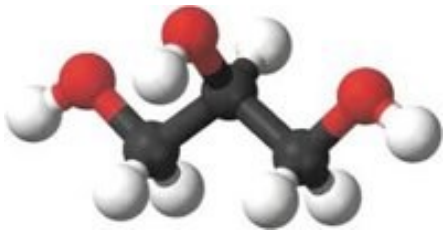
Assay of Glycerin by Titration

Manual Assay:



- Light sensitive reagents & samples
- Reagents must be prepared on the day of analysis.
- Sample extraction has multiple reagent addition steps
- Reagent addition & reactions must be precisely timed for satisfactory completion = Linear Preparation
- Titration must be completed immediately due to the solution stability.

Development Objectives

- Assess the compatibility of BP (Glycerin) and USP (Glycerin) monographs for glycerin assay by automation.
- Integration of **METTLER TOLEDO LabX** instruments with **ePrep ONE**
- Compliance with BP, USP, and 21 CFR-Part 11 regulations
- Enhance efficiency by reducing time, solvent usage, and labor.

Design Objectives

Automate Reagent Preparation

Precision Timing

Improve Compliance

Connected Data 21 CFR Part 11

Validate Accuracy

Validate Equvalency

Sustainable Development

Decrease Costs

Improve Efficiency

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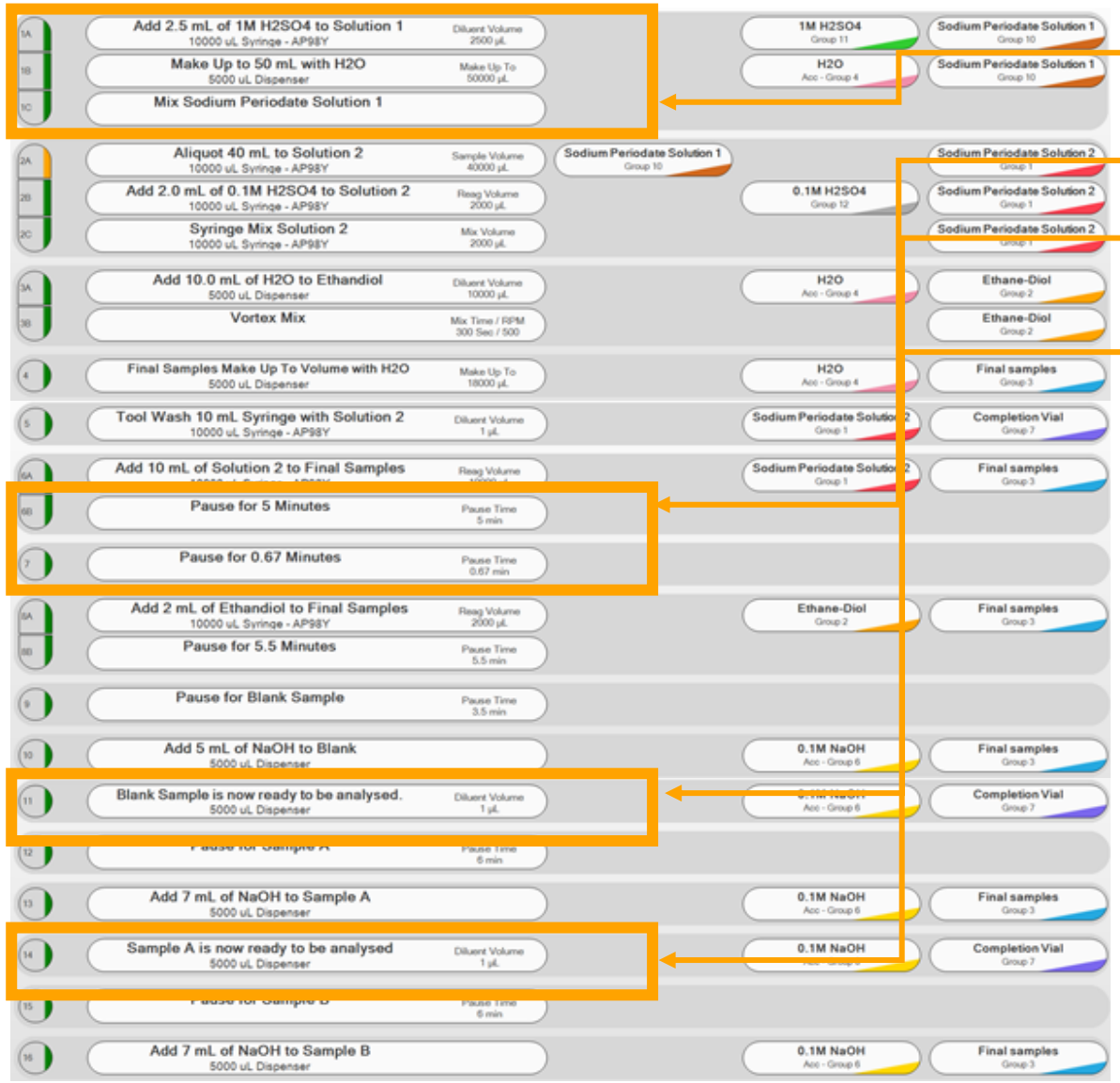
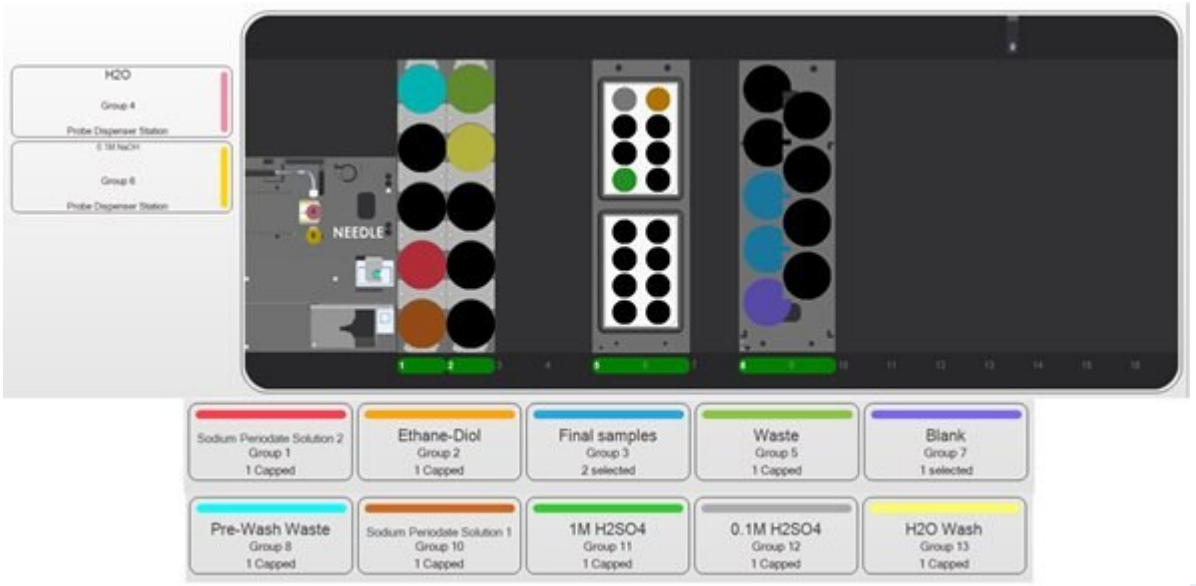
Application Design



- Reagents are freshly prepared at beginning of workflow.
- Precision Timing is Used to Complete Reactions.
- Analysts are alerted when Blank & Samples are ready.
- Analysed by METTLER TOLEDO Tx Auto Titrator.



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Validation Outcomes

Precision of Standard Preparation: < 2.0%

Linearity: $R^2 = 1.000$

Limit of Detection: Detectable below obtained sample results.

Intermediate Precision: Comparable to initial manual results.

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Potential Benefits

Potential Benefit	Manual Extraction	ePrep ONE	Benefit
Manual Labor	>30 Steps	One Step	>95% reduction
Multi-Tasking	Analyst cannot perform this simultaneously with another experiment	Set-and-Forget	Analysts can walk away until alerted that samples are ready for titration
Time	4 Hours	1.5 Hours	63 % reduction
Hands On Time	4 Hours	20 Minutes	92 % reduction
Solvent Usage	330 mL	140 mL	58 % reduction
Environment	Fume Hood Required	No Fume Hood	Energy Saving

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Inspiring Innovation

Project 2020 Progress…

Target	Petroleum Jelly LLE	Liquid Paraffin LLE	HPLC Product Assay 1	HPLC Product Assay 2	Raw Material HPLC Assay	Cl^- RM Assay	Glycerin RM Assay
Analyst Time Saved	-80%	-82%	-77%	-77%	-93%	-94%	-92%
Solvent & Waste	-76%	-76%	-87%	-87%	-90%	-86%	-58%
Cost $	-87%	-86%	-84%	-84%	-91%	-90%	-74%

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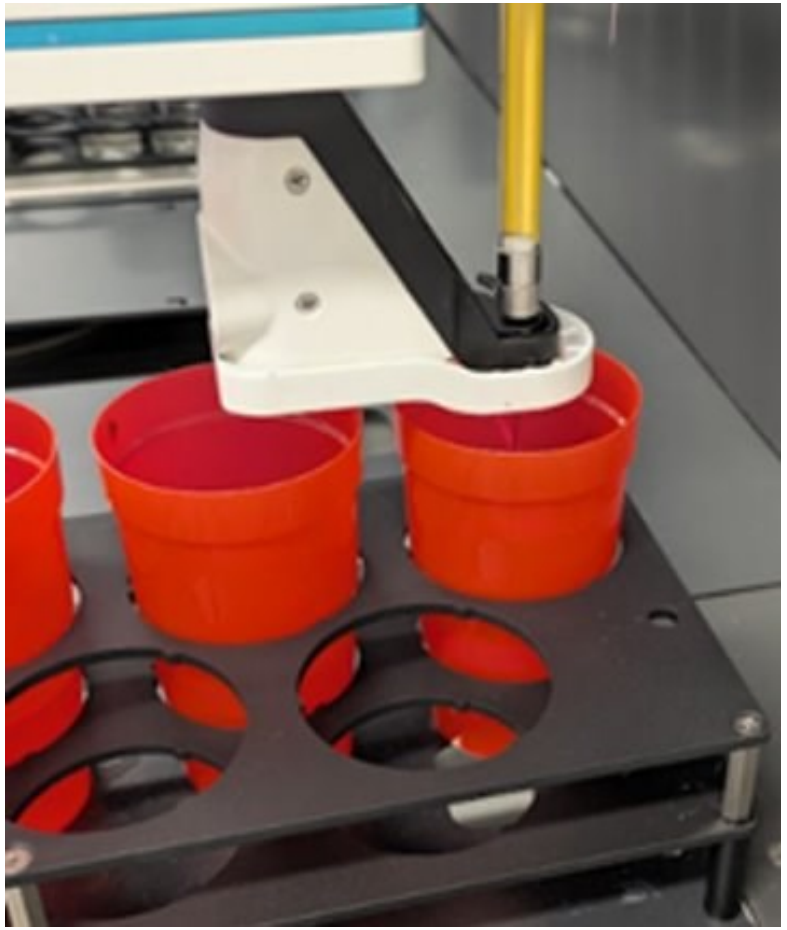
Scalability & Future Applications



- Scalability of automation for complex workflows
- Expanding automation to additional sample preparation workflows
- Long-term data evaluation to quantify error reduction and compliance improvements

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Revolutionizing Labs with AI & Automation

AI Drives Compliance

AI integration helps laboratories meet higher compliance standards through precise, automated processes.

Reducing Environmental Impact

Automation reduces waste and energy consumption, supporting environmental sustainability in scientific work.

Enhancing Financial Performance

Intelligent systems improve efficiency and cost-effectiveness, enhancing overall financial outcomes for labs.

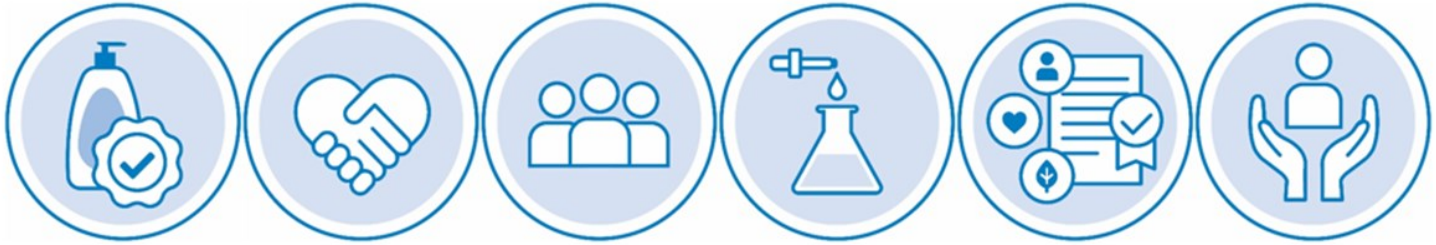
Supporting UN Sustainable Goals

AI and automation align laboratory practices with UN Sustainable Development Goals for responsible innovation.

Conclusion.

Thank You for Your Attention.

I welcome your thoughts and feedback &
Welcome you to connect with me on LinkedIn



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