



Speeding Up LIMS Implementations with Pre-Configured Solutions

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Key Topics



Industry Context and Trends



Industry Pre-Configured Solutions



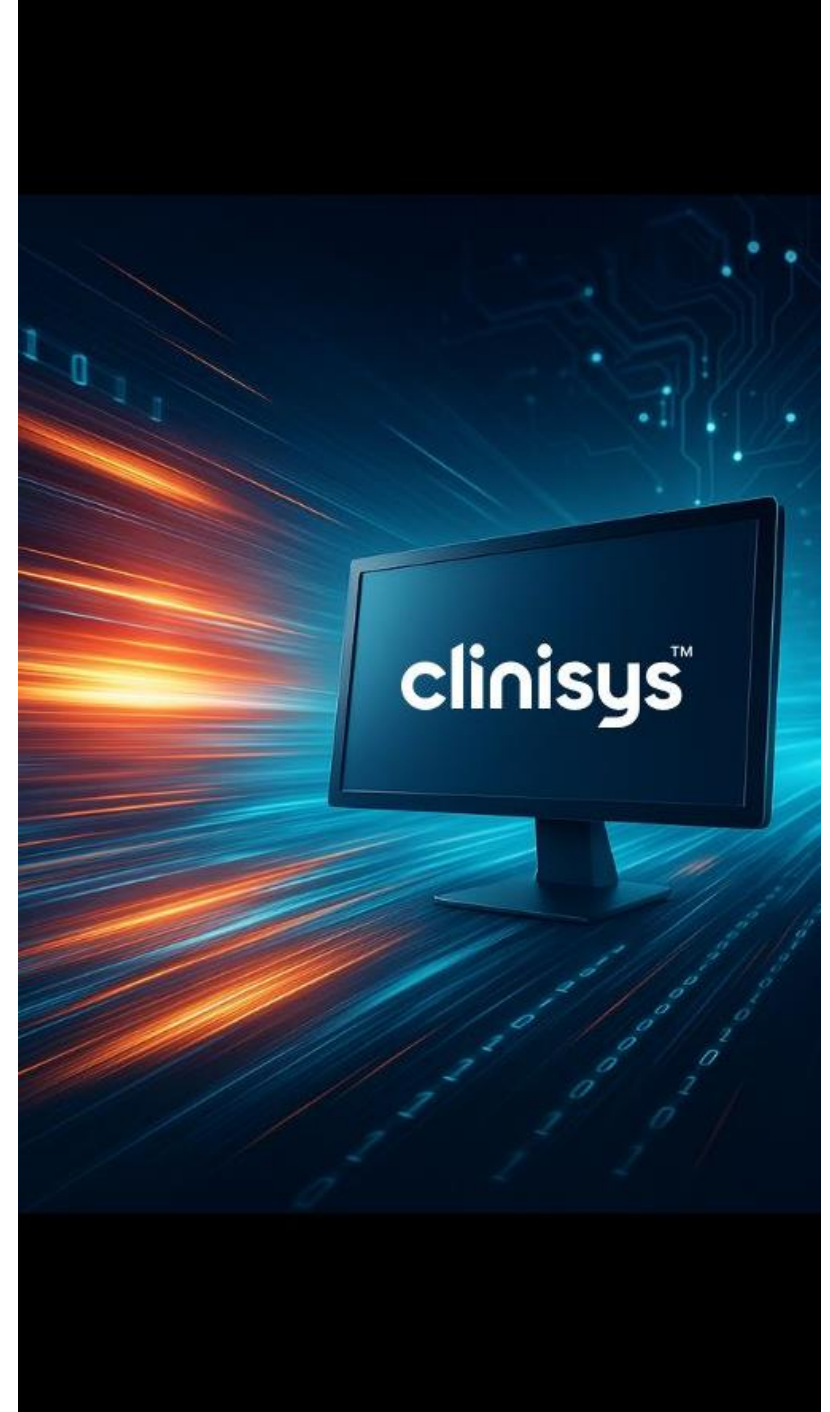
Quality & Compliance



Recap on Speeding Up LIMS
Implementations



Q&A





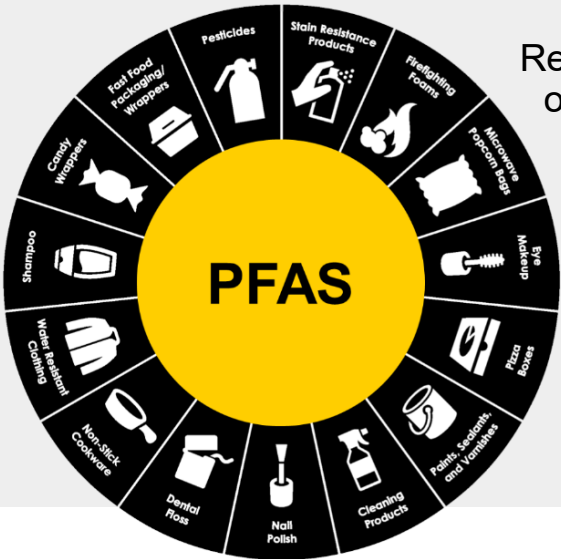
Industry Context and Trends

- Evolving Regulations & Market demands
- Industry Trends

Industry Context and Trends

Evolving Regulatory Landscape and Evolving Trends

Speeding Up LIMS Implementations
with Pre-Configured Solutions



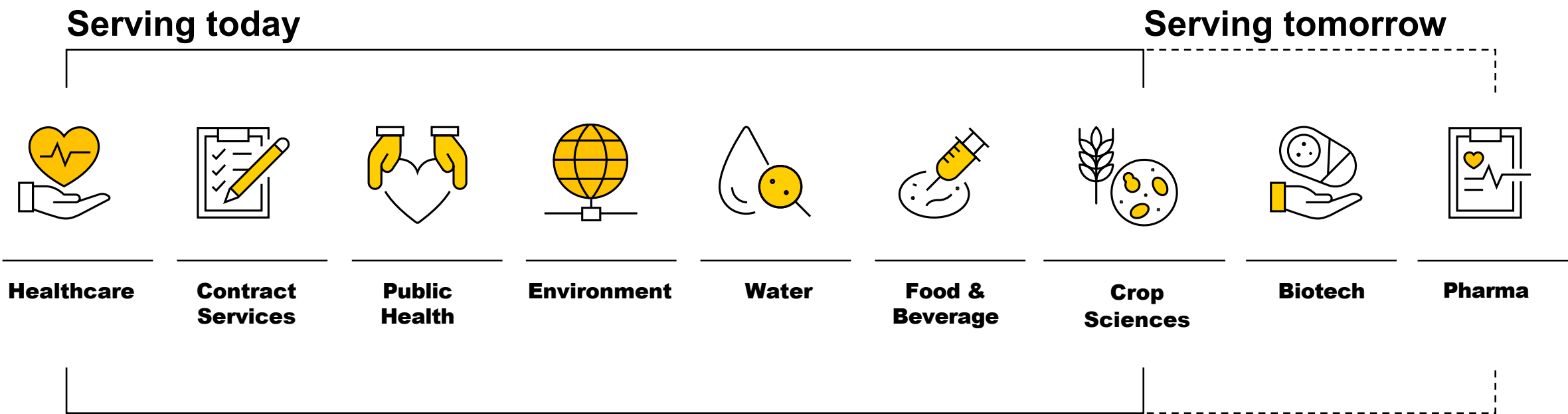
Regulation
of PFAS



Chemical
Materials

Industry Context and Trends

Speeding Up LIMS Implementations
with Pre-Configured Solutions



We serve all sizes of lab operation: scaleups, enterprise, regional, national, country-wide

Clinisys, focus on Product Leadership

Clinisys™ Laboratory Solution (CLS): One Product Platform. Configurable Offerings.

Speeding Up LIMS Implementations
with Pre-Configured Solutions

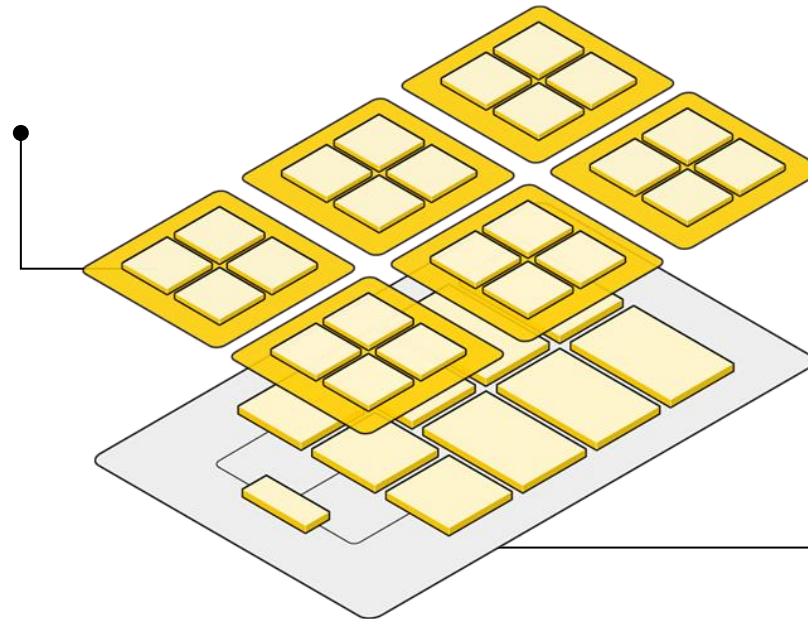
CLS Offerings

Healthcare

- Clinisys Toxicology Laboratory
- Additional offerings under development
 - Clinisys Clinical Pathology Laboratory
 - Clinisys Genomics Laboratory
- Additional offerings being scoped
 - Clinisys Anatomic Pathology Laboratory
 - Clinisys Blood Bank Laboratory
 - Clinisys Order & Results Management

Scientific

- Clinisys Toxicology Laboratory
- Clinisys Contract Services Laboratory
- Clinisys Food and Beverage Laboratory
- Clinisys Environmental Laboratory
- Clinisys Water Quality Laboratory
- Clinisys Public Health Laboratory



CLS: One Product Platform

A data model, workflow engine and platform services that scales from the smallest to the largest multi-country laboratories and across different sectors, disciplines, and specializations

*Solutions are delivered as **industry content packages** overlayed onto the CLS Platform*

Industry Context and Trends

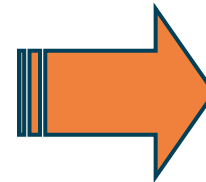
Speeding Up LIMS Implementations
with Pre-Configured Solutions



Global Regulatory Changes, Multi-Discipline
Needs & Technological Advancements



Increased Pressure on Labs



Operational Impacts to Increasing Demands on labs

- Adoption and alignment with the methodologies withing designated timeframes
- Elevate throughput to cope with the increased demand for testing
- Significant investments in lab equipment, lab informatics and human resources
- Shorter time to adoption/to value
- Increased competition

Industry Pre-Configured Solutions

- Industry Methodologies
- Standards & Naming Conventions
- Preconfigured Content Packages

Industry Pre-Configured Solutions

Speeding Up LIMS Implementations
with Pre-Configured Solutions

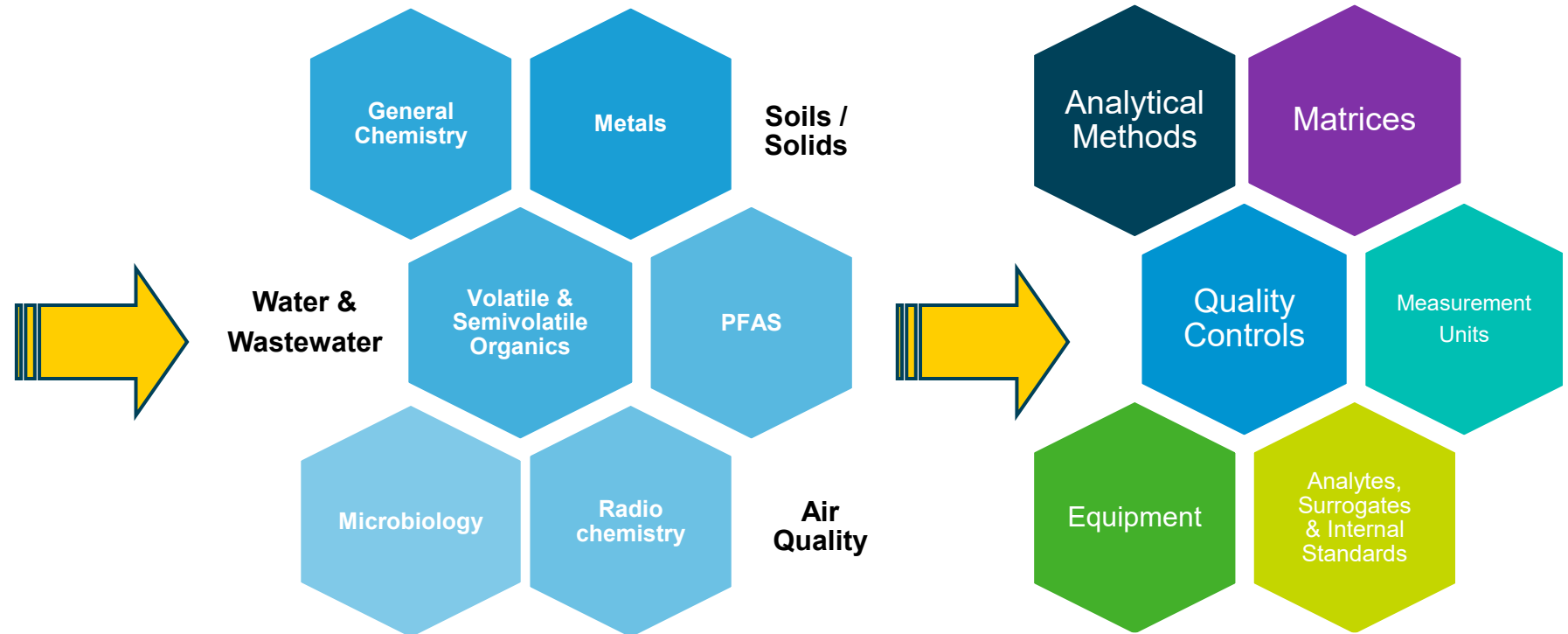
Regulations, Rules & Guidelines



European
Environment
Agency

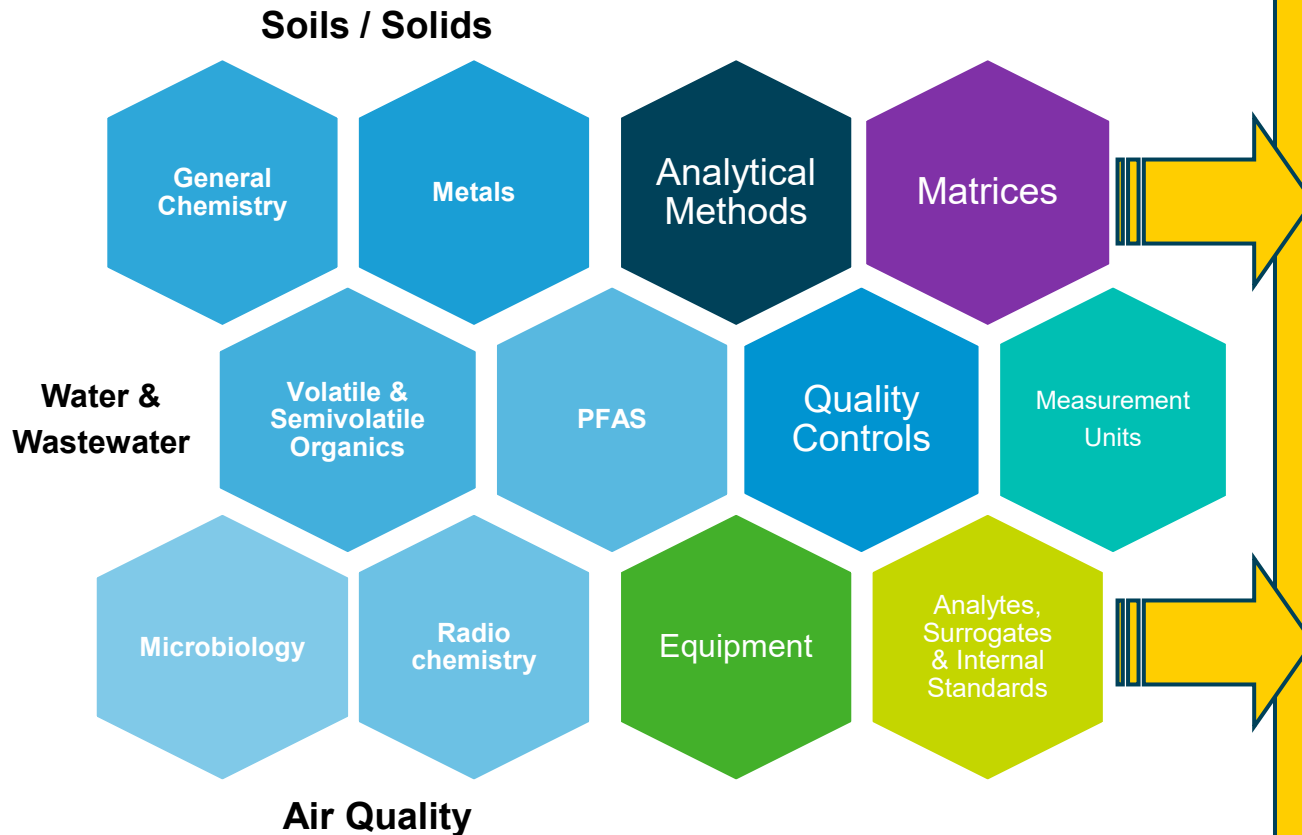


Test Workflows & Industry Foundational Data



Industry Pre-Configured Solutions

Speeding Up LIMS Implementations
with Pre-Configured Solutions



Standard Naming Conventions

- Did research across the analytical methods and consulted guidelines
- Compared naming conventions (target analytes, surrogates, internal standards) and decided on the best one to use
- Validates names and CAS# against official sources (EPA, CAS Registry, PubChem, TNI, etc.)
- Harmonized on Matrices, Equipment Types, Measurement Units, Container Types, Preservatives, Quality Controls, etc. across methodologies
- Set Default Values for MDL and PQL/MRL and well as for Control Limits

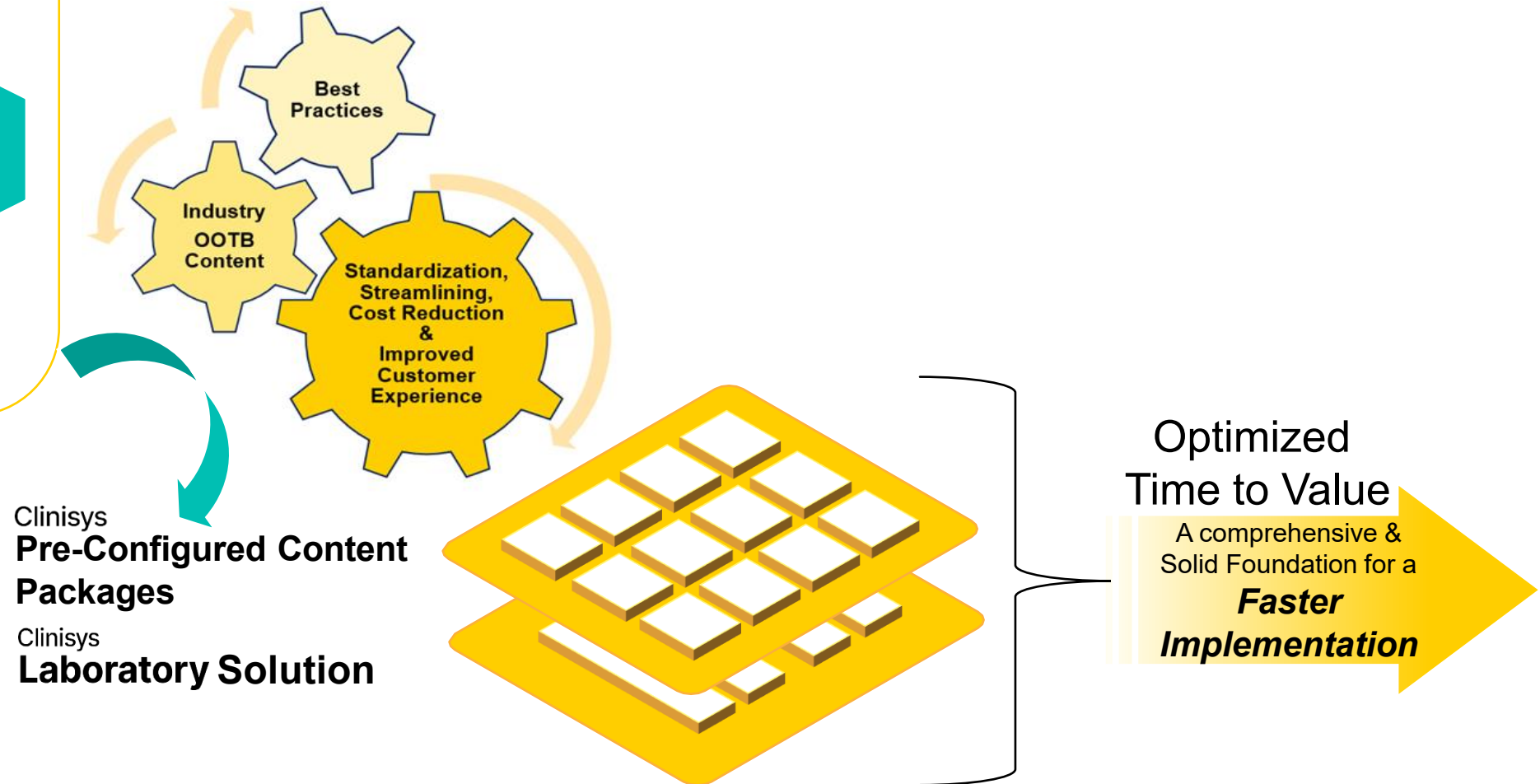
Industry Pre-Configured Solutions

Speeding Up LIMS Implementations
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Preconfigured Content Packages



Our Response to Helping Labs



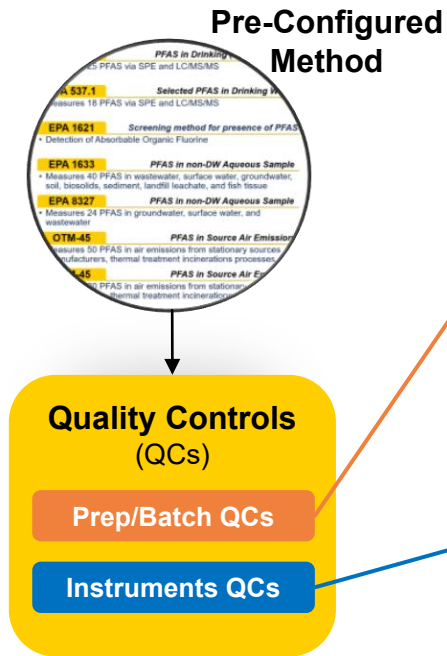
Quality & Compliance

- Quality Controls
- Automated Results Imports
- Data Reviews

Quality & Compliance

Quality Controls

Speeding Up LIMS Implementations with Pre-Configured Solutions



Pre-Configured Templates

Details Creation Posting **Templates** Spike Amounts

Templates

Add Copy Bulk Edit Delete Examine Undo Pending

Position	Sample Type	Matrix
1	MB - Method Blank	Reagent Water
2	LCS - Lab Control Sample	Reagent Water
4	MS - Matrix Spike	
5	MSD - Matrix Spike Duplicate	

Details Creation Posting **Templates** Spike Amounts

Templates

Add Copy Bulk Edit Delete Examine Undo Pending

Position	Sample Type	Matrix
1	ICV - Initial Cal Verification	Reagent Water
2	ICB - Initial Calibration Blank	Reagent Water
13	CCB - Continuing Calibration Blank	Reagent Water
14	CCV - Continuing Cal Verification	Reagent Water
35	CCB - Continuing Calibration Blank	Reagent Water
36	CCV - Continuing Cal Verification	Reagent Water
998	CCB - Continuing Calibration Blank	Reagent Water
999	CCV - Continuing Cal Verification	Reagent Water

Batch: 1017

Department: PFAS (PFAS)

Prep/Extraction Batch

BATCH DETAILS

Created: 04/11/2025 15:00 Batch rule: EPA 8327 - PFAS Prep - WA (8327WP) Scanned ID: 0 comment

Closed: 04/11/... 15:01 Batch owner: Lab site: Main (*) Other criteria: Edit

Analysis & Admin Tasks Batch-level Tasks Additional Info

Add Existing Task Add QC Sample Remove Task Limits

Pos	Identifier	Task ID	Matrix	Sample Type	Sample ID	CC	Active Status	Original	Paired
1	1190014	14794	Reagent Water	MB	MB for HBN 753 [PFAS/1017]	OK	Released		
2	1190015	14796	Reagent Water	LCS	LCS for HBN 753 [PFAS/1017]	OK	Released		
3	1190001	14583	Water	SAMPLE	WA Tests	OK	Released		
4	1190016	14798	Water	MS	WA Tests(1190001MS)	OK	Released	1190001	
5	1190017	14800	Water	MSD	WA Tests(1190001MSD)	OK	Released	1190001	1190016
6	1190002	14620	Water	SAMPLE	WA Tests	OK	Released		
7	1190003	14657	Water	SAMPLE	WA Tests	OK	Released		

Batch: 1018

Department: PFAS (PFAS)

Analytical Batch

Batch is reviewed and is protected

BATCH DETAILS

Created: 04/11/2025 15:01 Batch rule: EPA 8327 - PFAS - WA (8327W) Scanned ID: 0 comment

Closed: 04/11/... 15:21 Batch owner: Lab site: Main (*) Other criteria: Edit

Analysis & Admin Tasks Batch-level Tasks Additional Info

Add Existing Task Add QC Sample Remove Task Limits

Pos	Identifier	Task ID	Matrix	Sample Type	Sample ID	CC	Active Status	Original	Paired
1	1190018	14803	Reagent Water	ICV	ICV for HBN 754 [PFAS/1018]	OK	Released		
2	1190019	14805	Reagent Water	ICB	ICB for HBN 754 [PFAS/1018]	OK	Released		
3	1190014	14795	Reagent Water	MB	MB for HBN 753 [PFAS/1017]	OK	Released		
4	1190015	14797	Reagent Water	LCS	LCS for HBN 753 [PFAS/1017]	OK	Released		
5	1190001	14584	Water	SAMPLE	WA Tests	OK	Released		
6	1190016	14799	Water	MS	WA Tests(1190001MS)	OK	Released	1190001	
7	1190017	14800	Water	MSD	WA Tests(1190001MSD)	OK	Released	1190001	1190016
8	1190002	14621	Water	SAMPLE	WA Tests	OK	Released		
9	1190003	14658	Water	SAMPLE	WA Tests	OK	Released		
10	1190020	14807	Reagent Water	CCB	CCB for HBN 754 [PFAS/1018]	OK	Released		
11	1190021	14809	Reagent Water	CCV	CCV for HBN 754 [PFAS/1018]	OK	Released		

QC failures can be handled too!

Sample Type	CC	Status
ICV	QF	In Review
CCV	OK	In Review
MB	OK	In Review
LCS	OK	In Review
SAMPLE	QF	In Review
MS	OK	In Review
MSD	OK	In Review

Condition code:

QC Failure (QF)

Condition code: QC Failure (QF)

Run date: 07/30/2024 11:13

Condition code:

QC Failure (QF)

Successful (OK)

Successful, Immediate Release (ok)

Rerun All Analytes, No Reprep (RR)

Rerun Some Analytes, No Reprep (rr)

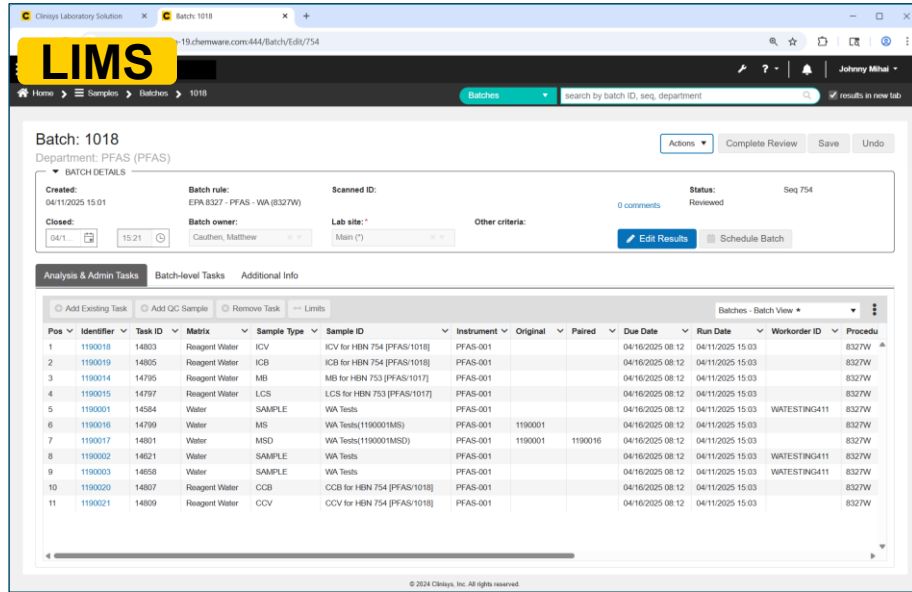
Reprep and Rerun All Analytes (RP)

Reprep and Rerun Some Analytes (rp)

Cancelled (CA)

Quality & Compliance

Automated Result Imports



LIMS

Batch: 1018
Department: PFAS (PFAS)

Created: 04/11/2025 15:01
Batch rule: EPA.8327 - PFAS - WA (8327W)
Scanned ID: Seq 754
Status: Reviewed

Batch owner: Caution, Matthew
Lab site: Main (*)
Other criteria: Edit Results Schedule Batch

Analysis & Admin Tasks Batch-level Tasks Additional Info

Pos	Identifier	Task ID	Matrix	Sample Type	Sample ID	Instrument	Original	Paired	Due Date	Run Date	Workorder ID	Procedu
1	1190018	14803	Reagent Water	ICV	ICV for HEN 754 [PFAS/1018]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W
2	1190019	14805	Reagent Water	ICB	ICB for HEN 754 [PFAS/1018]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W
3	1190014	14795	Reagent Water	MB	MB for HEN 754 [PFAS/1017]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W
4	1190015	14797	Reagent Water	LCS	LCS for HEN 753 [PFAS/1017]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W
5	1190001	14564	Water	SAMPLE	WA Tests	PFAS-001			04/16/2025 08:12	04/11/2025 15:03	WATESTING411	8327W
6	1190016	14799	Water	MS	WA Tests(1190001MS)	PFAS-001	1190001	1190016	04/16/2025 08:12	04/11/2025 15:03		8327W
7	1190017	14801	Water	MSD	WA Tests(119001MSD)	PFAS-001	1190001	1190016	04/16/2025 08:12	04/11/2025 15:03		8327W
8	1190002	14801	Water	SAMPLE	WA Tests	PFAS-001			04/16/2025 08:12	04/11/2025 15:03	WATESTING411	8327W
9	1190003	14658	Water	SAMPLE	WA Tests	PFAS-001			04/16/2025 08:12	04/11/2025 15:03	WATESTING411	8327W
10	1190020	14807	Reagent Water	CCB	CCB for HEN 754 [PFAS/1018]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W
11	1190021	14809	Reagent Water	CCV	CCV for HEN 754 [PFAS/1018]	PFAS-001			04/16/2025 08:12	04/11/2025 15:03		8327W

Load List / Batch
Sequence Setup



Secured
Locations
& Routes



Instrument Output
Files or Data Stream



Speeding Up LIMS Implementations
with Pre-Configured Solutions



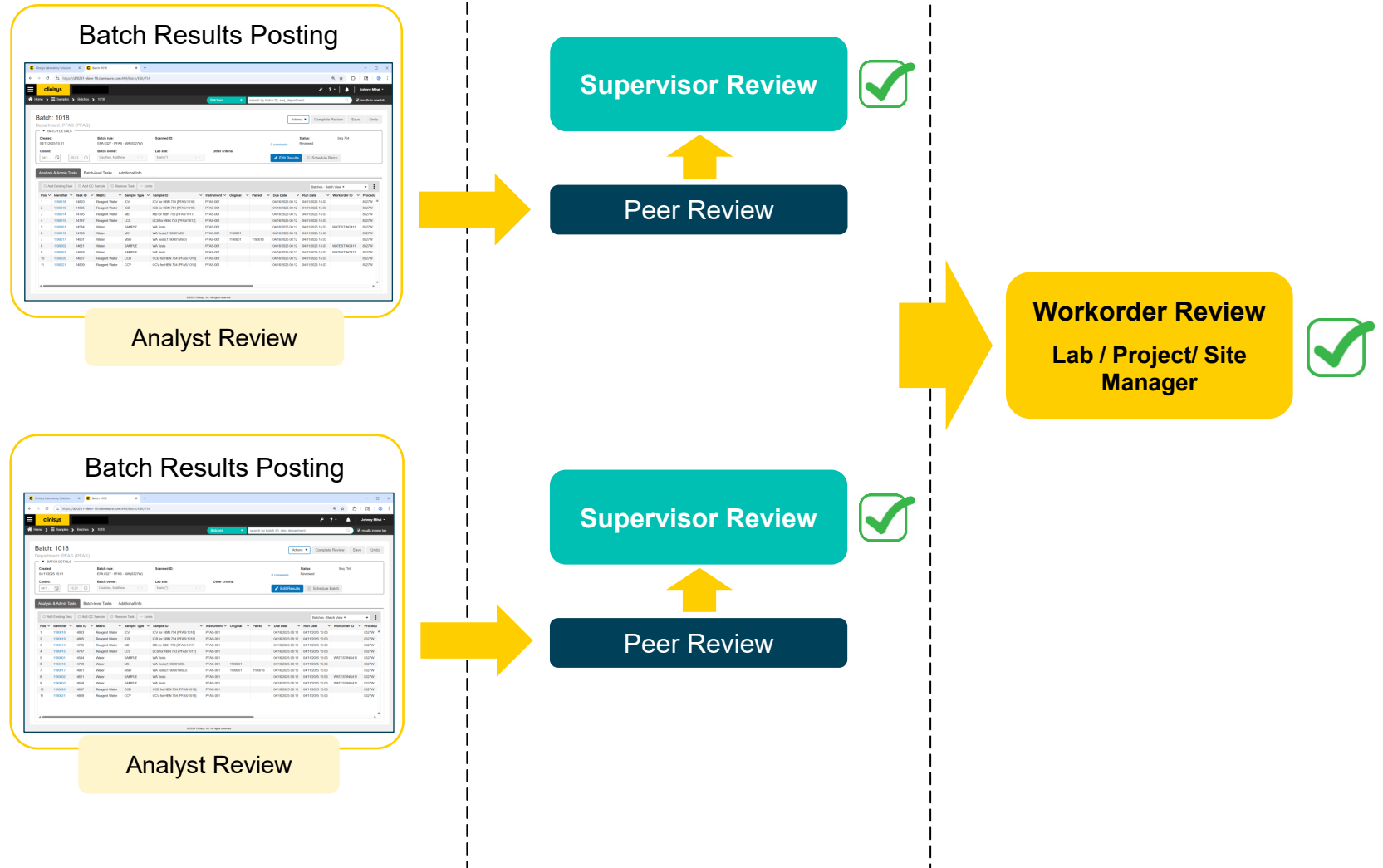
- Support for High-Throughput and Increased Efficiencies
- Pre-Configured Instrument Data Parsers
- Minimizes Manual Interventions and Transcription Errors
- Data Integrity & Traceability (linked to tests/procedures, users, equipment, reagents, standards, etc.)
- Compliant with 21 CFR Part 11 and FDA ALCOA Principles

Quality & Compliance

Data Reviews

- Data Reviews – Integral Part of the QA Process
- Pre-Configured Multi-Level Reviews
- Pre-Configured Data Review Reports

Speeding Up LIMS Implementations with Pre-Configured Solutions

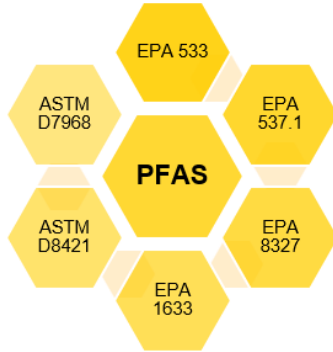


Recap on Speeding Up LIMS Implementations

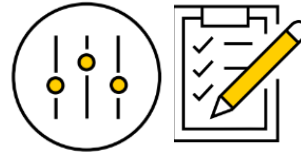
- Methods/Standards & Key Quality Aspects
- Visual Tools
- Other References/Resources

Recap on Speeding Up LIMS Implementations

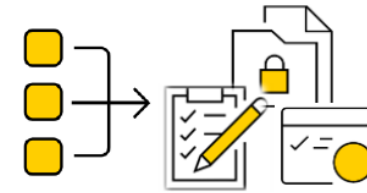
Methods/Standards & Key Quality Aspects



Comprehensive set of
Pre-Configured
Methods & Tests



Standardized & Pre-
Configured Quality
Controls



Pre-Configured Multi-Level
Data Reviews



Standardized &
Harmonized Naming
Conventions



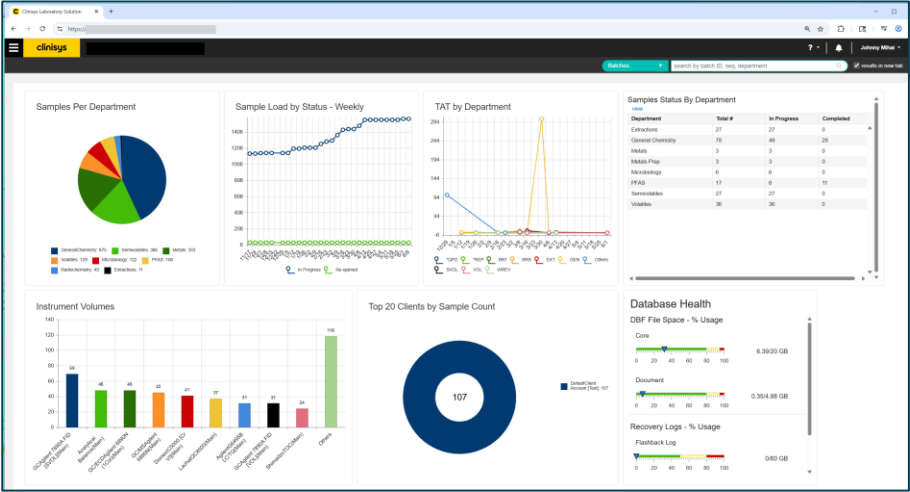
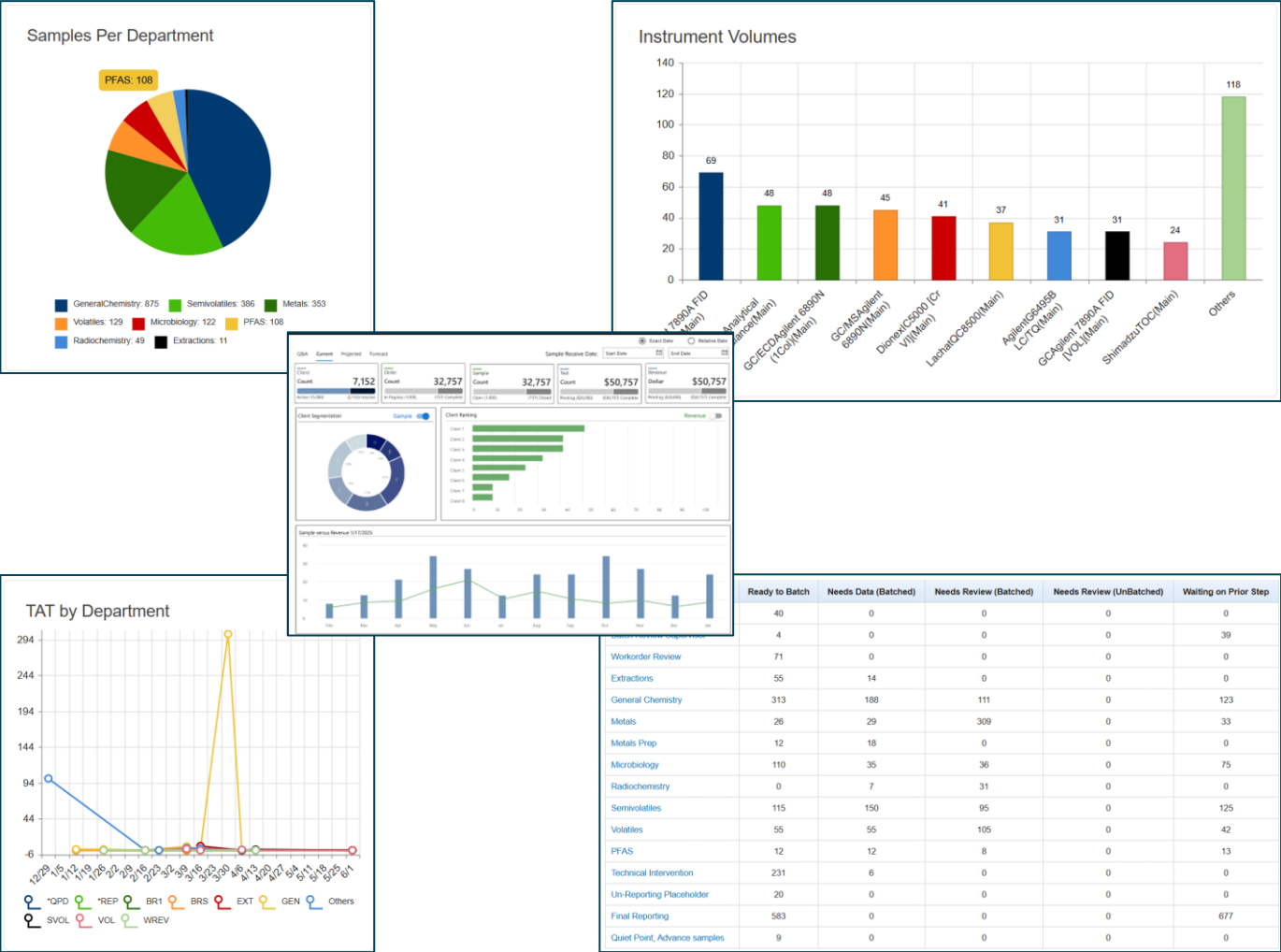
Automated Results Imports
& Traceability



Alignment with Published
Guidelines and Analytical
Methods Applicable for the
Industry

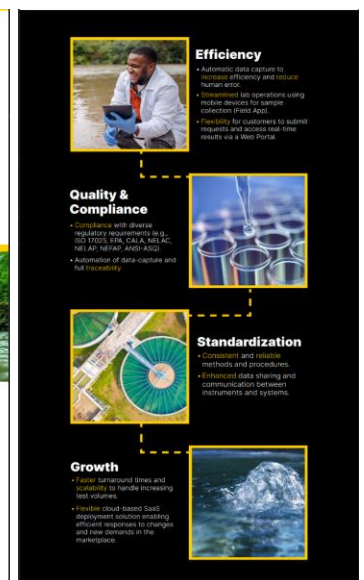
Recap on Speeding Up LIMS Implementations

Visual Tools



Other References/Resources

Package Infographics



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Selecting lab software: Are you asking the right questions?

<https://www.clinisys.com/us/en/news-events/category/insight/>

Q&A



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Thank you!



Helping enable healthier
and safer communities

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