



# Clinisys™ Laboratory Solution

## Speeding Up LIMS Implementations with Pre-Configured Solutions

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Director, Product Packaging

**clinisys™**

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# Key Topics



Industry Context and Trends



Industry Pre-Configured Solutions



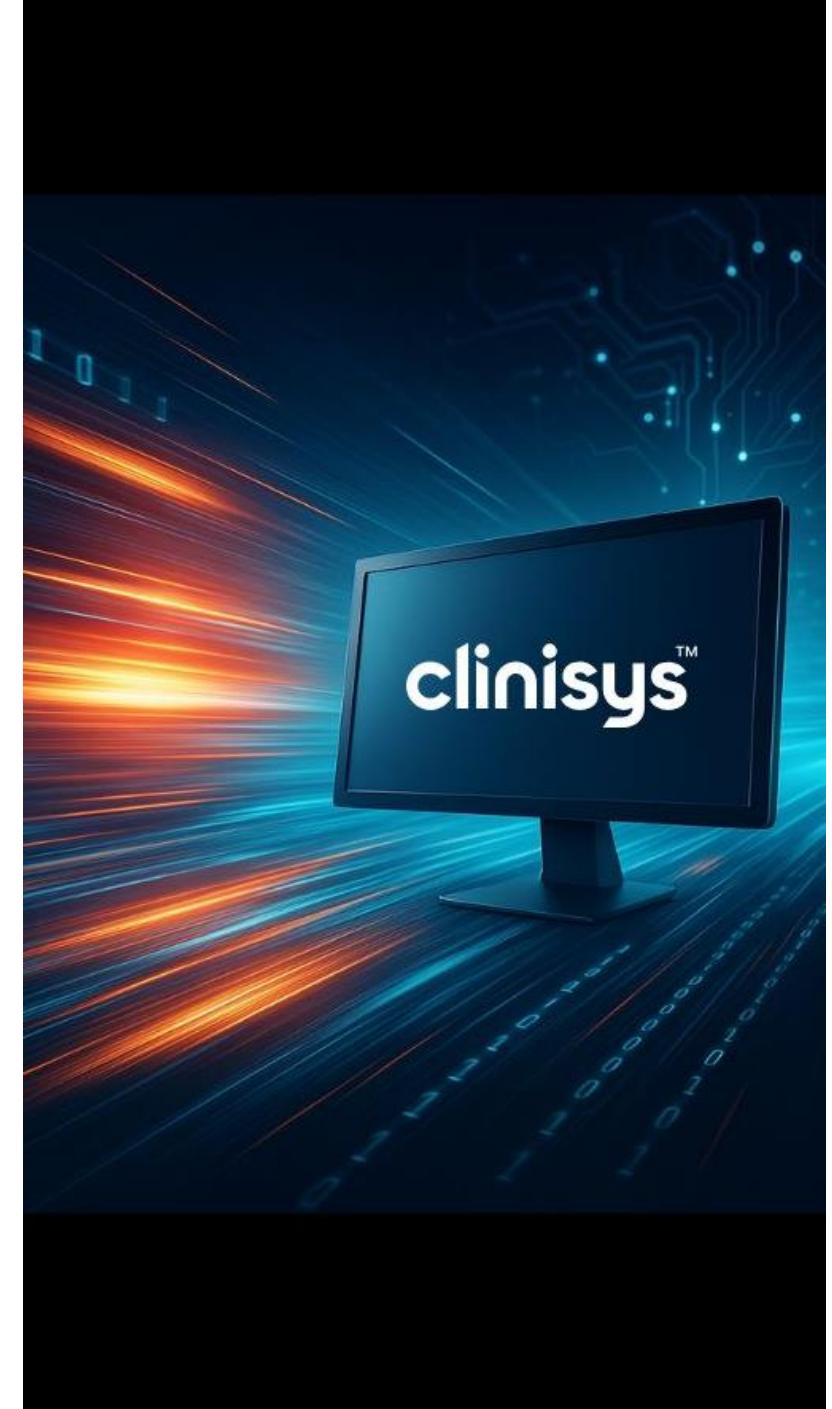
Quality & Compliance



Recap on Speeding Up LIMS  
Implementations



Q&A





# Industry Context and Trends

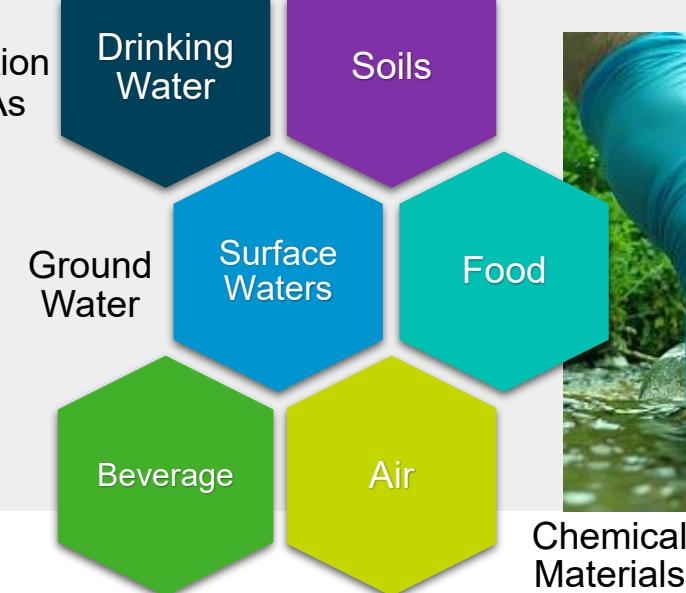
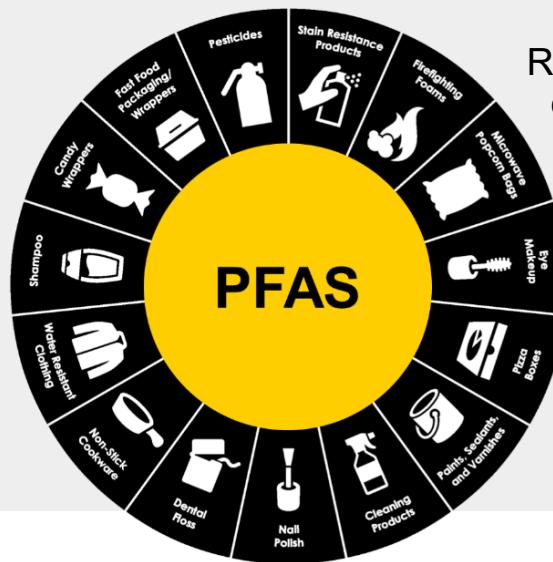
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- Evolving Regulations & Market demands
- Industry Trends

# Industry Context and Trends

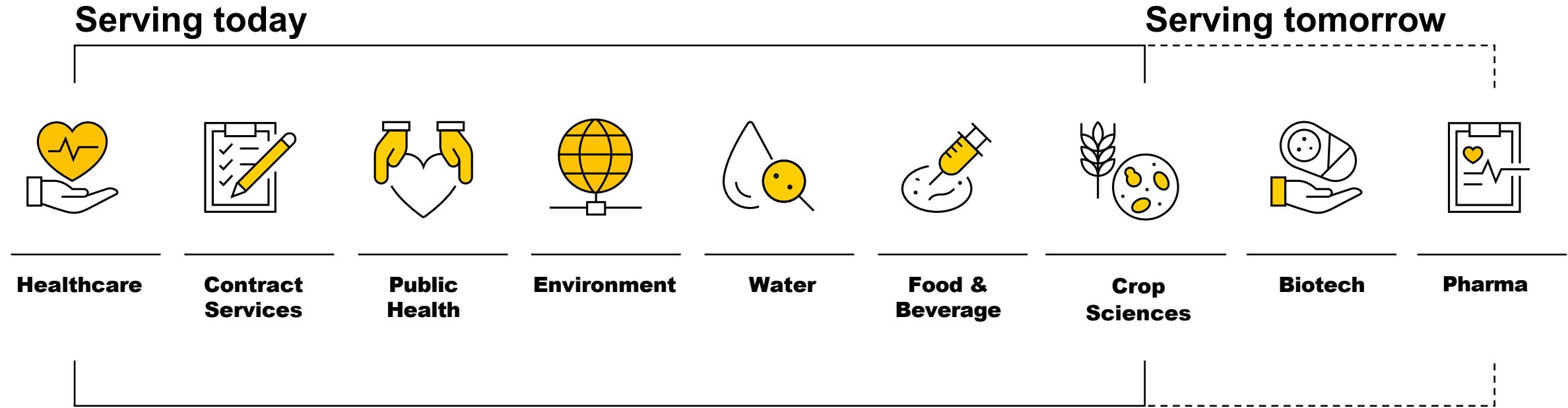
## Evolving Regulatory Landscape and Evolving Trends

Speeding Up LIMS Implementations  
with Pre-Configured Solutions



# 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

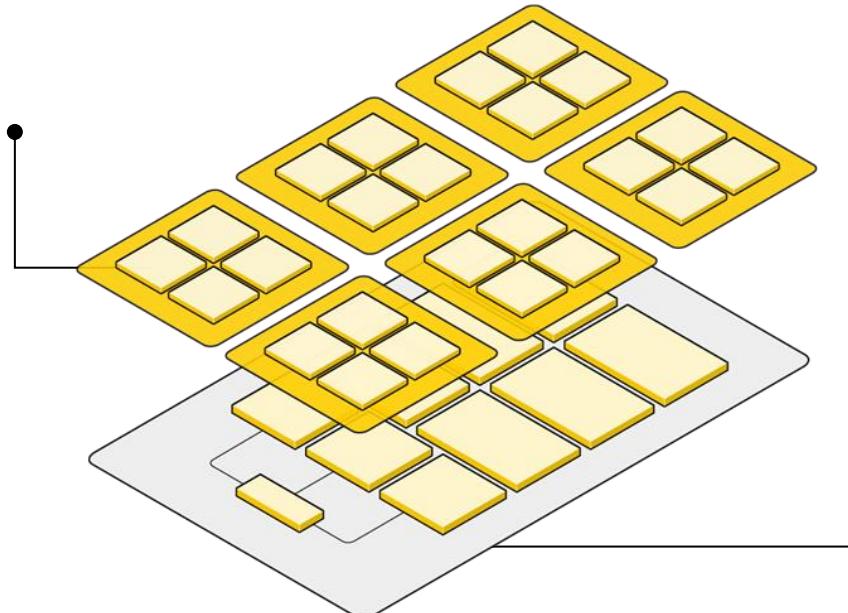
## CLS Offerings

### 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

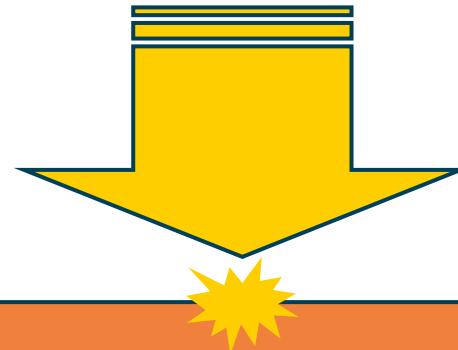
*Solutions are delivered as **industry content packages** overlayed onto the CLS Platform*

# Industry Context and Trends

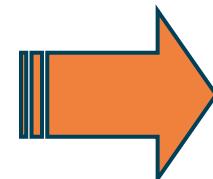
Speeding Up LIMS Implementations  
with Pre-Configured Solutions



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 within 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

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

# Industry Pre-Configured Solutions

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with Pre-Configured Solutions

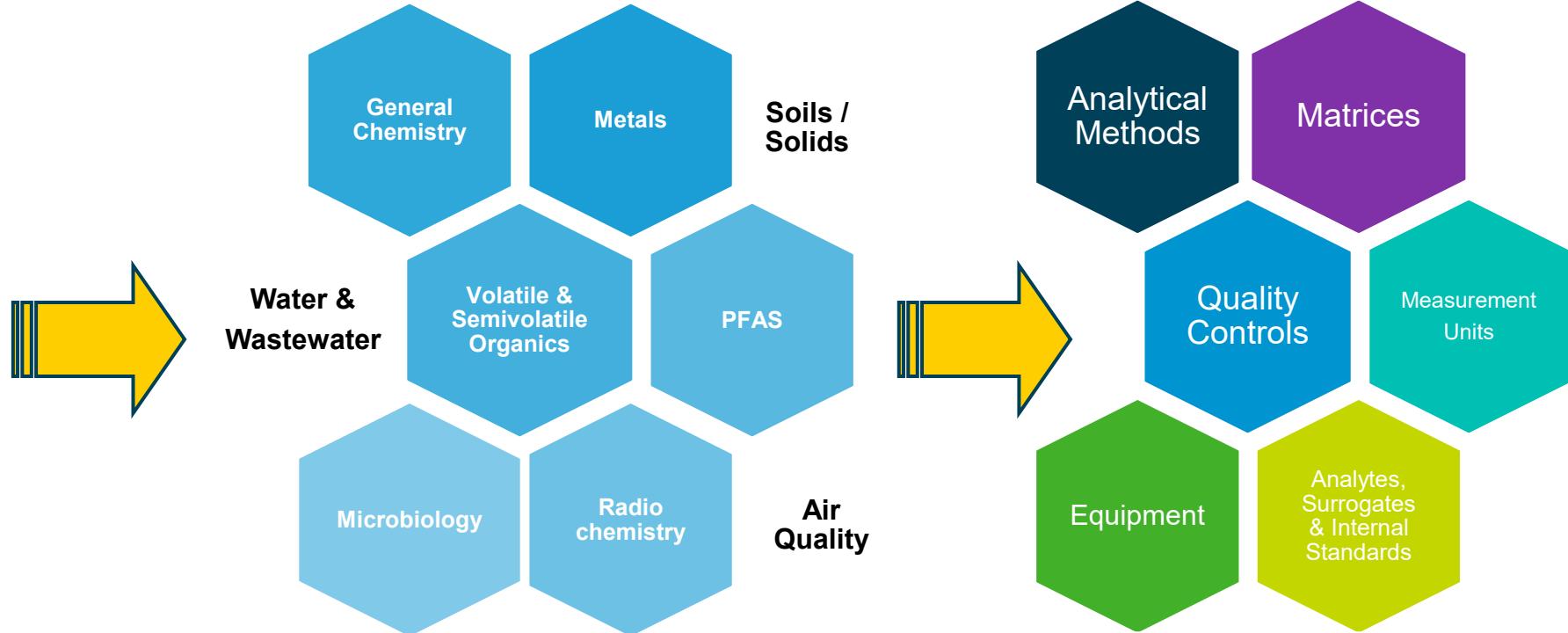
## Regulations, Rules & Guidelines



## European Environment Agency

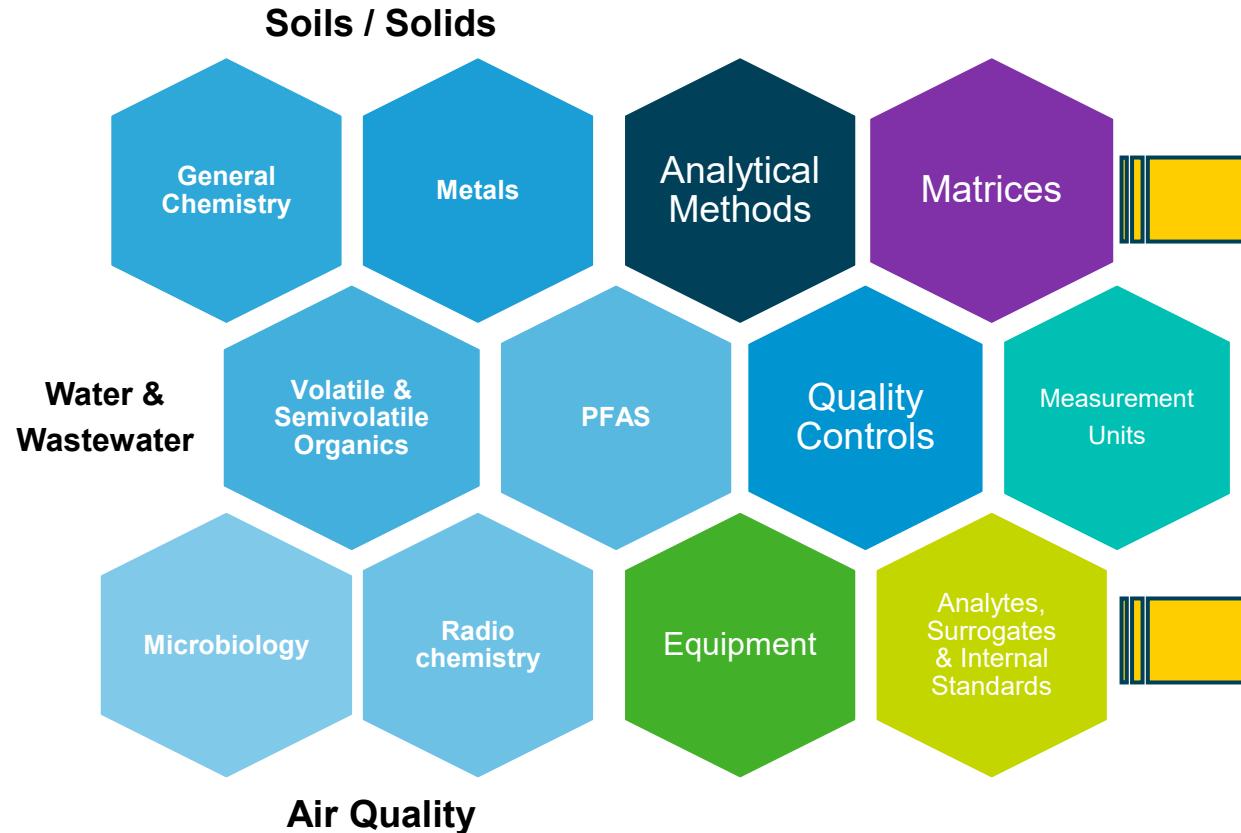


## Test Workflows & Industry Foundational Data



# Industry Pre-Configured Solutions

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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

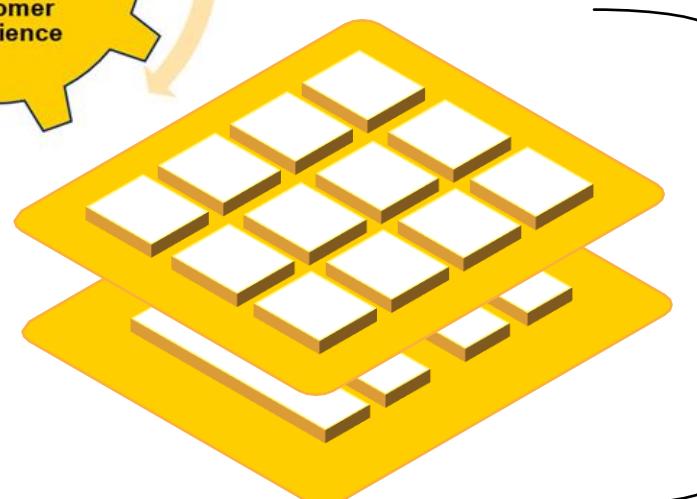
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## Preconfigured Content Packages



Clinisys  
**Pre-Configured Content  
Packages**  
Clinisys  
**Laboratory Solution**

## Our Response to Helping Labs



# Quality & Compliance

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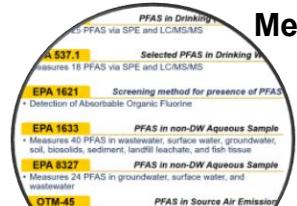
- Quality Controls
- Automated Results Imports
- Data Reviews

# Quality & Compliance

Speeding Up LIMS Implementations with Pre-Configured Solutions

## Quality Controls

### Pre-Configured Method



### Quality Controls (QCs)

Prep/Batch QCs

Instruments QCs

### Pre-Configured Templates

Details	Creation	Posting	Templates	Spike Amounts
Templates				
<a href="#">+ Add</a>	<a href="#">Copy</a>	<a href="#">Bulk Edit</a>	<a href="#">Delete</a>	<a href="#">Examine</a>
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				
<a href="#">+ Add</a>	<a href="#">Copy</a>	<a href="#">Bulk Edit</a>	<a href="#">Delete</a>	<a href="#">Examine</a>
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		

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

RUN HEADER

Condition code: **QC Failure (QF)**

Condition code: **QC Failure (QF)**

Run date: 07/30/2024 11:13

Condition code: **QC Failure (QF)**

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)

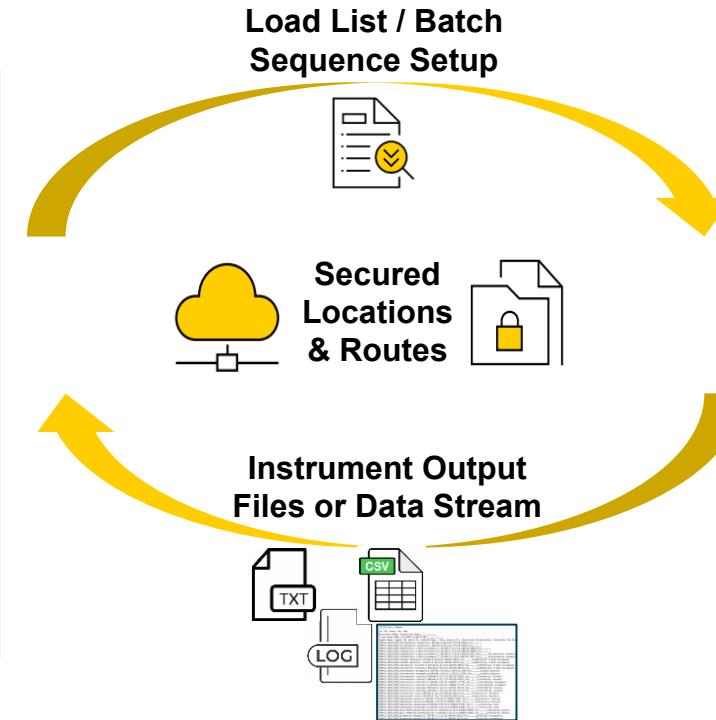
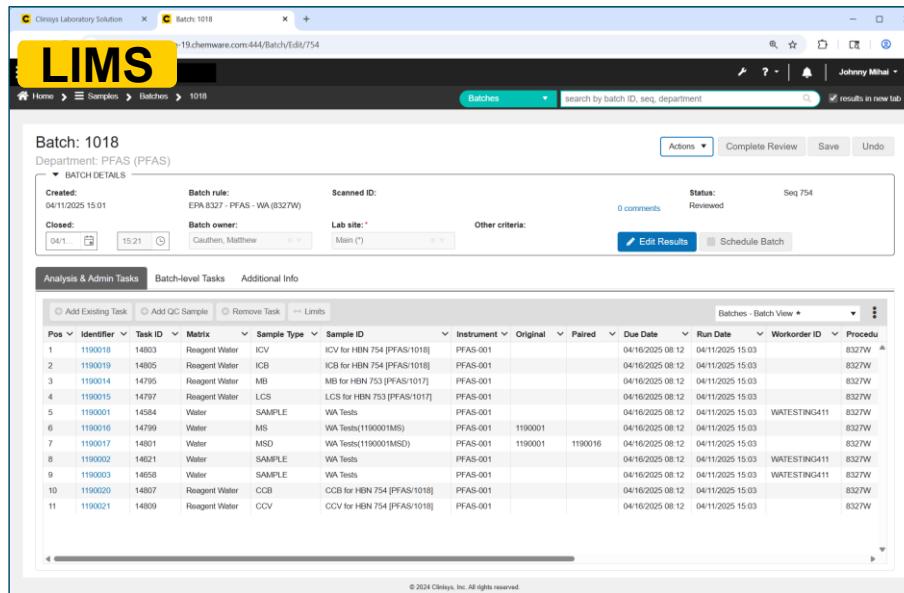
Cancelled (CA)

Batch: 1017										
Department: PFAS (PFAS)										
Created: 04/11/2025 15:00										
Batch rule: EPA 8327 - PFAS Prep - WA (8327WP)										
Scanned ID: <input type="text"/>										
Closed: 04/11/2025 15:01										
Batch owner: <input type="text"/>										
Lab site: <input type="text"/> Main (*)										
Other criteria: <input type="text"/>										
Analysis & Admin Tasks Batch-level Tasks Additional Info										
<a href="#">Add Existing Task</a> <a href="#">Add QC Sample</a> <a href="#">Remove Task</a> <a href="#">Limits</a>										
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)										
Batch is reviewed and is protected										
Batch Details										
Created: 04/11/2025 15:01										
Batch rule: EPA 8327 - PFAS - WA (8327W)										
Scanned ID: <input type="text"/>										
Closed: 04/11/2025 15:21										
Batch owner: <input type="text"/> <input type="text"/> Matthew										
Lab site: <input type="text"/> Main (*)										
Other criteria: <input type="text"/>										
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	14801	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			

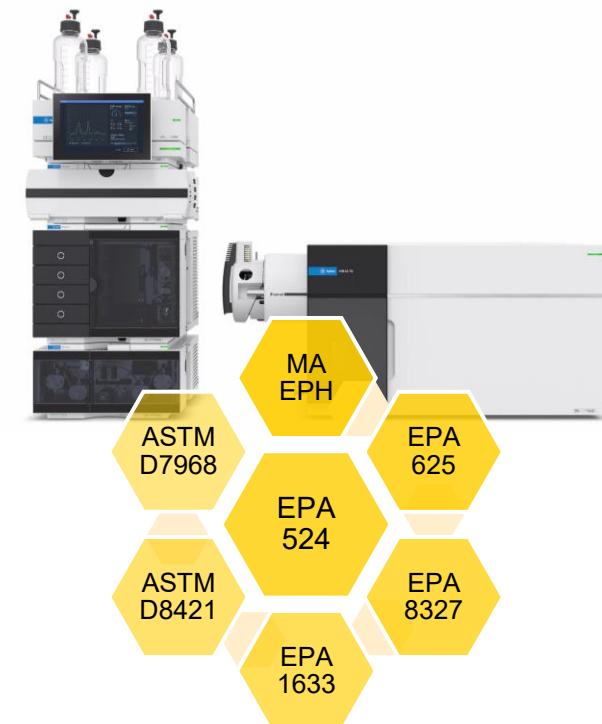
# Quality & Compliance

## Automated Result Imports



- 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

Speeding Up LIMS Implementations  
with Pre-Configured Solutions

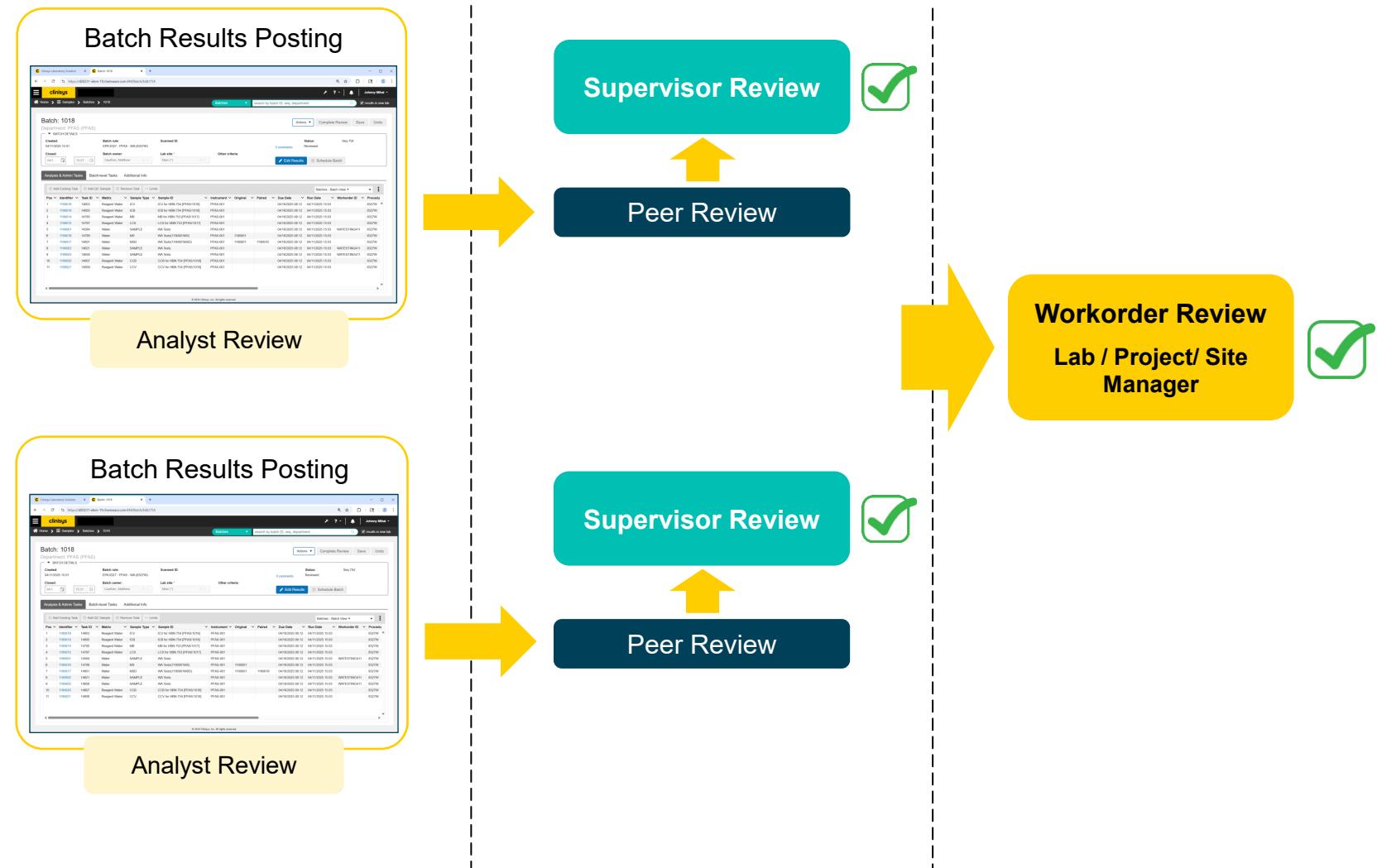


# Quality & Compliance

Speeding Up LIMS Implementations with Pre-Configured Solutions

## Data Reviews

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



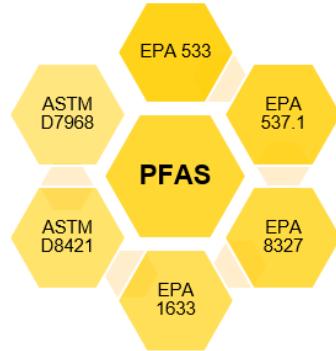
# Recap on Speeding Up LIMS Implementations

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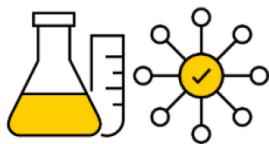
- Methods/Standards & Key Quality Aspects
- Visual Tools
- Other References/Resources

# Recap on Speeding Up LIMS Implementations

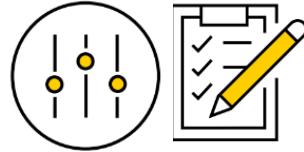
## Methods/Standards & Key Quality Aspects



Comprehensive set of  
Pre-Configured  
Methods & Tests



Standardized &  
Harmonized Naming  
Conventions



Standardized & Pre-  
Configured Quality  
Controls



Automated Results Imports  
& Traceability



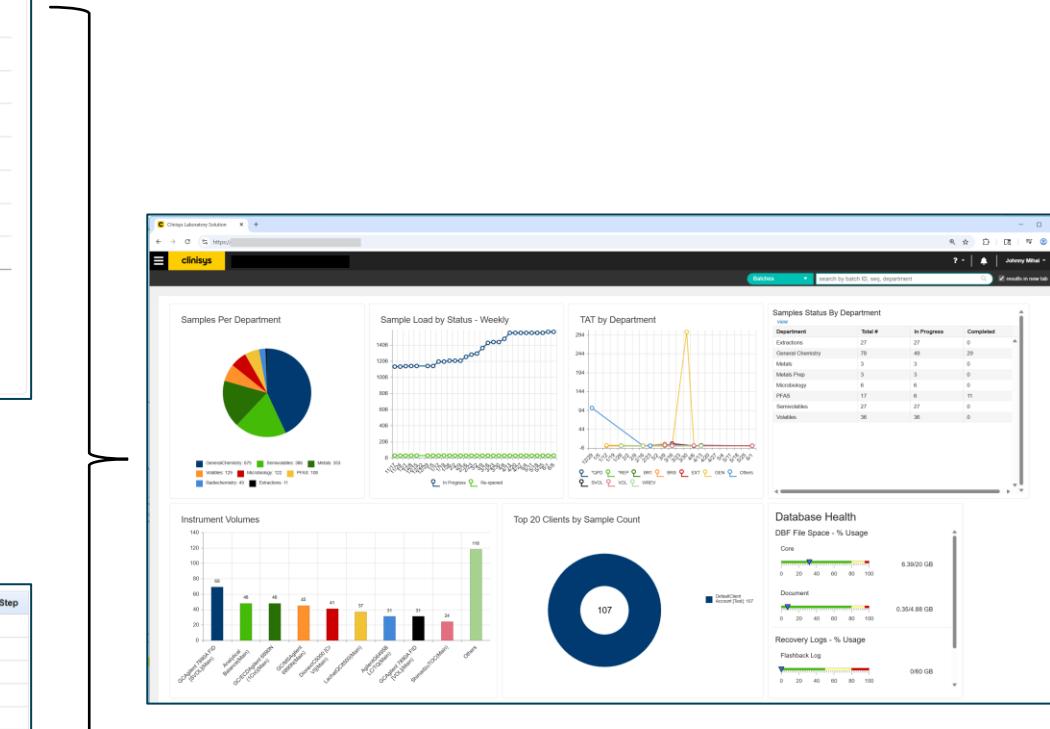
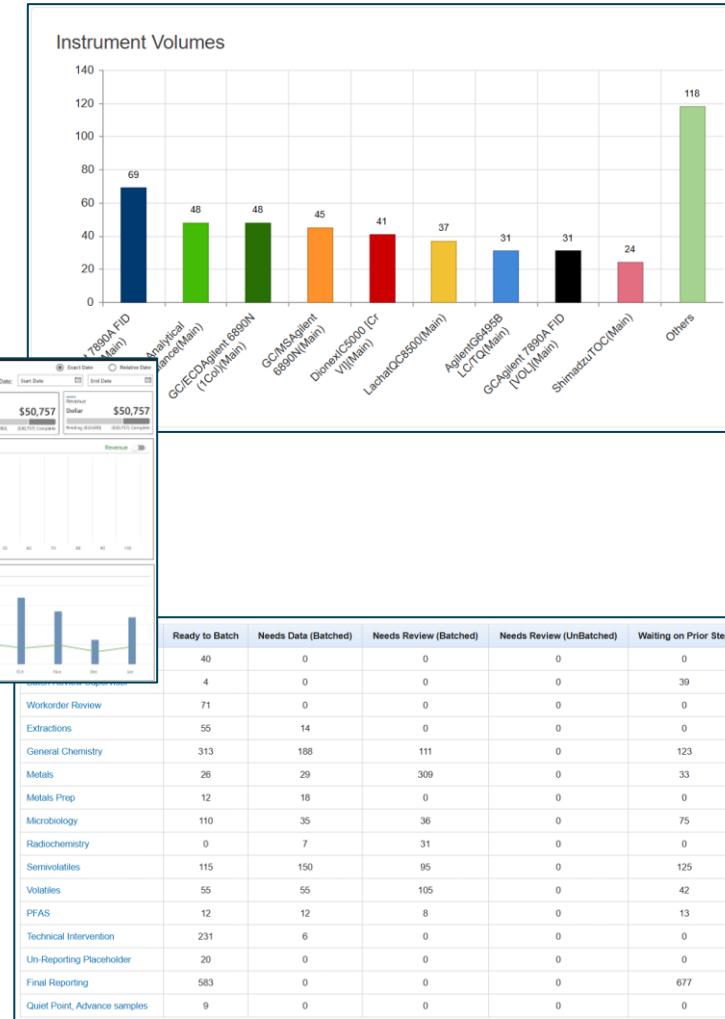
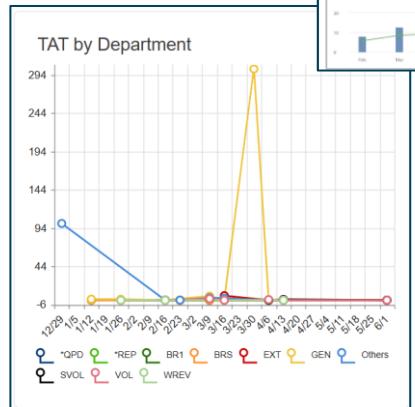
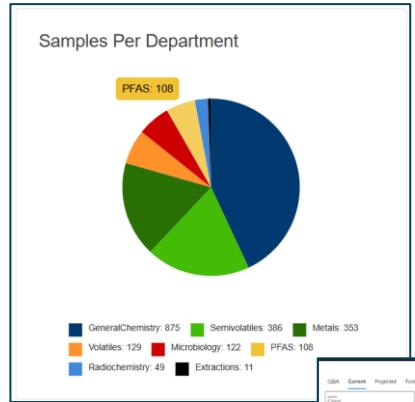
Pre-Configured Multi-Level  
Data Reviews



Alignment with Published  
Guidelines and Analytical  
Methods Applicable for the  
Industry

# Recap on Speeding Up LIMS Implementations

## Visual Tools

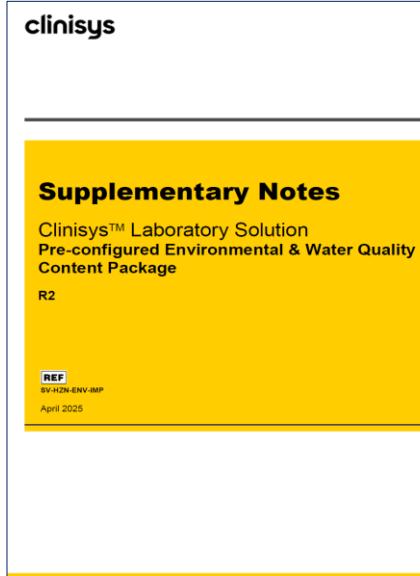


# Recap on Speeding Up LIMS Implementations

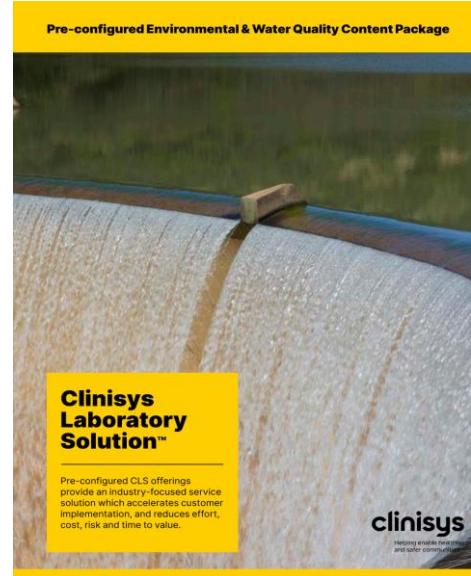
## Other References/Resources

### Brochures & Infographics

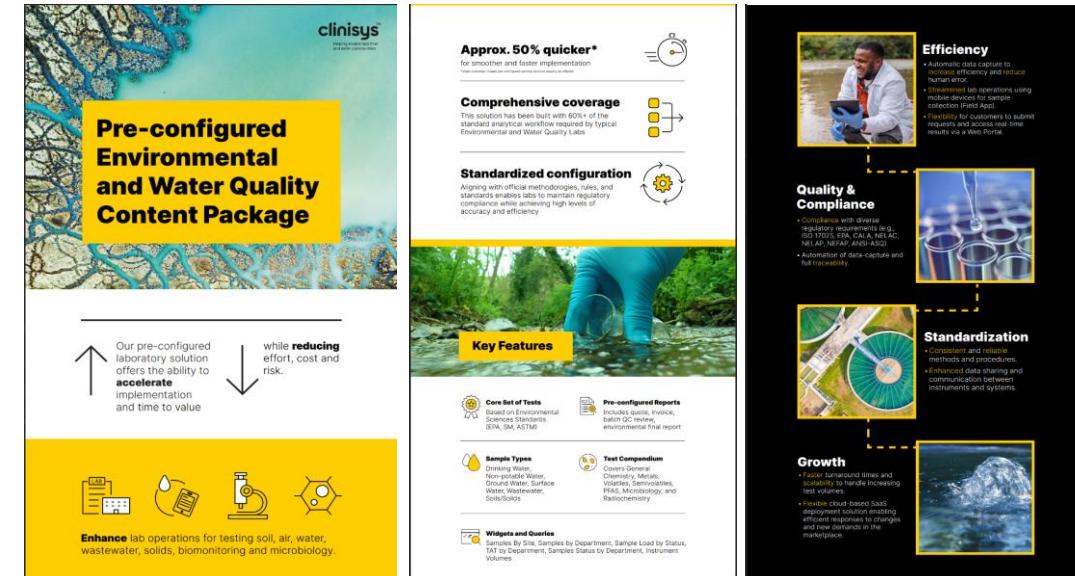
#### Release Notes



#### Package Brief



#### Package Infographics



### Insights & Articles



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Why PFAS, so called 'forever chemicals', are driving change in sample management

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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!

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and safer communities

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