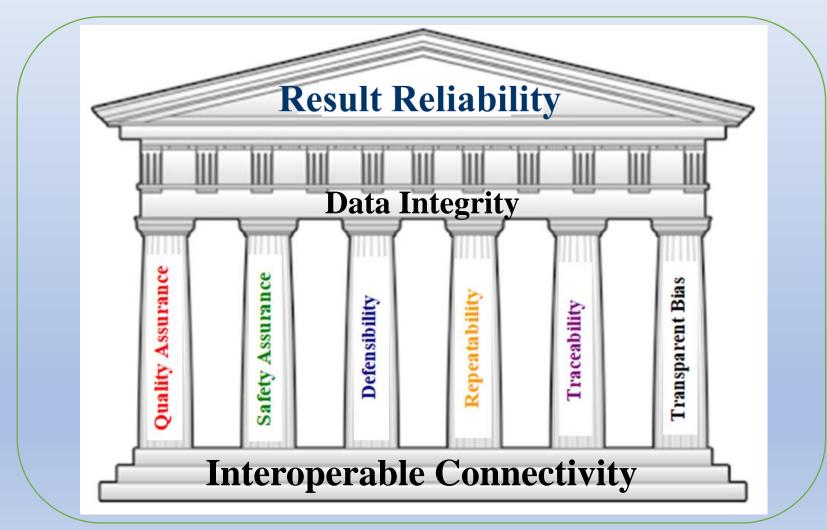




## The Pillars of Data Integrity in Laboratory Data Automation





## **AGENDA:** Data Integrity Automation

- Overview: Establishing the Components of Data Integrity
  - Importance of Result Reliability
  - When Results are Un-Reliable
  - Data Process Gaps in Lab Data Life Cycle
  - What are the Pain Points Inside the lab?
  - Pillars of Result Reliability for 100% Data Integrity
- Solutions
  - Automation and 100% Data Integrity
  - Quality Assurance (QC Samples)
  - Safety Assurance (Field Samples)
  - Defensibility, Repeatability, Traceability, and Transparent Bias
  - Early Notifications and Control Centers
- Use Case LCMS PFAS Analysis to UCMR





## **Importance of Result Reliability**





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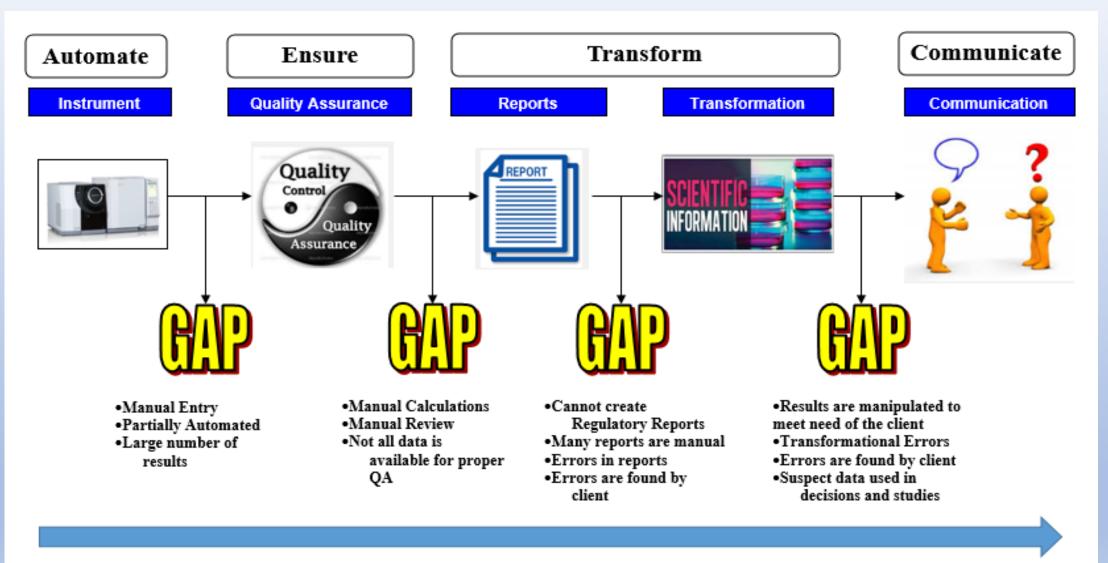
## Did I Learn About Lab Data Integrity in Kindergarten?..







## Problem: Data Process Gaps in the Lab Data Life Cycle

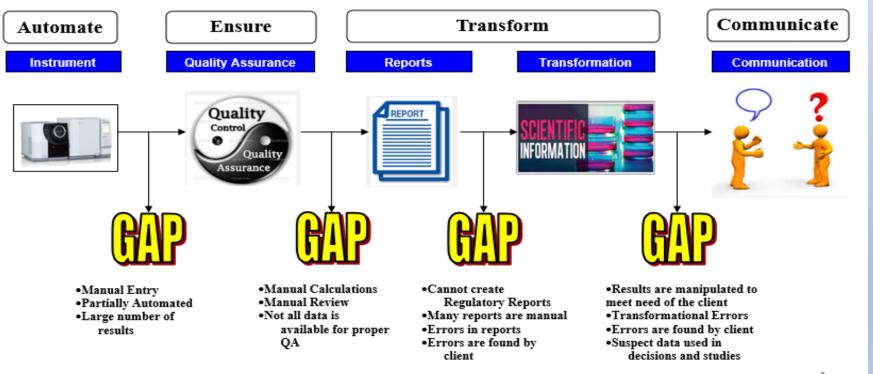






## Problem: What & Where are the Gaps?

- Manual and Duplicate Data Entry
- Disparate Data Sources
- LIMS/IMS/3<sup>rd</sup> Party Connection
- Manual Quality Assurance Process
- Data "Gymnastics" for Connectivity at Data Points of Transfer



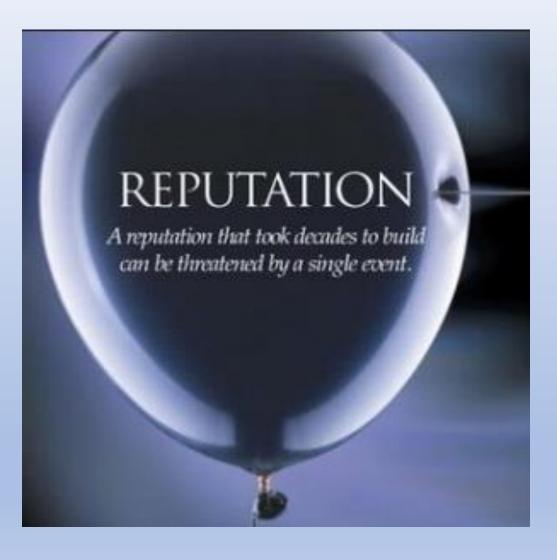




## When Results are Un-Reliable

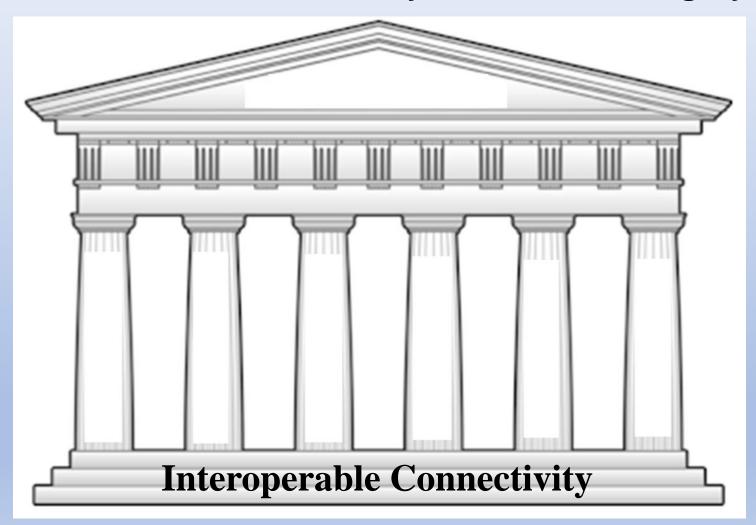
### **Data Integrity Effects All of Us**

- Falsifying Tune and Calibration samples on hazardous material analysis.
- Changing performance results to show low emissions.
- Toxic metals found in drinking water not revealed.
- Hazardous decisions due to data manipulation and no peer review.





#### Pillars of Result Reliability: 100% Data Integrity







## Automation Solutions for Functionality Gaps – Enhancing the Lab's Present Process

Interoperable Connectivity 3<sup>rd</sup> Party Notifications/ Electronic Instrument Connections **Transfer Results Automated QA System** Communication Interfacing Excel IMS LIMS ERP **Instrument 1 MEMS Real-Time Trending** LIMS MIMS **OMS Big Data Hubs** Instrument 2 Reference Libraries Reporting ... **Bi-Directional LIMS** Connection **Instrument 3 Real-Time Statistics** LIMS **Instrument 4** 





## Pillars of Automated Data Integrity: Automated Quality Assurance



- All Quality Control
  - Field
  - Sampling
  - Instrument
  - Preparation
  - Sample Parameter QC
- Association of QC
- Communication of QC Exceedance

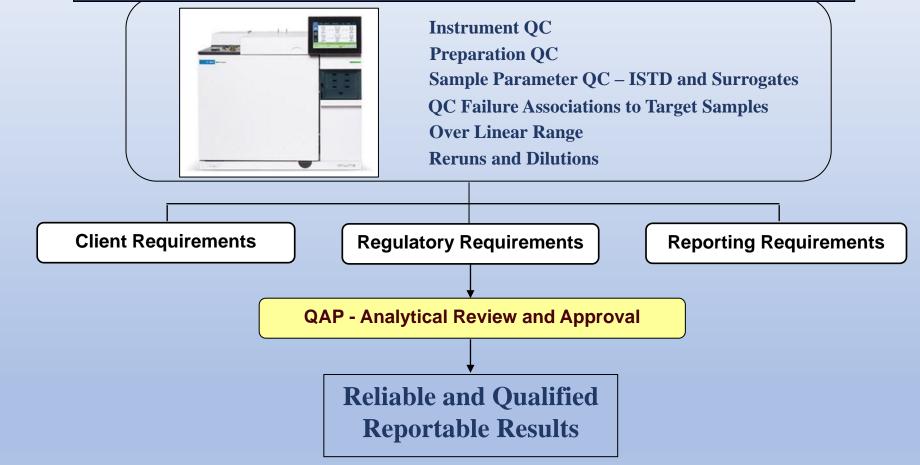




## **Key Elements of Automated Quality Assurance**



Priority Order of Analytical Review – Method, Client, Regulatory, Reporting

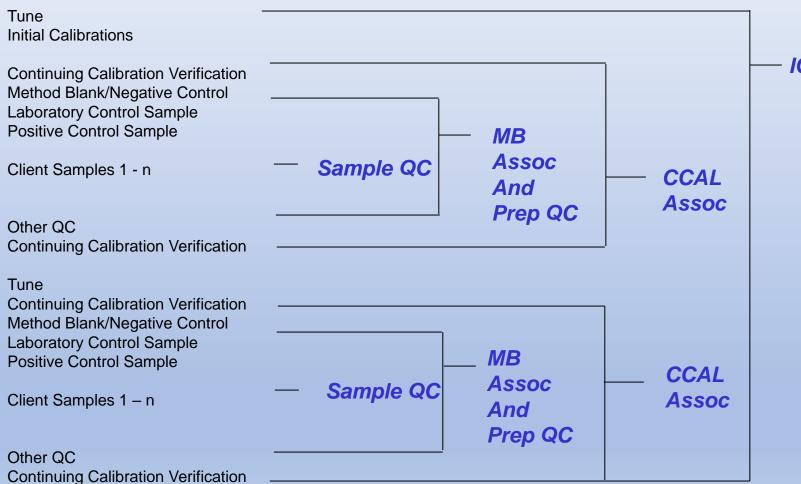






## **Key Batch Associations**

#### **Analytical Batch Example**



ICAL Assoc

#### **Key Batch Types**

Sampling Batch Shipping Batch Delivery Batch Storage Batch Raw Material Batch Manufacturing Batch Preparation Batch Analytical Batch Reporting Batch Compliance Batch



Assurance

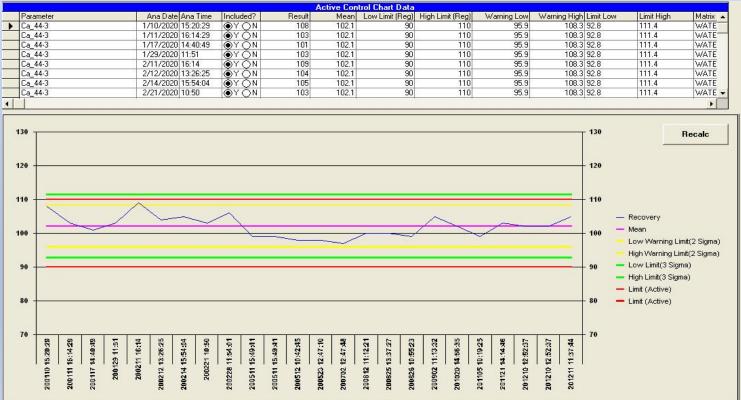
Quality



## Pillars of Automated Data Integrity: Safety Assurance



- QA Communication
  - Trending/Z-Scoring
    - Establish acceptance windows
    - Result comparisons

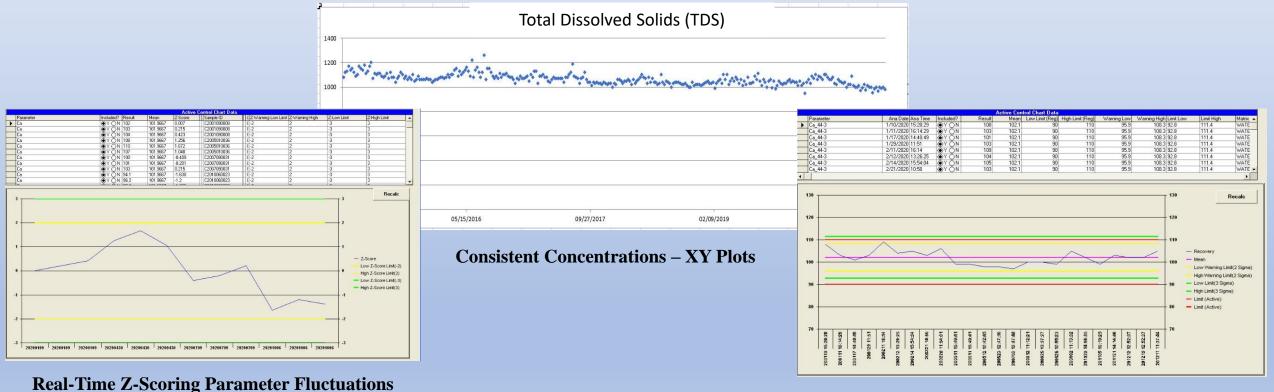






## Trending – Z Scoring: Brings Anomalies to the Surface

### Is something different occurring with the target sample? Or did something go wrong during the process?



#### **Real-Time QC Control Charts**



Assurance

afety



## Key Notification Alerts: Field Samples Outside Compliance Limits and QC Exceeding Acceptance Limits



- QC early detection builds a strong QA and risk aversion program for the lab
  - Target result early detection builds a strong risk aversion program for the use of the results
- Early Detection Rapid Response
- Proactive rather than reactive
- Experts can address issues early to minimize the severity of the problems



afety Assurance



## Pillars of Automated Data Integrity: Defensibility



- Communicating that all QA/QC was analyzed to ensure precision & accuracy of target results
- Monitor for instability or deviation in:
  - Method
  - Instrument
  - Preparation
  - Sampling
  - Preservation
  - Storage
  - Shipping





## **Key Elements of Defensibility**

ments			Defensibility -																		
Analytical Review List		nitiat	of each sample type. Associated QC review with			Lists			Analyst Note(s)			(s)	View Checklist Item				Return				
Summary			target	samples.						Char	klist										
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ALs-% Difference																				•	
Iding Times-Holding Time Extra																					
Iding Times-Holding Time Analy											formatio										
Contamination-MB Contaminat	Samp	11. CO. C.	Client ID	Repo	ort?		Ana Date			Samp \	₩t/Vol	Extract Vol (uL)	Dil	% Moisture		Z FI		a File R		s R	
Ds-Response Review		080102-1	ISC-50	X	2.3		1/2/2018	11:08:2		10	2	10	1	100	WATER	N		0203.LC n		S	
Ds-Retention Time Review		3 (16-20)	VAP-23 (16-20)	×	12	SAM		11:29:5		1000		1000	1	100	WATER	N		0204.LC n		S	
rrogates-% Recovery er Range-Over Range Review	VAP-23	3 (26-30)	VAP-23 (26-30)	×		SAM	1/2/2018	11:51:4	43	1000		1000	1	100	WATER	N	L801	0205.LC n	g/L	S	
S/LCSD-% Recoverv	VAP-23	3 (36-40)	VAP-23 (36-40)	×		SAM	1/2/2018	12:13:2	29	1000	1	1000	1	100	WATER	N	L801	0206.LC n	g/L	S	
S/LCSD-% RPD	VAP-24	4 (26-30) MS	VAP-24 (26-30) M			MS	1/2/2018	12:35:1	14	125	Ĩ	10	1	100	WATER	N	L801	0207.L( n	- 1/L	S	
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/MSD-% RPD	VAP-23	3 (6-10) MS	VAP-23 (6-10) MS			MS	1/2/2018	13:30:5	53	125		10	1	100	WATER	N	L801	0209.L( n	- 1/L	S	
ociated Issues-Associated Par		3 (6-10) MSD				MSD	1/2/2018	13:52:3		125		10	1	100	WATER	N		0210.LC n		S	
tected Values-Detected Values	PBLK 1		PBLK			MB		14:14:2	2.2	125		10	1	100	WATER	N		0211.LC n		S	
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	PFBS		375-73-5 MS.	LCS TRG				X		2	x	286	114	1	1.42	0.74	1.42	250		-	
	PFHpA			LCS TRG				X	No.	11	x	244	98		8.00	1.35	8.00	250		-	
Direct Qualification	M4PFH	52	IST					X			2	800			212.53		0.000	1.000		-	
Direct quaineation	Br-PFH			LCS TRC Re	run due to	ICS Low		IX		-	X	25.8	10		3.44	1.60	4.00	250			
	PFOA			LCS TRO	run duo to	LOO LOW		X			ÎX I	256	102		2.00	0.376	3.20	250			
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o sina to hoporting	PFNA			LCS TRE				×	1.1		×	249	100	<u> </u>	3.20	0.76	3.20	250			
	Total P			LCS TRO				X			×	242	97		3.44	0.83	4.00	250		_	
Direct Qualification	T-PFO			LCS TRE Re	run due to	LCS Low		×	and the second se		×	40.5	16		4.00	1.60	4.00	250			
	MPF03	5-5	SUF	R I				×			×		17					250			
Direct Qualification																					
	MBPF0 M8PF0 PF0S		IST	D /LCS TRG				×	ī			800	75		1.56		1.56	_			



Defensibility

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## Types of Internal and External Lab Report Deliverables

#### Full Defensible Deliverables

#### Investigations

Waste Streams (Air, Liquid, Solids)

#### Remediation

Accidents

#### **Potential Liabilities**

#### **Potential Litigation**

# Tank

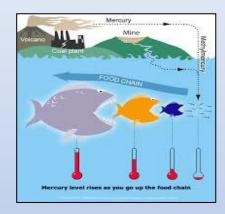


#### **Every Analytical Sequence**

#### **PDF of Analytical Sequence:** Title Page Table of Contents Brief Summary of Project, Study, Job Sample Collection Info (if applicable) Sample Receipt Info (if applicable) **Case Narrative or Analytical Notes** Target Sample Results (calculated) Initial Raw Data Chromatograph Final Raw Data Chromatograph (if professional judgements are applied) **Target Sample QC Summary Results** Preparation QC and Raw Data Instrument QC and Raw Data Prep Log Run Log

## Centralized database of all results for target and all QC samples. Real-Time sample z-scoring, trending, and statistics. Real-Time Control Charting for QC, Precision, and Accuracy.

#### **Smaller Deliverables**



#### Monitoring

Compliance

**Process or Manufacturing Control** 

**Certificate of Analysis** 

**Content Labels for Product** 





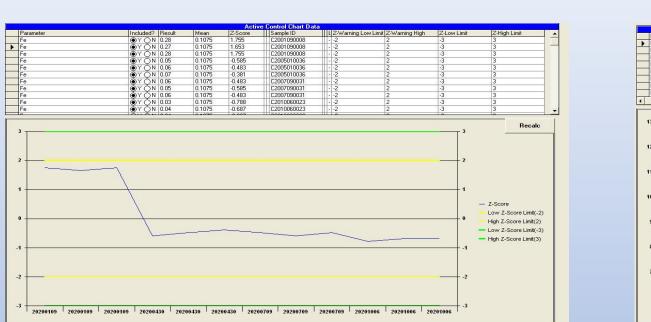
## Pillars of Automated Data Integrity: Repeatability

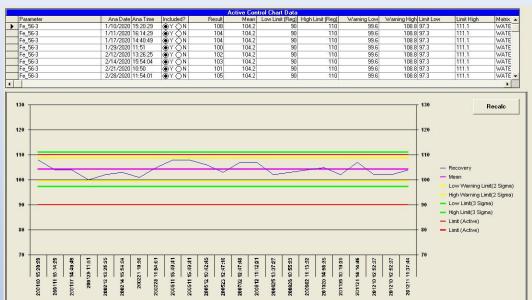


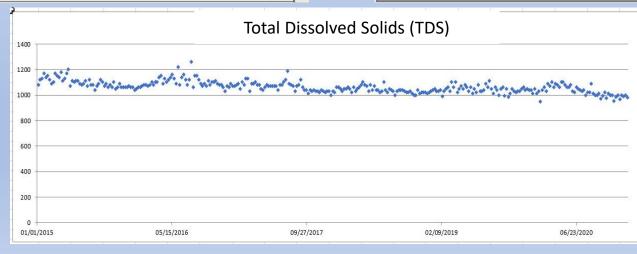
- Must first align with:
  - Quality Assurance
  - Safety Assurance
- Method Performance, Precision, & Accuracy
- Analyst Competency
- Instrument Performance













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## Pillars of Automated Data Integrity: Traceability



Ability to Trace Data Back to Its Source

- Prep analyst
- Instrument analysis
- Instrument software
- Processing software
- Analyst that performed the analysis
- Electronic signature
- Primary/secondary review
- Raw, meta & calculated results
- Audit trail



## **Key Elements of Traceability**

ed CCV QC	Water	Treatment Sit	e		r	1.1														
						Instr	ument	A	cquistio	n		Analyst M	lote(s)	Vi	iew Chec	<mark>klist Ite</mark>	em		Datu	
Review st								-	-			-					F	Percer	nt Solie	ds
ion Repo	Section	Seq Check t Item	n		C	eck Sta	tus	eport	Analy	tical Dil	lution *	Anal	vtical B	latch	-			0.00.		
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CSAB % Re ecovery Cl	FAIL	420406	CCV1 for [METL/		X		and provide the second	6/1/2020	11:54	CCV1		178	Т		1	1	0	mg/Kg		Total
ntamination	20	420407	CCB for [METL/2	C 200 T 200 T	X			6/1/2020	11:59	CCB	1. Kar (2.1.8)	178	Т		1.5.5	1	0	mg/Kg	-	Total
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ecovery	FAIL	420396	ShudgePS		×		ICPMS2	6/1/2020	12:18	PS	19.6 21	178	T		0.2553	0.5	14.17	mg/Kg		Total
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V Frequenc B Frequenc Gele Samples ms by un/QC	Pass/Fail	Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107	01083 0 0 0 0 01063 0 01078 1	OK X OK X OK X OK X OK X DR	rt?	REG ISTD ISTD ISTD REG REG		ted?	<b>Rpt</b> 1 1.40053 1.20010	Result         Rave           5.06         5.00           35E+07         1.40           4E+07         1.20           394897         185           0.99         0.99           0.24         0.24	61 00535E+07 00104E+07 94897 93 42	mg/kg CPS CPS CPS mg/kg mg/kg	UM UM UM UM UM UM	101 5 102.6 1.3 99.3 1.2 97.2 19 99 1 48 0.5	36507E+0 208213E+ 248815	Rpt RP	5385808 1.40053: 1.200104 1894897 208702.0 140230.0	3 SE+07 4E+07 7 8 6	0.50	0.0
V Frequenc B Frequenc Sele Samples ms by vn/QC ical Review		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111	01083 0 0 0 01063 0 01078 1 01028 0	OK X OK X OK X OK X OK X DR OK X	rt?	REG ISTD ISTD ISTD REG REG REG		rted?	Rpt1 1.40053 1.20010 18	Result         Rav           5.06         5.0           35E+07         1.4           14E+07         1.2           394897         185           0.99         0.9           0.24         0.2           0.98         0.9	61 00535E+07 00104E+07 04897 93 93 42 83	mg/kg CPS CPS CPS mg/kg mg/kg mg/kg	UM UM UM UM UM UM UM	101 S 102.6 1.3 99.3 1.2 97.2 19 99 1 48 0.5 98 1	36507E+0 208213E+ 248815 5	Rpt RP	5385808 1.400533 1.200104 1894897 208702.8 140230.6 122833.3	3 SE+07 4E+07 7 8 6 1	0.50	0.0
V Frequenc B Frequenc Gele Samples ms by un/QC		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115	01083 0 0 0 01063 0 01078 1 01028 0	OK X OK X OK X OK X OK X DR C OK X OK X	rt?	REG ISTD ISTD ISTD REG REG ISTD		ted?	Rpt1 1.40053 1.20010 18	Result         Rave           5.06         5.0           35E+07         1.4           14E+07         1.2           394897         185           0.99         0.9           0.24         0.2           0.98         0.9           0.52         0.9           15E+07         1.3	61 00535E+07 00104E+07 94897 93 42	mg/kg CPS CPS CPS mg/kg mg/kg mg/kg CPS	UM UM UM UM UM UM	101 S 102.6 1.3 99.3 1.2 97.2 19 99 1 48 0.3 98 1 101.8 1.3	36507E+0 208213E+ 248815 5 5 332213E+	Rpt RP	5385808 1.40053: 1.200104 1894897 208702.8 140230.8 122833 1.35604:	8 SE+07 4E+07 8 8 6 1 SE+07	0.50	0.0 0.0 0.0
V Frequenc B Frequenc Sele Samples ms by vn/QC ical Review		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118	01083 0 0 0 01063 0 01078 1 01028 0 0 0 1 01028 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	OK X OK X OK X OK X OK X DR C OK X OK X NR C	rt?	REG ISTD ISTD ISTD REG REG ISTD REG		:ted?	Rpt1 1.40053 1.20010 18	Result         Rave           5.06         5.0           35E+07         1.4           14E+07         1.2           394897         185           0.99         0.9           0.24         0.2           0.98         0.9           ISE+07         1.3           ISE+07         1.3	61 00535E+07 00104E+07 93 42 83 56045E+07	mg/kg CPS CPS CPS mg/kg mg/kg CPS mg/kg	UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99         1           48         0.3           98         1           101.8         1.3	36507E+0 208213E+ 248815 5	Rpt RP	5385808 1.40053: 1.200104 1894897 208702.3 140230.6 122833 1.35604: 347262	8 SE+07 4E+07 7 8 6 6 1 5E+07 1	0.50 0.10 0.05 0.10	0.0
V Frequenc B Frequenc sele Samples ms by un/QC tical Review Steps		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119	01083 0 0 0 01063 0 01078 1 01028 0 0 01028 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	OK K OK K OK K OK K OK K DR C OK K NR C OK K	rt?	REG ISTD ISTD ISTD REG REG ISTD REG REG		:ted?	Rpt1 1.40053 1.20010 18	Result         Rave           5.06         5.00           35E+07         1.41           04E+07         1.21           394897         185           0.99         0.92           0.24         0.24           0.98         0.92           1.5E+07         1.31           0.5E+07         0.94           0.96         0.97	61 00535E+07 00104E+07 93 42 83 56045E+07 57	mg/kg CPS CPS CPS mg/kg mg/kg CPS mg/kg mg/kg	UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99         1           48         0.3           98         1           101.8         1.3           998         1	36507E+0 208213E+ 248815 5 5 332213E+	Rpt RP	5385808 1.40053: 1.200104 1894897 208702.3 140230.6 122833 1.35604: 347262 127072.3	\$ 5E+07 4E+07 7 8 8 6 1 1 5E+07 1 8	0.50	0.0
V Frequenc B Frequenc Sele Samples ms by vn/QC ical Review		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119           Sb_121	01083 0 0 01063 0 01078 1 01028 0 0 01028 0 0 0103 0 01098 0	OK K OK K OK K OK K OK K OK K OK K OK K	rt?	REG ISTD ISTD ISTD REG REG ISTD REG REG REG		:ted?	Rpt1 1.40053 1.20010 18	Result         Rave           5.06         5.00           35E+07         1.41           94E+07         1.21           394897         189           0.99         0.92           0.24         0.24           0.98         0.92           1.5E+07         1.31           1.5E+07         1.32           0.90         0.92           0.91         0.92           0.92         0.93           0.93         0.92           0.94         0.92           0.95         0.93           0.96         0.93	61 00535E+07 00104E+07 93 42 83 56045E+07 57 7	mg/kg CPS CPS mg/kg mg/kg CPS mg/kg mg/kg mg/kg	UM UM UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99.3         1           97.2         19           99.3         1           97.2         19           99.3         1           97.2         19           99.3         1           99.4         1           48         0.5           98         1           101.8         1.3           25         96           997         1	36507E+0 208213E+ 248815 5 5 332213E+	Rpt RP	5385808 1.40053: 1.20010 1894897 208702.3 140230.6 122833 1.35604: 347262 127072.3 472006	\$ SE+07 4E+07 7 8 6 1 SE+07 1 8 5 5	0.50 0.10 0.05 0.10 0.10 0.10 0.10	0.0
V Frequenc B Frequenc sele Samples ms by un/QC tical Review Steps		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119           Sb_121           Ba_137	01083 ( 01063 ( 01063 ( 01078 1 01028 ( 1 01103 ( 01098 ( 01008 (	OK K OK K	rt?	REG ISTD ISTD ISTD REG REG ISTD REG REG REG REG		:ted?	Rpt1 1.40053 1.20010 18	Result         Rav           5.06         5.00           35E+07         1.41           94E+07         1.21           394897         189           0.99         0.99           0.24         0.24           0.98         0.99           1.5E+07         1.31           1.5E+07         1.32           0.90         0.99           0.91         0.99           0.92         0.99           0.93         0.99           0.94         0.99           0.97         0.99           0.97         0.99           0.94         0.99	61 00535E+07 00104E+07 93 42 83 56045E+07 57 7 43	mg/kg CPS CPS CPS mg/kg mg/kg CPS mg/kg mg/kg mg/kg mg/kg	UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           98         1           101.8         1.3           96         1           97.1         1           97.1         1	36507E+0 208213E+ 248815 5 332213E+ 50	Rpt RP	5385808 1.40053: 1.20010 1894897 208702.3 140230.6 122833.3 1.35604: 347262.3 127072.3 472006.3	SE+07 4E+07 8 6 1 SE+07 1 8 5 5 4	0.50	0.0
V Frequenc B Frequenc isele Samples ms by m/QC iscal Review Steps er Compari		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119           Sb_121           Ba_137           Tb_159	01083 ( 01063 ( 01063 ( 01078 1 01028 ( 01028 ( 01003 ( 01098 ( 01008 ( 010	OK K OK K OK K OK K OK K OK K OK K OK K		REG ISTD ISTD ISTD REG REG ISTD REG REG REG REG ISTD		:ted?	Rpt) 1.40053 1.20010 18 1.35604	Result         Rav           5.06         5.00           35E+07         1.41           94E+07         1.21           394897         189           0.99         0.99           0.24         0.24           0.98         0.99           0.55E+07         1.31           05E+07         1.32           0.96         0.99           0.97         0.99           0.97         0.99           0.97         0.99           0.97         0.99           0.94         0.99           0.97         0.99           0.94         0.99	61 00535E+07 00104E+07 93 42 83 56045E+07 57 7 43 87681E+07	mg/kg CPS CPS CPS mg/kg mg/kg CPS mg/kg mg/kg mg/kg mg/kg CPS	UM UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           98         1           101.8         1.3           96         1           97.1         1           94         1           10.4         1.3	36507E+0 208213E+ 448815 5 332213E+ 50 906574E-	Rpt RP	5385808 1.40053: 1.20010 1894897 208702.3 140230.6 122833 1.35604: 347262 127072.3 472006 170485.4 1.98768.	SE+07 4E+07 8 6 1 SE+07 1 8 8 5 5 4 4 1E+07	0.50 0.10 0.05 0.10 0.10 0.10 0.10	0.0
V Frequenc B Frequenc Sele Samples ms by In/QC cical Review Steps er Compari d CCV QC		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119           Sb_121           Ba_137           Tb_159           Tb_159-2	01083 ( 01063 ( 01063 ( 01078 1 01028 ( 01028 ( 01003 ( 01098 ( 01008 ( 010	OK K OK K OK K OK K OK K OK K OK K OK K		REG ISTD ISTD REG REG ISTD REG REG REG REG ISTD ISTD		:ted?	Rpt) 1.40053 1.20010 18 1.35604	Result         Rav           5.06         5.00           35E+07         1.41           94E+07         1.21           394897         189           0.99         0.99           0.24         0.24           0.98         0.99           0.55+07         1.31           055+07         1.32           0.90         0.99           0.91         0.99           0.92         0.99           0.93         0.99           0.94         0.99           0.97         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.94         0.99           0.95         0.99           0.95         0.99           0.99         0.99	61 00535E+07 00104E+07 93 42 83 56045E+07 57 7 43 87681E+07 42859E+07	mg/kg CPS CPS mg/kg mg/kg mg/kg CPS mg/kg mg/kg mg/kg mg/kg CPS CPS	UM UM UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           98         1           101.8         1.3           96         1           97.1         94           102.4         1.3	36507E+0 208213E+ 248815 5 332213E+ 50	Rpt RP	5385808 1.40053: 1.20010 1894897 208702.3 140230.6 122833 1.35604: 347262 127072.3 472006 170485.4 1.98768. 1.742859	8 SE+07 4E+07 8 8 6 1 SE+07 1 8 SE+07 1 8 5 5 4 4 1E+07 9E+07	0.50 0.10 0.05 0.10 0.10 0.10 0.10 0.10	0.0
V Frequenc B Frequenc isele Samples ms by m/QC iscal Review Steps er Compari		Sr_88           Y_89           Y_89-2           Y_89-3           Mo_95           Ag_107           Cd_111           In_115           Sn_118           Sn_119           Sb_121           Ba_137           Tb_159	01083 0 01063 0 01063 0 01078 1 01028 0 01008 0 01008 0 01008 0 01008 0 01008 0 01008 0 010073 0	OK K OK K OK K OK K OK K OK K OK K OK K		REG ISTD ISTD ISTD REG REG ISTD REG REG REG REG ISTD		:ted?	Rpt) 1.40053 1.20010 18 1.35604	Result         Rav           5.06         5.00           35E+07         1.41           94E+07         1.21           394897         189           0.99         0.99           0.24         0.24           0.98         0.99           0.55E+07         1.31           0.96         0.99           0.97         0.99           0.96         0.99           0.97         0.99           0.96         0.99           0.97         0.99           0.94         0.99           0.97         0.91           0.98         0.92           0.97         0.94           0.97         0.94           0.98         0.92           0.94         0.94           0.95         0.94           0.94         0.94	61 00535E+07 00104E+07 93 42 83 56045E+07 57 7 43 87681E+07 42859E+07	mg/kg CPS CPS CPS mg/kg mg/kg CPS mg/kg mg/kg mg/kg mg/kg CPS	UM UM UM UM UM UM UM UM UM UM	101         5           102.6         1.3           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           97.2         19           99.3         1.2           98         1           101.8         1.3           96         1           97.1         1           94         1           10.4         1.3	36507E+0 208213E+ 448815 5 332213E+ 50 906574E-	Rpt RP	5385808 1.40053: 1.20010 1894897 208702.3 140230.6 122833 1.35604: 347262 127072.3 472006 170485.4 1.98768.	8 SE+07 4E+07 8 6 6 1 SE+07 1 8 SE+07 1 8 5 5 4 1 E+07 9E+07 3	0.50 0.10 0.05 0.10 0.10 0.10 0.10	0.0



Traceability



## **Pillars of Automated Data Integrity: Transparent Bias**



Capture

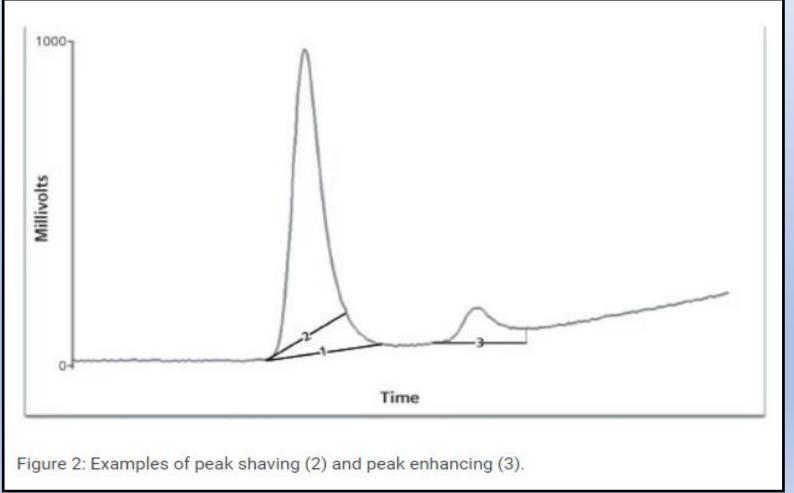
- Manual integrations
- Deletion of interfering peaks
- Professional judgments
- Professional notes
- Professional comments





## **Key Elements of Transparent Bias**

Professional judgments that are hidden or unknown become biases for the use of the results.



**Continual monitoring for:** 

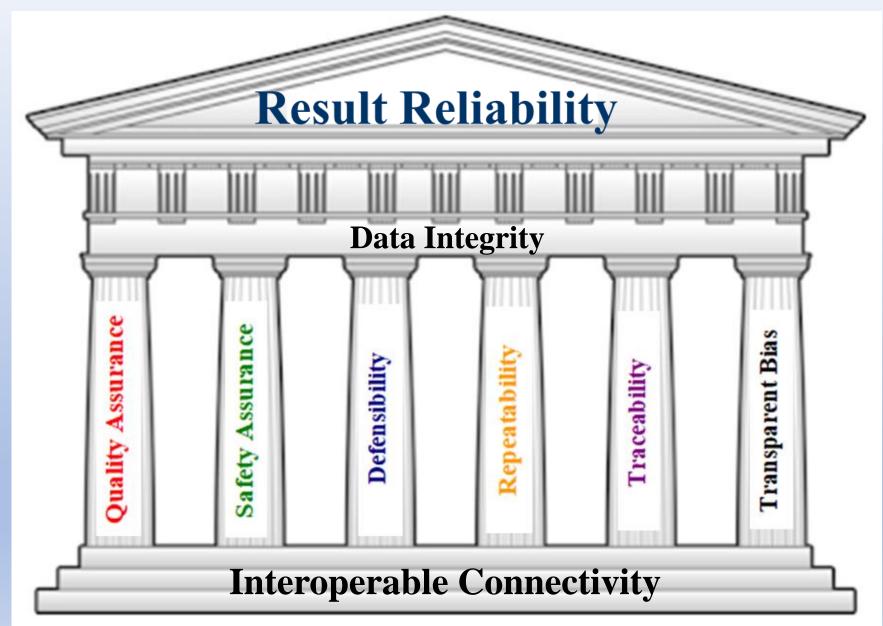
- Bad Habits
- Poor Judgments
- Shortcuts



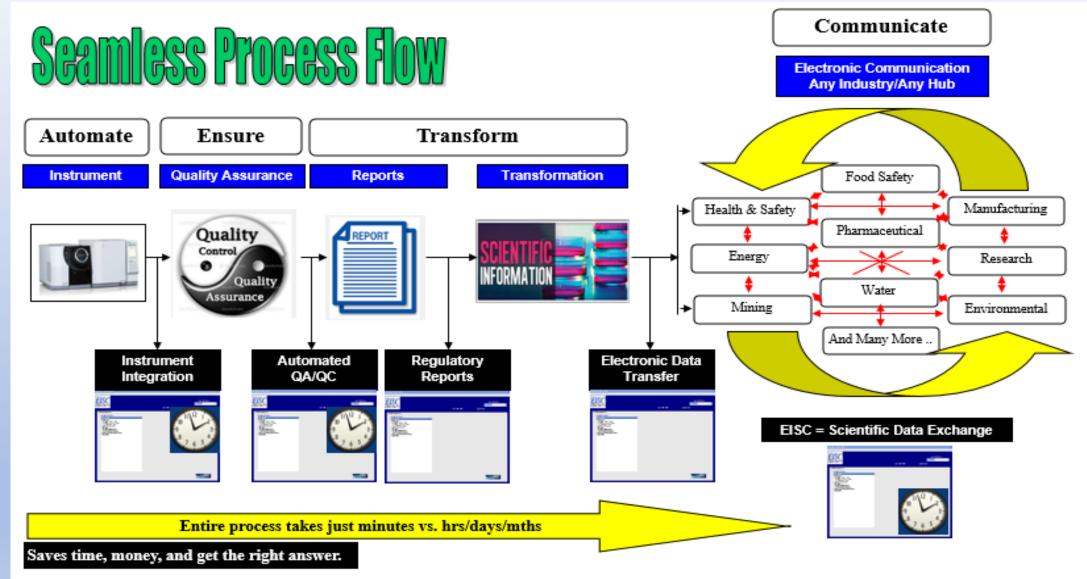
ransparent



## **Pillars of Automated Data Integrity: Result Reliability**











## **Steps to Automated Data Integrity**





One Instrument, One Analysis at a Time

- Choose a Key Instrument and Analysis
- Determine Notification Alerts
- Determine Quality Control
- Determine Deliverables Required
- Connect to the Lab's Additional Data Sources
- Creates Template for Next Instrument and Analysis





## Thank you!

**Contact Information:** 

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