

## Make a Difference Together — Best for Our Customers —

Creating value that meets the challenges of the new normal Let's create surprise, joy, and excitement through work that exceeds expectations!





## Data Integrity Challenges of Analytical Instrumentation

Although there is currently a significant industry focus on data integrity within the pharmaceutical and wider life sciences industry, this is not a new issue.

As we have seen in the previous presentations, data integrity guidelines have existed in the regulatory world since 2015/16

Don't buy into the scare mongering, it's not as complicated as it seems



- 1) Who is responsible for what?
  - Design specifications (DS)
- 2) Three paths to data integrity
  - File based
  - Database (DB)
  - Client Server (CS)

• 3) Am I 21 CFR part 11 compliant?



## Design specification – What is it and why we do it?

DS – Sets out the client's decisions on items like, user rights, password length, domain policies, database polices etc

Sending the DS documents to a client in advance (60-100 pages) helps educate them on the practical considerations of implementing a DB or CS system and allows for discussion between the client and instrument / software vendor, **prior to installation**.

It also means critical decisions are documented in advance before the vendor engineers arrive to perform IQ/OQ



## <u>Design specification – example index</u>

1.	System Information	
2.	Hyper-V Configuration	
3.	OS Configuration Information	5
4.	Domain Policy	6
5.	Local Security Policy	9
6.	Accounts Settings	
7.	Information and Settings of SQL Server (DB Server)	
8.	SQL Server Database Setting	
9.	Virtual Apps Settings	
10.	RemoteApp Settings	
11.	Information and Settings of LabSolutions	
12.	Multi Data Report	
13.	LIMS Connection Option Settings	
14.	i-QLinks Settings	
15.	Analysis Sequence Application Settings	
16.	Revision History	

\*



## Example file-based system.

Everything is stored on the Instrument PC and all data integrity is managed by Microsoft Windows policies - Typically considered unsecure



File based systems can be compliant, but you better have a good IT department as it's not the vendors responsibility.



## What is a database?

With specific reference to data integrity, a database is a software program like SQL or Oracle which holds all your instrument files ie methods, reports, data etc securely. It is the shield that protects the integrity of your data.

Specific database security policies prevent files being overwritten or deleted.





## Example Databased system. Ie Labsolutions DB

Everything is stored on the acquisition PC inside a secure database. Data integrity is managed by vendors software - typically considered secure.



# #

All methods, data, reports etc are securely stored inside the database on each AQPC



## Example Client server system. le Labsolutions CS

Nothing is permanently stored on the Instrument pc, but inside a secure database on the network server. Data integrity is managed by vendors software - typically considered secure.

# #





## File based

#### Pros

Cheaper to purchase than CS

#### <u>Cons</u>

Not secure unless you have a very good IT group, which is expensive.

Audit trail /electronic records are limited

### <u>Database</u>

#### <u>Pros</u>

Cheaper to purchase than CS. Easier to qualify than file base.

#### <u>Cons</u>

More expensive to maintain and qualify than CS

#### **Client server**

#### <u>Pros</u>

Easier to maintain and qualify than file based or DB. Lower ongoing cost

#### <u>Cons</u>

Most expensive upfront cost if you don't already own a suitable server.

Data processing speed is network dependent



Having an IQ/OQ'd instrument and software platform does not make you compliant.

## Why?

The vendor can install and qualify their hardware and software solution but only the client can ensure it is fully compliant.

Only the client has full control over their security polices, acceptance of results / reports, backups etc

Therefore, the responsibility lies with the client to ensure data integrity and compliance.



## Useful links – even if they are from Shimadzu ©

https://www.shimadzu.com/an/sites/shimadzu.com.an/files/pim/pim\_document\_file/brochure s/14044/c191e047.pdf

https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/pim/pim\_document\_file/ssi/other s/14282/C10G-E071-Data-Integrity-WhitePaper-2.pdf

https://www.ssi.shimadzu.com/sites/ssi.shimadzu.com/files/pim/pim\_document\_file/ssi/other s/14284/Practical-Procedures-for-Compliance-with-Data-Integrity-Requirements-in-Analytical-Laboratories.pdf



# Questions ?

\*