# Data integrity in CDS

# The Practical Approach….


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*Application Engineer*



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# Agenda…..

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- Regulatory Focus…..
- Data Integrity Statistics related to CDS…..
- The Analytical Workflow…..
- User Profiles…..
- Data Management…..
- Managing your CDS…..
- Questions and Answers…..

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# *Regulatory Focus…..*

# Regulatory Focus…..

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- **Regulatory Inspectors…..**
  Have been trained by Data Integrity experts…..
- **Detailed Knowledge…..**
  Of Chromatography Data Systems (CDS) from all major vendors…..
- **Experience…..**
  Locating and interpreting the meta data within your CDS…..
- **Focussed…..**
  On security and controls being used by your company within the CDS…..


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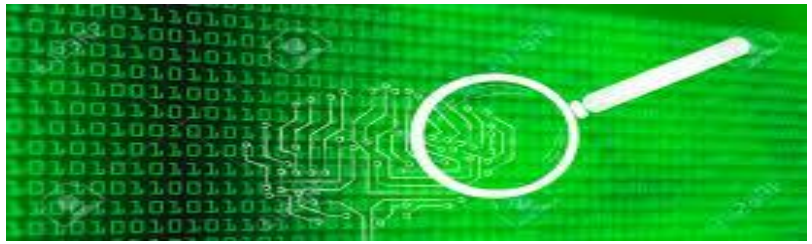

# Regulatory Focus Areas…..

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- **Generic log-ons…..**

Lack of traceability within CDS (ALCOA)…..

- **Administration…..**

Capability within the laboratory…..

- **Delete…..**

Users have the ability to delete, move or over-write data…..

- **Segregation of Duties…..**

Specific profiles within the CDS for specific tasks…..



# Regulatory Focus Areas…..

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- ***Controlled…..***

Methods and reporting templates…..

- ***Minimise…..***

Manual integration wherever possible…..

- ***Quantitation…..***

Within the CDS not using external software packages like Excel…..

- ***Audit Trail…..***

Being used and review process in place…..


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# *Data Integrity Statistics related to CDS…..*

# Data Integrity Statistics…..

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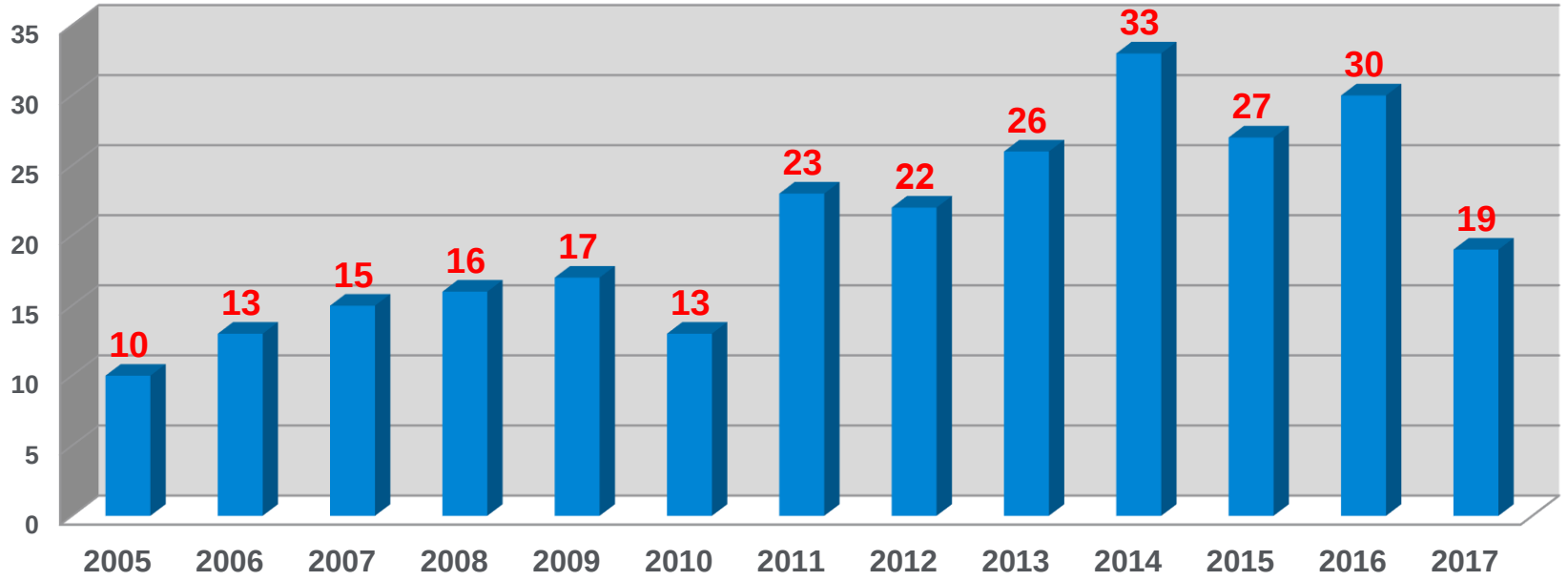


- The number of Data Integrity related Warning Letters issued by the FDA continues to increase…..
- Many of these Warning Letters relate to how companies use their CDS…..

- ***Are you using all of the security and compliance features within your CDS to ensure the integrity of electronic data….?***

# Data Integrity Statistics related to CDS…..

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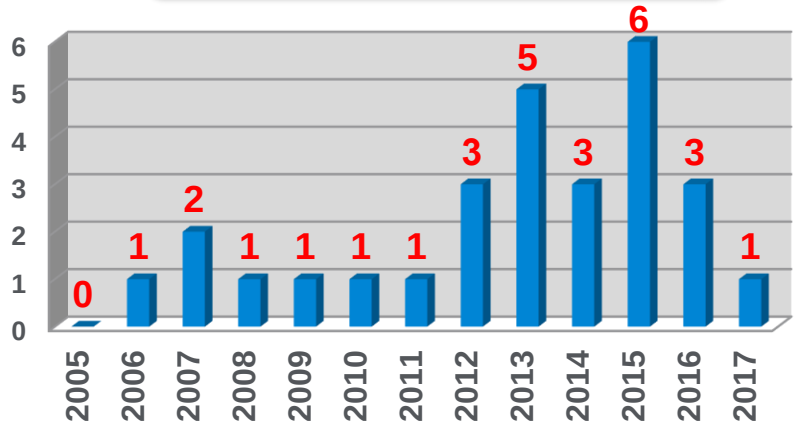
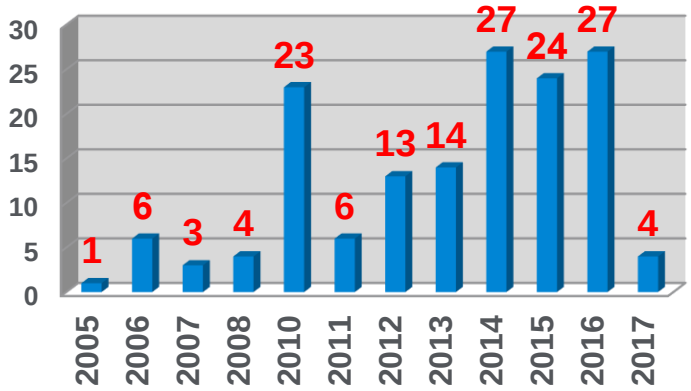
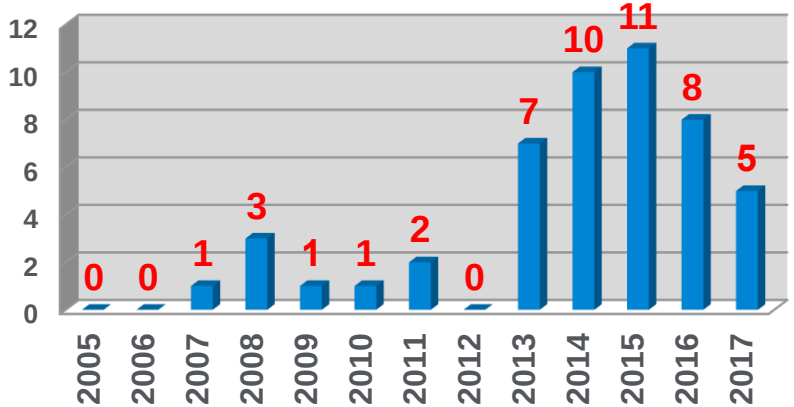
## Password…..



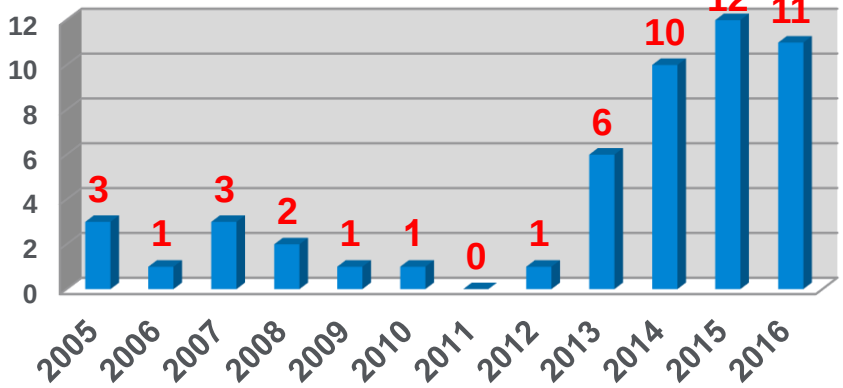

## Security…..




## Deletion…..




## Audit Trail…..



# *Data Integrity Waring Letters…..*
# *2017 Examples Issued by CDER…..*

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"Audit trail functionality was enabled the day before the inspection"…..

"No procedures in place to review audit trails"…..

"x HPLC systems had audit trail features disabled even though they had this capability"……

"Your company used stand-alone, uncontrolled systems to perform OOS investigations"…..


"Your analysts used a shared log-on account for HPLC systems providing lack of traceability"……

"Audit trails confirmed that injections had been deleted and sequences were incomplete"…..

"Your analysts manipulated date and time settings after deleting original data"…..

"We recommend use of a cGMP consultant to remediate the Data Integrity issues identified"…..

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# *The Analytical Workflow…..*

# The Analytical Workflow…..

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- ***Consider…..***

What type of analytical tasks you will be performing within the CDS…..

- ***Assess…..***

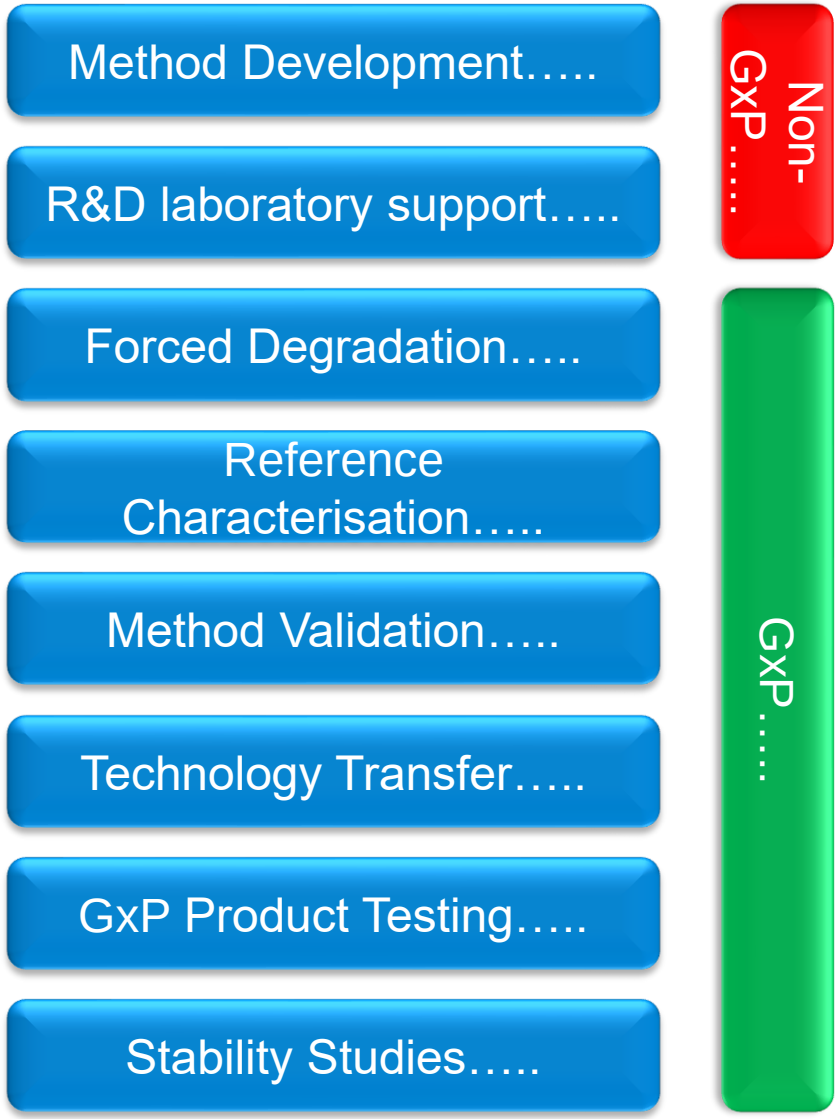
Whether the workflow will be similar or different for each of these analytical tasks…..

- ***Define…..***

Whether different user profiles and privileges are needed for the different analytical tasks…..

- ***Categorise…..***

Each analytical task as either GxP or non-GxP…..



# The Analytical Workflow…..
# Across the Data Lifecycle…..

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| | | | |
|---|---|---|---|
| Data Generation….. | Analyst Profile….? | Data Archiving….. | Supervisor or Admin Profile….? |
| Data Processing….. | Analyst Profile….? | Data Retrieval….. | Admin Profile….? |
| Data Reporting….. | Analyst Profile….? | Data Destruction….. | Admin Profile….? |
| Data Review….. | Reviewer Profile….? | | |

**How many user profiles do you need to cover the full Data Lifecycle….?**

# The Analytical Workflow…..
# Across Individual Lifecycle Phases…..

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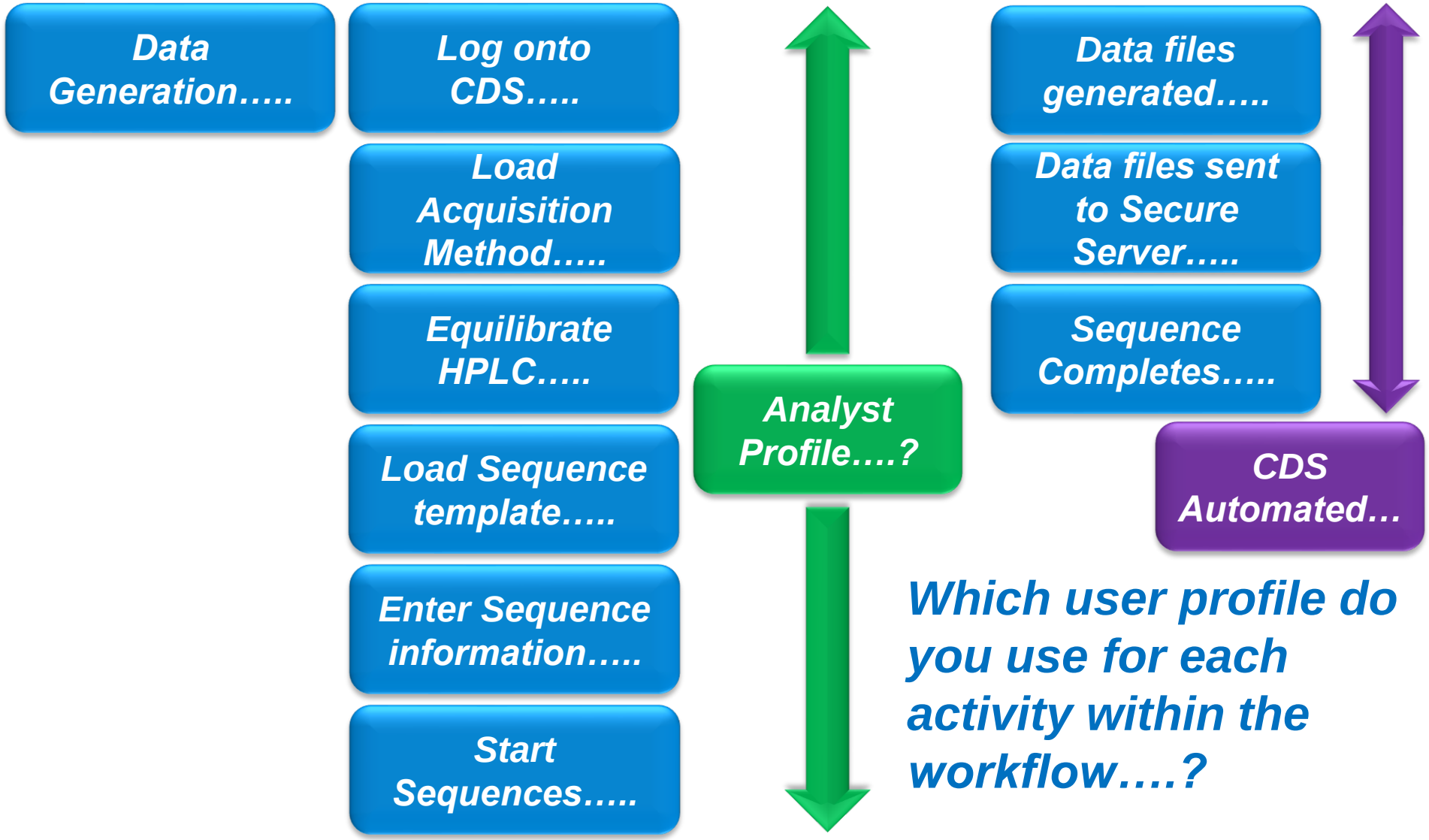


**Which user profile do you use for each activity within the workflow….?**

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# User Profiles…..

# How Many User Profiles will you need….?

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## Or More….?

# User Profiles…..

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- **Consider…..**

How many user profiles you need to adequately support your workflow within the CDS…..

- **Segregation of Duties…..**

Required to demonstrate control within the CDS…..

- **Specific…..**

Profiles for specific tasks within the workflow…..

- **Common Practice…..**

For companies to be using 4+ user profiles within the CDS…..

# Development Analyst…..

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- **Works…..**

Exclusively in the Non-GxP environment supporting method development and R&D laboratory support…..

- **Needs…..**

To create and modify methods during the development process so needs these privileges within the CDS…..

- **Restricted Access…..**

To the GxP folders and data within the CDS…..

- **Restricted Privileges…..**

Shouldn't be able to delete or move data once acquired within the Non-GxP folder…..

# QC Analyst…..

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- ***Works…..***

Exclusively in the GxP environment and will need to have restricted privileges compared to the Development Analyst…..

- ***Needs…..***

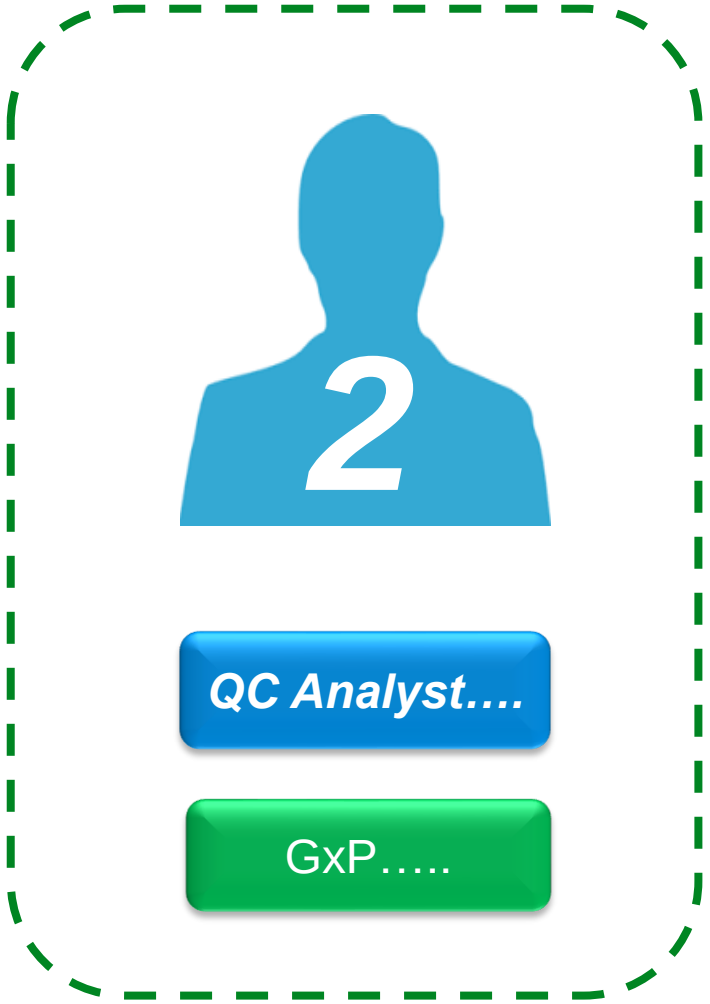
To be able to acquire and process data using locked methods and reporting templates within the GxP folder only…..

- ***Restricted Access…..***

To the Non-GxP folders and data within the CDS…..

- ***Restricted Privileges…..***

Shouldn't be able to delete or move data once acquired within the GxP folder…..



# Data Reviewer…..

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- **Works…..**

Exclusively in the GxP environment reviewing electronic data that has been acquired and processed by the QC Analyst…..

- **Needs…..**

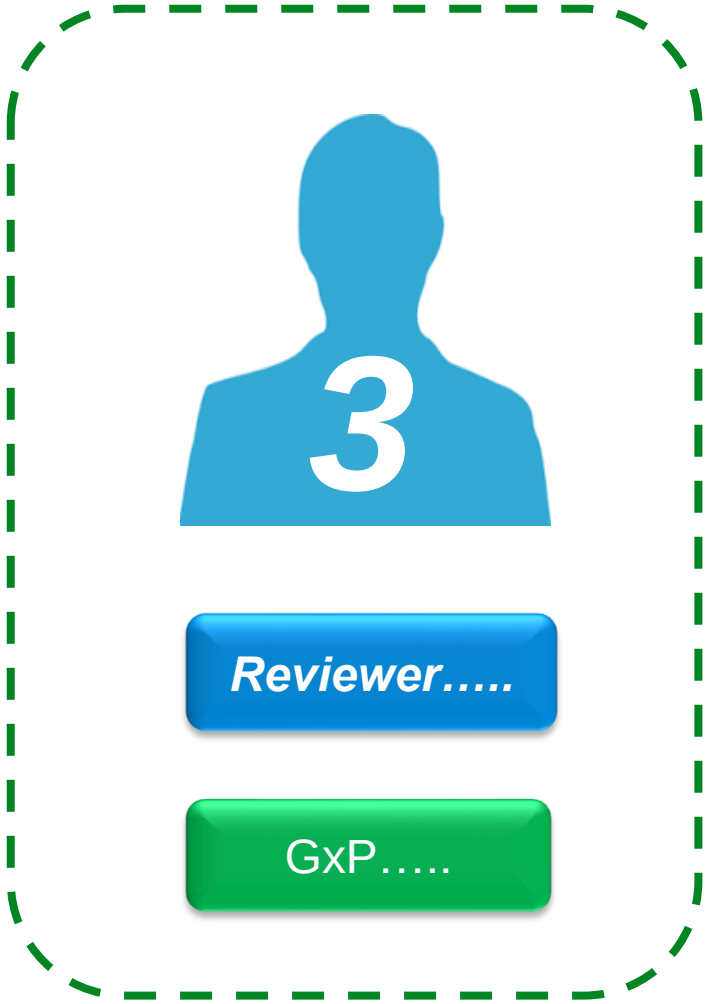
To be able to review the electronic data including methods, sequences, chromatography and audit trails…..

- **Restricted Access…..**

To the Non-GxP folders and data within the CDS…..

- **Restricted Privileges…..**

Shouldn't be able to modify the electronic data submitted for review by the QC Analyst…..



# Supervisor…..

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- ***Works…..***

In both the Non-GxP and GxP folders within the CDS…..

- ***Provides…..***

Basic Administration to the CDS in terms of folder creation, resetting passwords and locking methods before loading into the GxP folder…..

- ***Restricted Privileges…..***

Should ***NOT*** be used to acquire, process or review any data within the Non-GxP or GxP folders…..

Should ***NOT*** have the ability to create users, modify user profiles or delete data from any folder…..

# Administrator…..

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- ***Independent…..***

Of the analytical function and have no vested interest in the electronic data…..

- ***Preferably…..***

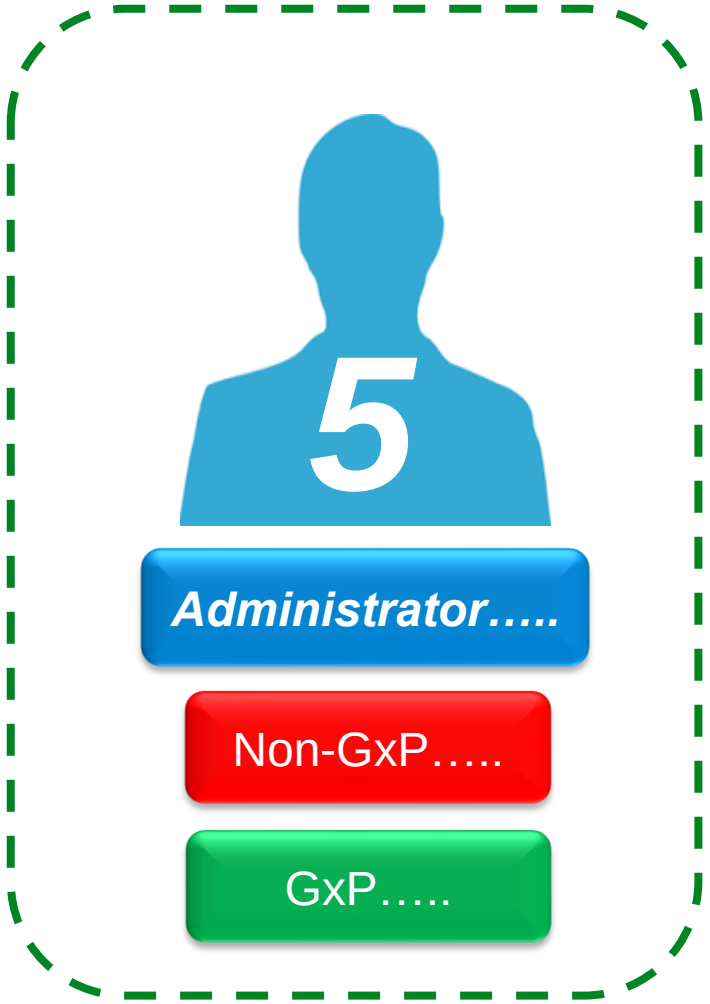
From your IT department to remove any conflict of interest…..

- ***Nobody…..***

Within the analytical function should have administration privileges for the CDS…..

- ***Responsible…..***

For creating / deactivating users, maintaining user profiles / privileges, monitoring administration audit trail, archiving / back-up of data…..



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# Data Management…..

# Data Management…..

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- ***Consider…..***

The different types of data that you generate within the CDS…..

- ***Segregate…..***

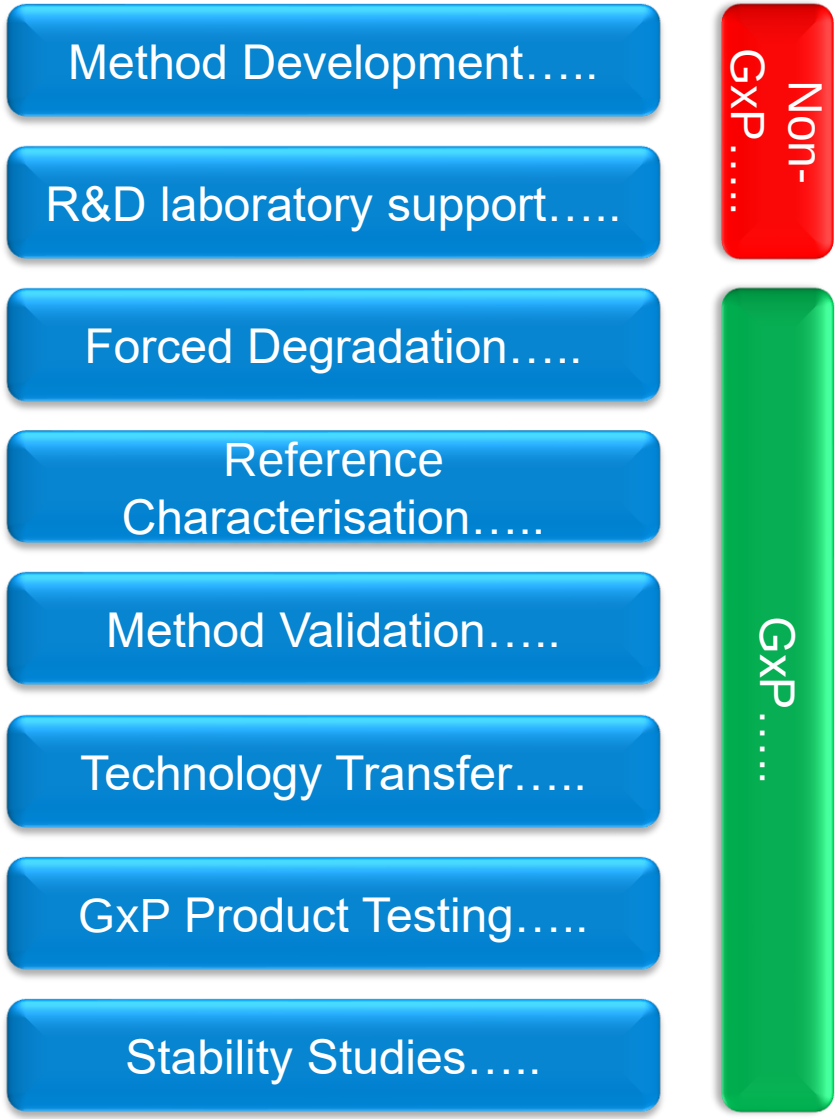
GxP and Non-GxP data as a minimum…..

- ***Manage…..***

Data using a variety of folder descriptions…..
Year, Month, Product, Stage and Test…..

- ***Effective…..***

Data management will give an inspector confidence you are controlling electronic data and help during the data retrieval process…..



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# *Managing your CDS…..*

# Managing your CDS…..

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- ***Software Vendors…..***

Provide CDS with default settings enabled…..

- ***Review and Risk Assess…..***

The vendors default setting against your “intended use” of the software…..

- ***Define and Document…..***

The workflow you will use within the CDS in your SOP…..

- ***Create…..***

Specific user profiles within the CDS for specific tasks within the workflow…..


# Managing your CDS…..

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- **Check…..**

User profiles have appropriate privileges to perform specific tasks…..

- **User Specific Log-On…..**

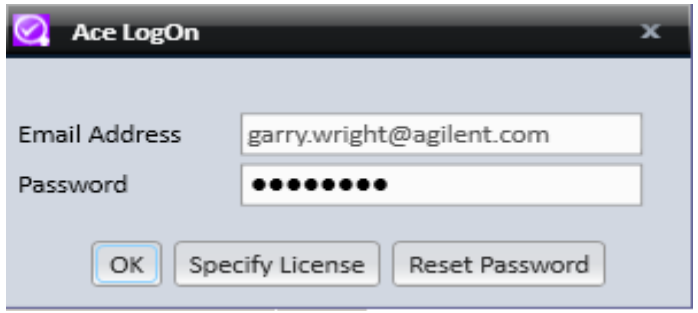
For each user to provide traceability and comply with ALCOA requirements…..

- **Data Management…..**

Define a data management structure which segregates different types of data…..

- **Segregate…..**

Development and GxP data…..






# Managing your CDS…..

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- **Naming Conventions…..**

Required for method, sequences and datafiles and document in your SOP…..

- **Lock…..**

Data acquisition methods that are used for commercial GxP product testing…..

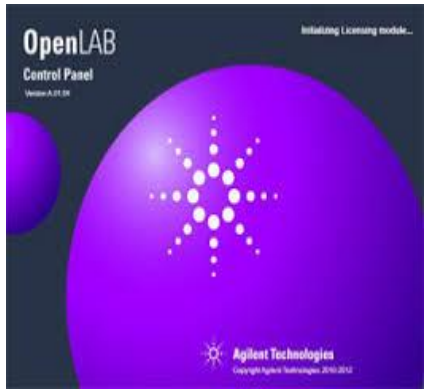
- **Process…..**

Electronic data within the CDS wherever possible…..

- **Move away…..**

From validated Excel sheets which involve manual transcription of data from the CDS…..

***Product_Stage_HPLC_Assay…..***
***Analyst_DDMMYYYY_01…..***
***DDMMYYYY_01, 02, 03…..***




# Managing your CDS…..

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- ***Integration…..***

Use pre-defined integration events within processing methods wherever possible…..

- ***Minimise…..***

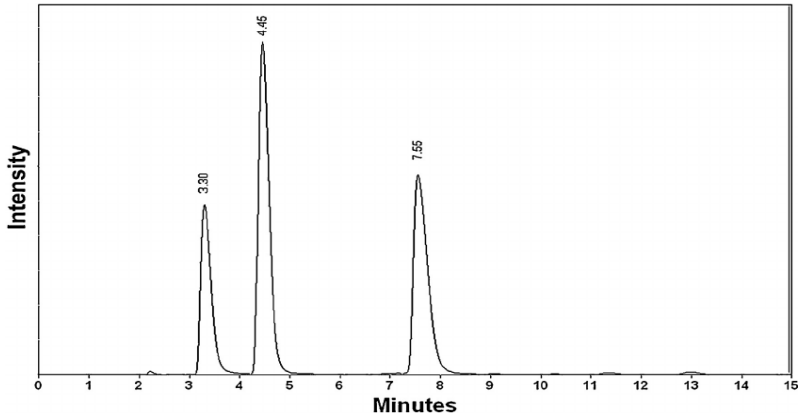
Manual integration and only perform when absolutely necessary…..

- ***Chromatography…..***

Must be appropriately scaled so integration is clearly visible…..

- ***Validate…..***

Report templates that are used for quantitative analysis if custom calculations have been utilised…..




# Managing your CDS…..

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## Review…..

The electronic data within the CDS using a specific profile with restricted privileges…..

- ## Audit Trail…..

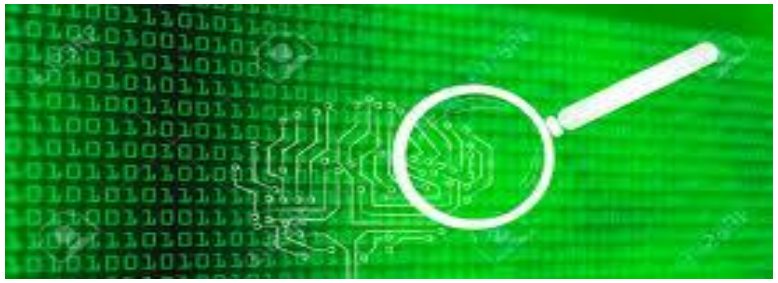
Review all relevant audit trails to ensure that no suspicious activity has taken place during data acquisition or processing…..

- ## Approve…..

Electronic data within the CDS using a user specific electronic signature…..

- ## Archive…..

Electronic data as soon as it has been approved to protect the data from further access and potential reprocessing…..





# Managing your CDS…..

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- ***Self-Inspection…..***

Perform regular Data Integrity inspections of your electronic data and document the findings…..

# Conclusions…..

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- *Regulatory inspectors will take an active interest in how you manage your CDS Data…..*
- *An inspector may spend a number of hours during the audit looking at electronic data within your CDS…..*
- *You need to demonstrate that you have full control of the electronic data within the CDS…..*
- *Assure the inspector that electronic data cannot be manipulated or falsified based on procedural and security controls that you have implemented within the CDS…..*

# *Thank you for your time and attention…..*


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