



**NATIONAL EDUCATION
CONFERENCE** February 3-5, 2026



Catching Errors

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Outline



- The violations discovered
- How was it caught ?
- Leadership response
- Systematic corrective action process
- Key lessons learned



The Violations Discovered

Primary Violations 1: Direct Data Manipulations

- Modified chromatogram area counts in Xcalibur software
- Changed Integration codes (MA→AA) inappropriately
- Used pdf editors to alter exported reports

Primary Violations 2: Data Trail Destruction

- Generated modified data in quantitation software
- Exported excel and pdf files from altered data
- Deliberately failed to save Quan files (eliminating audit trail)

Motivation identified

- Improving calibration curve R2 values
- Meeting 20% replicate injection difference requirements



How was it caught?



| Name | Date modified | Type | Size |
|--------------------------------------------|-------------------|--------------|-------|
| 042823_MP_A12DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A13DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A14DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A15DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A16DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A17DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A18DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A19DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A20DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A21DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A22DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A23DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A24DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A25DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |

pdf data from August

| Name | Date modified | Type | Size |
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| 042823_MP_A12DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:49 PM | Adobe Acr... | 67 KB |
| 042823_MP_A13DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:49 PM | Adobe Acr... | 100 KB |
| 042823_MP_A14DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A15DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:54 PM | Adobe Acr... | 66 KB |
| 042823_MP_A16DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A17DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A18DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A19DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
| 042823_MP_A20DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:26 AM | Adobe Acr... | 17 KB |
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| 042823_MP_A22DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:55 PM | Adobe Acr... | 67 KB |
| 042823_MP_A23DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:55 PM | Adobe Acr... | 67 KB |
| 042823_MP_A24DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 10:25 AM | Adobe Acr... | 17 KB |
| 042823_MP_A25DPX_Chromat_Root_020123_MP_#5 | 5/1/2023 12:55 PM | Adobe Acr... | 67 KB |

pdf data from October

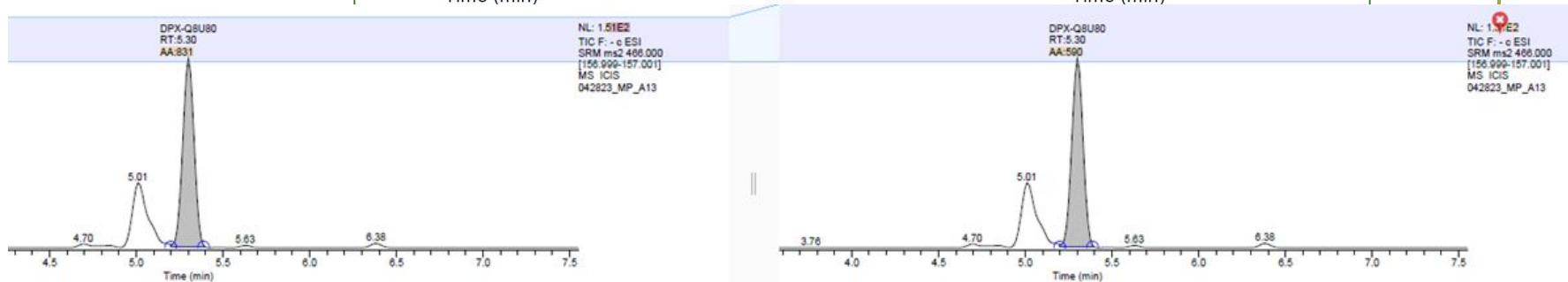
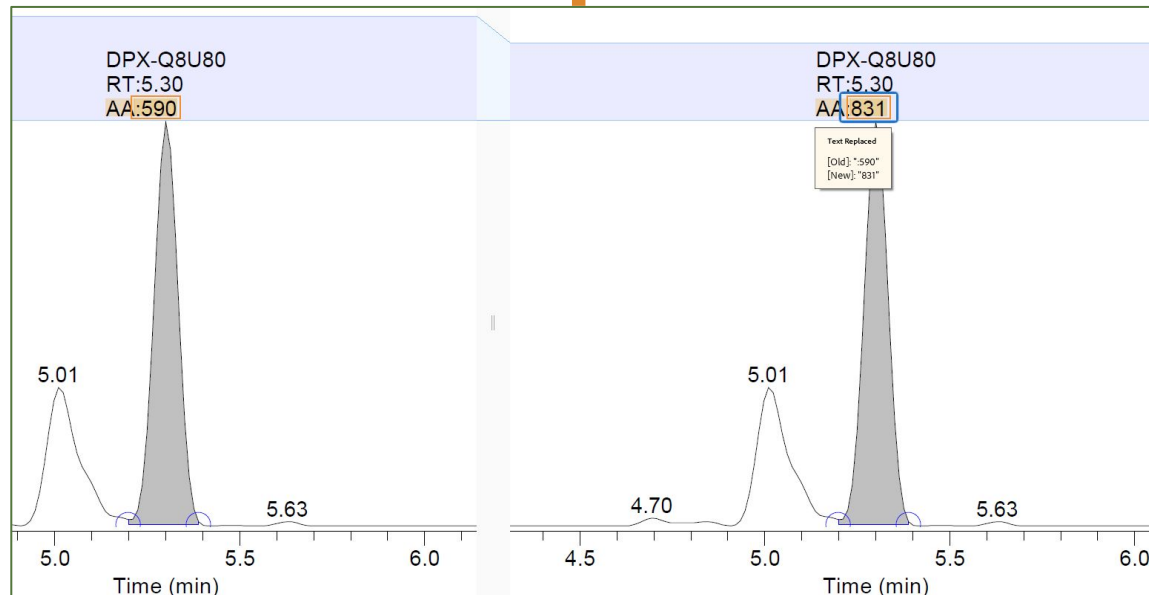
Acrobat metafile comparison

Compare Results

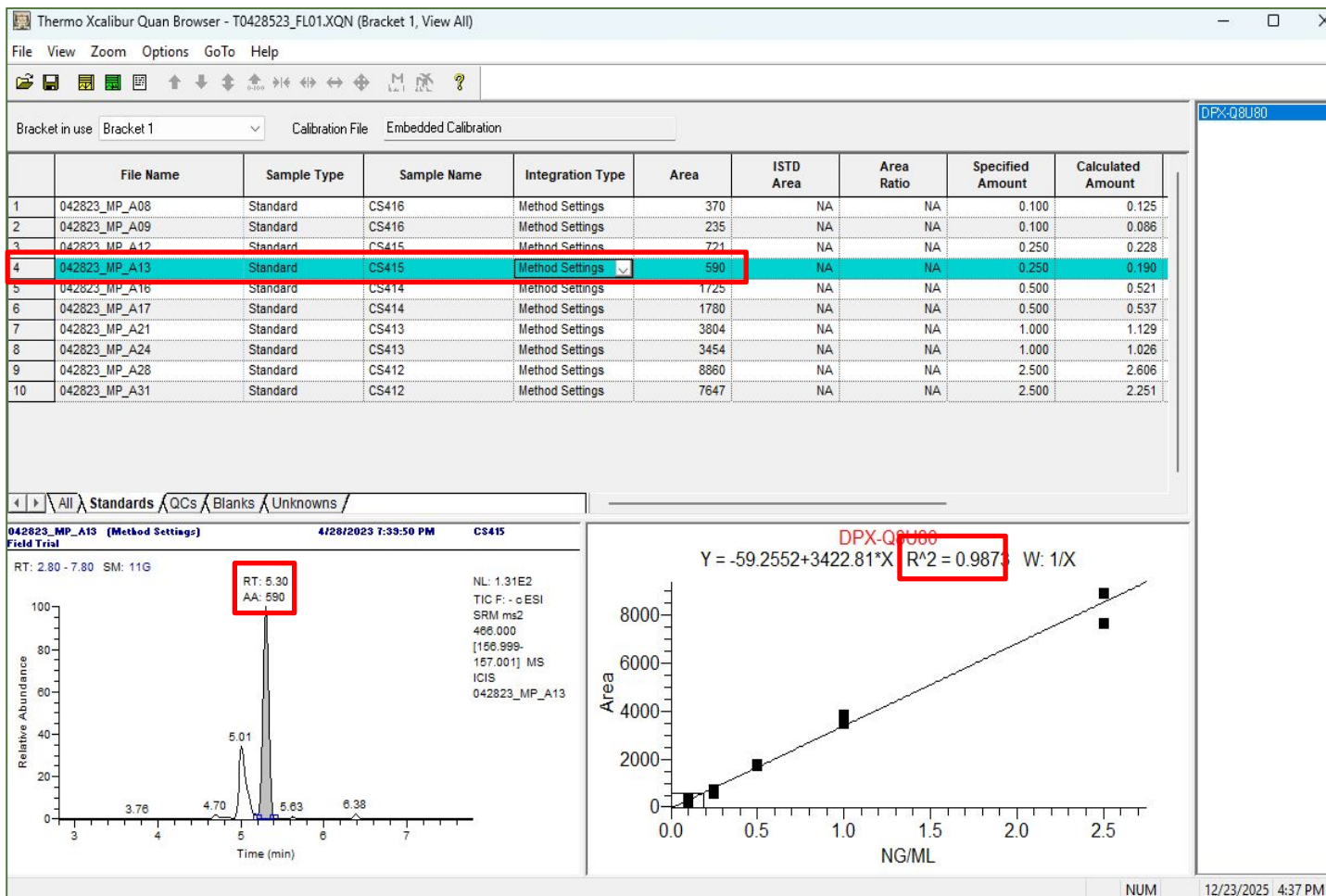
| | | |
|--------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------|
| Old File: 042823_MP_A13DPX_Chromat_Root_020123_MP_#5.pdf 1 page (16 KB) | versus | New File: 042823_MP_A13DPX_Chromat_Root_020123_MP_#5.pdf 1 page (99 KB) 5/1/2023 11:49:43 AM |
|--------------------------------------------------------------------------------------|--------|--------------------------------------------------------------------------------------------------------------|

| | | |
|----------------------|-------------------------------------------------------------------|------------------------------------------|
| Total Changes | Content | Styling and Annotations |
| 4 | 3 Replacements 1 Insertion 0 Deletions | 0 Styling 0 Annotations |

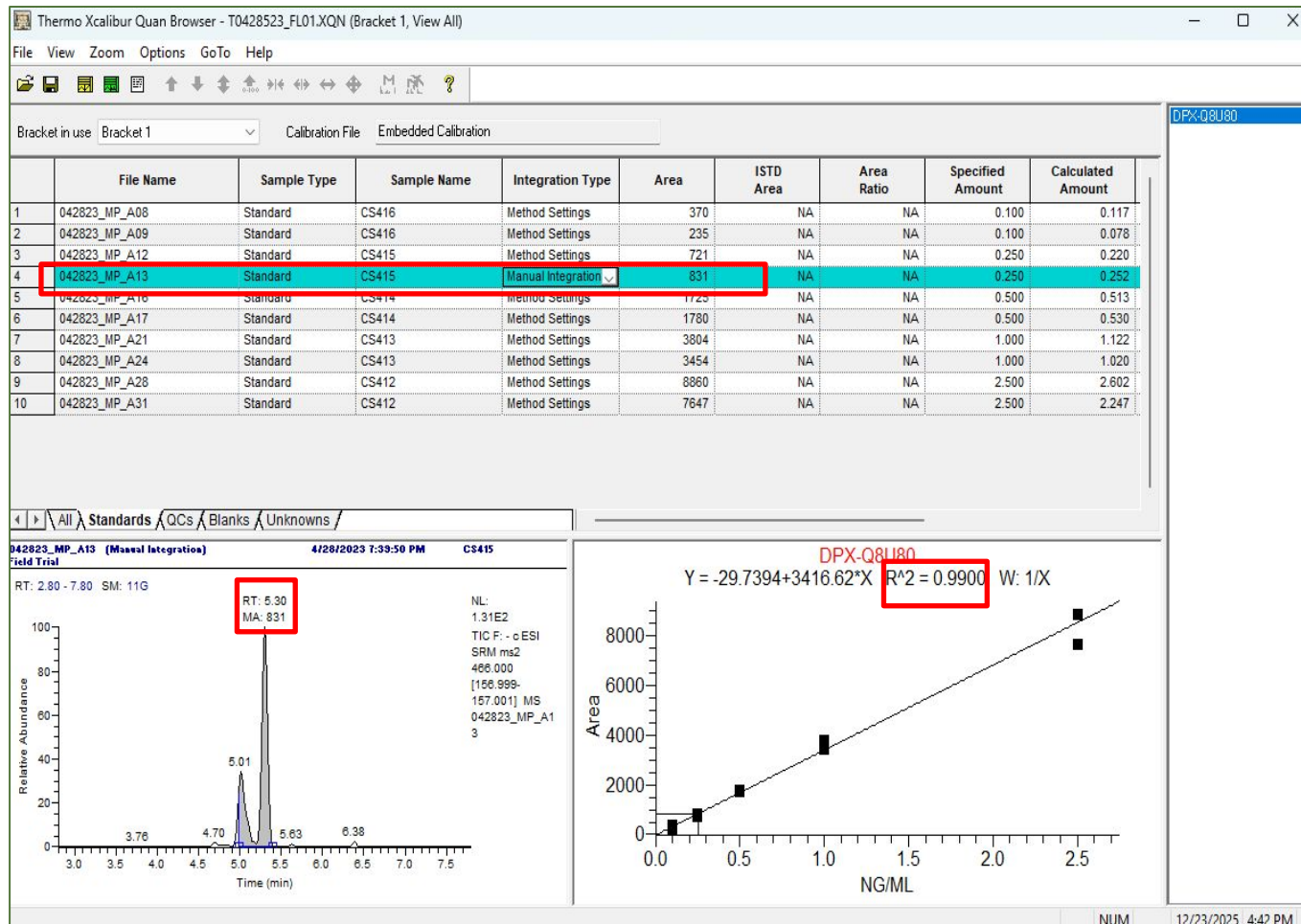
Acrobat metafile comparison



Quan Browser



Quan Browser





Leadership Response: The Critical Meeting

- **Key Stakeholders:**
 - Laboratory Research Director (LRD)
 - Quality Assurance (QA)
 - Regional Director (RD)
 - HQ Management
 - SDs
 - National QA Manager
- **Initial reaction of RD, Full Transparency for QA and LRD**
(Complete access, collaboration, and open communication throughout remediation)
- **Corrective action plan** with deadline was shared with management



Systematic Corrective Action Process

1 Reprocessing all data (LRD) and In-life audit (QA)

2 Generating amended ASR (LRD)

3 Auditing amended ASR & ARD (QA)

4 Generating eQA Reports (QA)

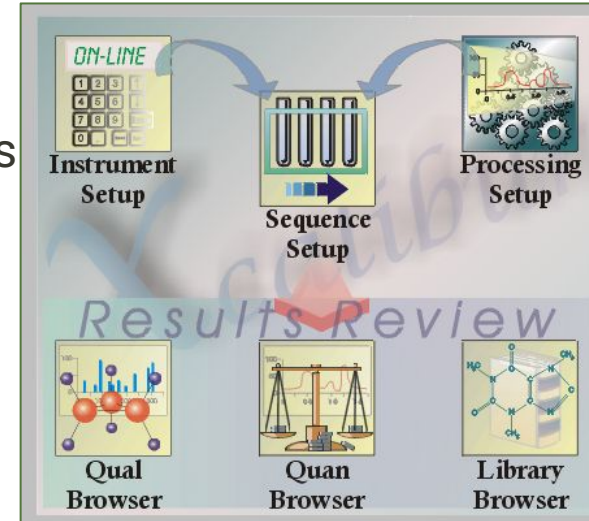
5 Responding eQA findings/ Updating ASR (LRD)

6 Sending the amended ASR to HQ (LRD)



1 Reprocessing all data and audit methodology

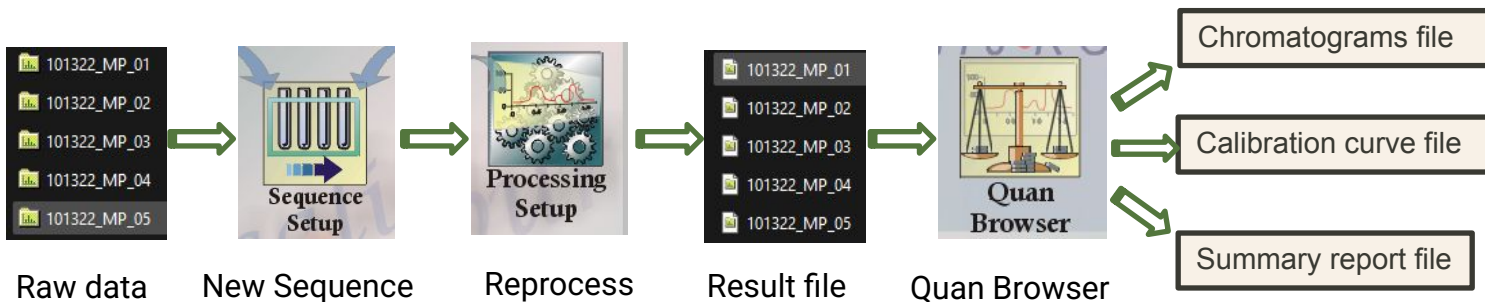
- Reprocessing Approach : The LRD reprocesses all data with an in-life auditing
- Real-time oversight ensured:
 - Correct use of original raw data files
 - Proper integration parameters
 - Appropriate calibration application
 - Accurate result calculations



1 Reprocessing all data and audit methodology cont'd

Thermo Xcalibur Sequence Setup - 101322_CA59_CA60_PR285_MP_#5_20221013161547_RP010924GM [Open]

| | Sample Type | File Name | Sample ID | Path | Inst Meth | Proc Meth | Position | Inj Vol | Level | Sample Wt | Sample Vol | TD | Corr | An | Dil | Factor | PR# | Lab ID | Trial ID | Company | Phone | Comment | amp |
|---|-------------|--------------|---------------|------------------------------------------------------------------------------------------------|-----------|-----------|----------|---------|-------|-----------|------------|----|------|----|-----|--------|-------------|--------------|----------------|---------|-------|---------------|---------|
| 1 | Unknown | 101322_MP_01 | Primer | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\RA1 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 4ng 1.1 |
| 2 | Unknown | 101322_MP_02 | Primer | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\R.b2 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 202143 |
| 3 | Unknown | 101322_MP_03 | Primer | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\R.b3 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 202143 |
| 4 | Unknown | 101322_MP_04 | Primer | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\R.b5 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 202143 |
| 5 | Unknown | 101322_MP_05 | Primer | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\R.b5 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 202143 |
| 6 | Unknown | 101322_MP_06 | Blank Control | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\RA2 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | Blank 0 |
| 7 | Std Bracket | 101322_MP_07 | 4ng 1.1 MAT | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\RA1 | | | 25.00 | 4.00 | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | CS.21 |
| 8 | Unknown | 101322_MP_08 | Control | C:\Vocalbur\data\Dimethand\PPromegranate\101322\010924\data\C:\Vocalbur\di\C:\Vocalbur\di\R.H1 | | | 25.00 | | | 0.000 | 0.000 | | | | | 1.000 | PR No: 1308 | Lab ID: 1308 | Trial ID: 1308 | | | Field Treated | 202143 |



② Generating amended ASR (LRD)

- All amendments shown in **bold italics** for easy identification

LIST OF CHANGES INCORPORATED INTO THE AMENDED REPORT - continued

| Original Report Page | Amended Report Page | Change |
|----------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 78 | 81 | Updated peak responses, avg peak area, final extract concentration, amount found (µg), amount found (ppm), and Fort. Recovery (%) for CR sample. |
| 80 | 83 | Updated 2 calibration standard responses. Updated intercept, slope, R squared value, CR amount found (ppm), and CR Fort. Recovery (%) |
| 81 | 84 | Updated amount fortified (µg), fortification level (ppm), and dilution factor for one CR sample. |
| 83 | 86 | Updated one calibration standard response. Updated intercept, slope, R squared value, CR and treated samples final extract concentration, amount found (µg) and amount found (ppm), and CR Fort. Recovery (%) |

| Sample ID Lab# - Rep. | Sample Wt. (g) | Amount Fortified (µg) | Fortification Level (ppm) | Final Ext. Volume (mL) | Dilution Factor | Peak Area (1) | Peak Area (2) | Average Peak Area | Final Ext. Conc. (ng/mL) | Amount Found (µg) | Amount Found (ppm) | Fort. Recovery (%) | Percent Equivalents (ppm) |
|--------------------------|-------------------|--------------------------|------------------------------|---------------------------|-----------------|----------------------|----------------------|----------------------|-----------------------------|----------------------|-----------------------|-----------------------|------------------------------|
| Control | | | | | | | | | | | | | |
| 190109H | 2.00 | --- | --- | 80 | 1 | 4910 | 6035 | 5472 | -- | -- | <0.01 | | <0.0108 |
| Recovery | | | | | | | | | | | | | |
| 190109I | 2.00 | 0.0200 | 0.0100 | 80 | 1 | <i>211407</i> | <i>211435</i> | <i>211421</i> | <i>0.164</i> | <i>0.0132</i> | <i>0.00658</i> | <i>66</i> | |
| Treated | | | | | | | | | | | | | |
| 190110E | 2.00 | --- | --- | 80 | 1 | 19128 | 19286 | 19207 | --- | --- | <0.01 | | <0.0108 |
| 190111E | 2.00 | --- | --- | 80 | 1 | 16594 | 15565 | 16080 | --- | --- | <0.01 | | <0.0108 |

Note: Any values formatted with **bold italics** indicate changes from the values reported in the analytical summary report signed 01/31/22.



③ Auditing amended ASR & ARD

- Original and amended ASRs audited with raw data
- Electronic files compared to hard copies (chromatograms, calibration curves, reports, raw data, results/Quan files)
- Electronic data timestamps and file sizes verified





4 Generating eQA reports

- Amended ASR & ARD reports generated in eQA

The IR-4 Project eQA/eDOCs

QUALITY COMPLIANCE SOFTWARE
Form Detail
Analytical Summary Report Audit

Go Back | Back To List | Show Activities / Workflow Status Page | Show Audit Trail Page | Print Page

Menu (Yavuz Yagiz) Log Out Home

Record 7 of 12

[1. Cover Sheet](#) [2. Analytical Summary Report Checklist](#) [3. QA Findings/Recommendations](#) [4. Response to QA Findings](#) [5. SD/TFM Approval Page](#)
[Go To Bottom](#)

The IR-4 Project eQA/eDOCs

QUALITY COMPLIANCE SOFTWARE
Form Detail
Analytical Raw Data Audit

Go Back | Back To List | Show Activities / Workflow Status Page | Show Audit Trail Page | Print Page

Menu (Yavuz Yagiz) Log Out Home

Record 3 of 8

[1. Cover Sheet](#) [2. Analytical Raw Data Checklist](#) [3. QA Findings/Recommendations](#) [4. Response to QA Findings](#) [5. SD/TFM Approval Page](#)
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Record 3 of 8

- [1. Cover Sheet](#) [2. Analytical Raw Data Checklist](#) [3. QA Findings/Recommendations](#) [4. Response to QA Findings](#) [5. SD/TFM Approval Page](#)
[Go To Bottom](#)



⑤ Responding eQA findings/ updating ASR

eQA Reports (ASR & ARD)

- SD and LRD provided responses
- LRD updated reports accordingly



⑥ Sending the amended ASR to HQ

- Updated ASR reviewed for corrections
- QA signed QAS and LRD signed report
- Submitted to HQ





Future Audit Formats

Audit Package Contents

- Hard copies + electronic files
 - Chromatograms
 - Calibration curves
 - Summary reports (PDF)
 - Raw data, sequence files, result files, Quan files
 - Copy of all logs, communication etc.

Verification Process

- In addition to the regular audit, we compared the paper data against the electronic data



Key Lessons Learned – Critical Takeaways

- 1 Data Integrity is Non-Negotiable** – No performance metric justifies falsification
- 2 Technical Controls are Essential** – Systems must prevent, detect, and audit changes
- 3 Collaborative Remediation Works** – QA involvement is crucial
- 4 Culture Matters Most** – Ethics and integrity must be core values



Thank you!

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