



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

# Document Transfer to Headquarters

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## Types of GLP Document

- ❖ Raw Data
- ❖ ASRs
- ❖ Facility files
- ❖ eFDB Raw Data pages for auditing
- ❖ Corrected pages and deviations
- ❖ SOPs
- ❖ CRO Audits





# Outline

- Facility Files
- Raw Data Pages for Auditing
- Corrected Pages
- SOPs

# Facility Files

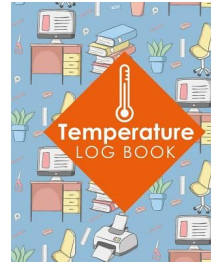
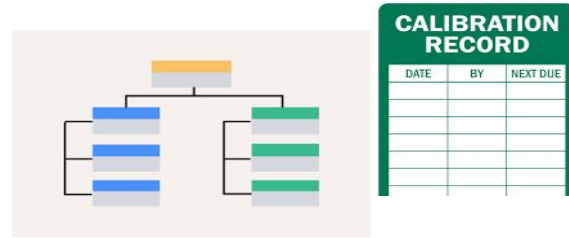
## To include, but not limited to:

- Org charts
- Personnel files
- Historical SOP
- Equipment maintenance logs
- Calibration logs
- Temperature logs

All these records should be signed and dated.

It's recommended that you maintain a copy.

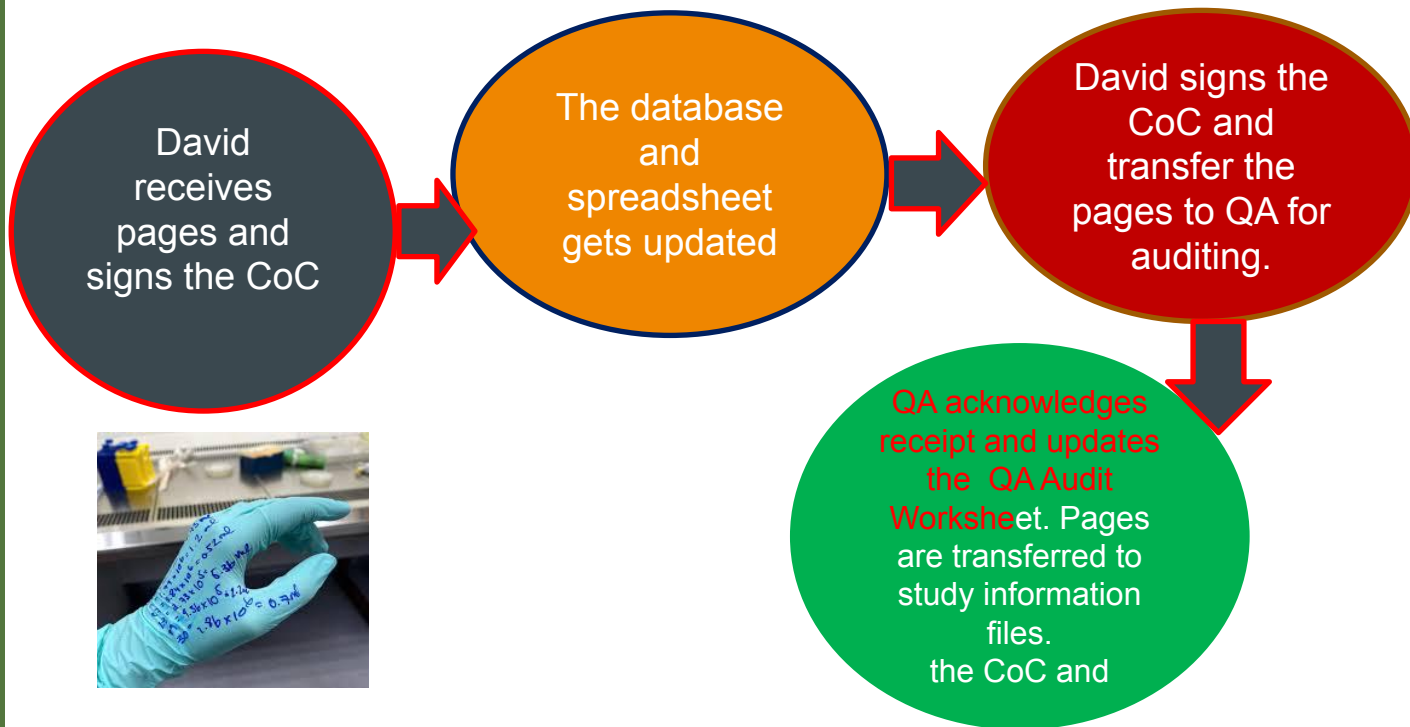
Once received at HQ, they are documented and archived.



## Raw Data Pages for Auditing

- Raw Data pages should be address to David Schnatter
- A completed CoC (Chain of custody) should be attached to the Raw Data pages

If this page is missing, you will receive a QA finding.





# Corrected Pages

Remember to attach paper corrected pages if you indicate “yes” to section 4 in eQA.

**The IR-4 Project eQA/eDOCs** **QUALITY COMPLIANCE SOFTWARE** **Form Detail**  
*Field Raw Data Audit*

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

Home ? HELP

FRD shall answer the following question upon completing responses,  
If you have no corrected pages, answer NO  
If you have attached corrected pages, answer YES and a date must be entered into the next field

FRD - Have you attached corrected/additional pages?: Yes

FRD - When did you mail/send the original un-paginated pages to HQ QA?: 11/29/2021

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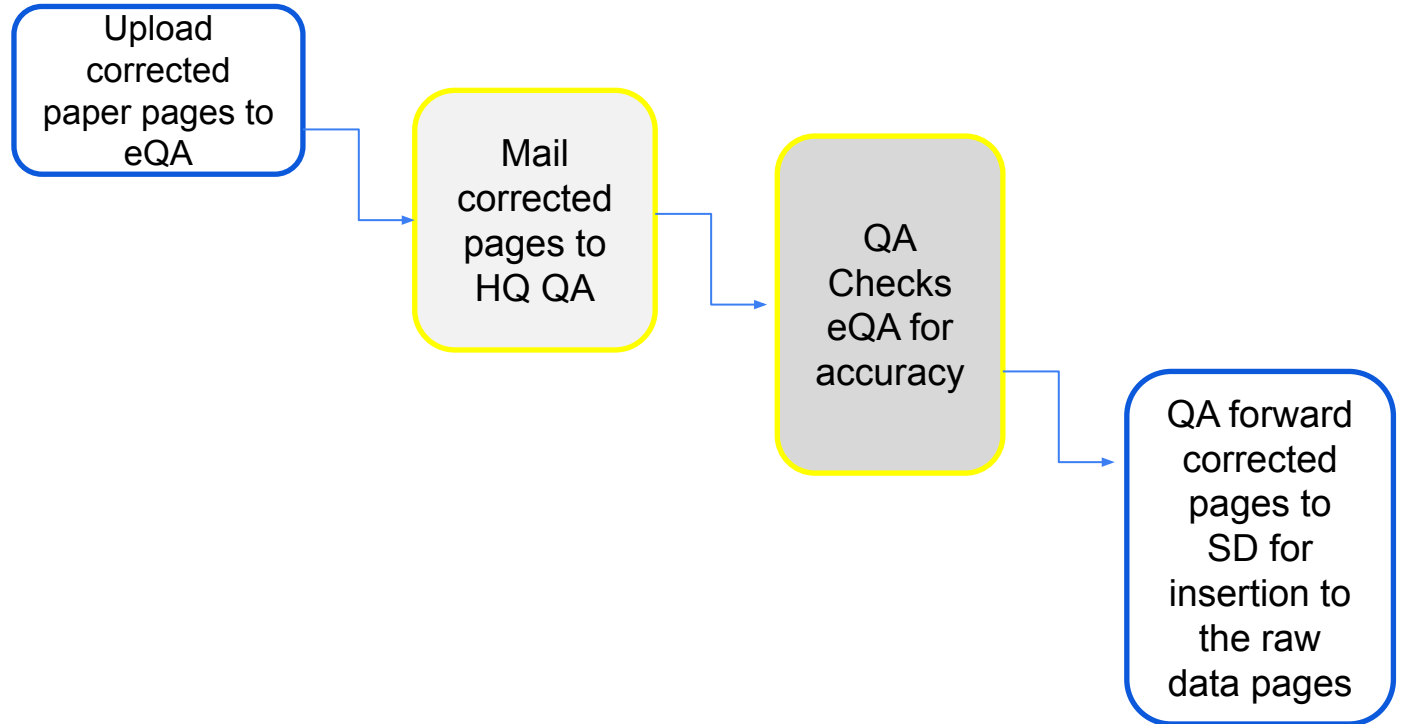
**Study Director**

Findings for Study Director. Please respond if applicable. Initial and Date each response. : NONE

Attachments #1: eQA changed pages [redacted].pdf

1. Cover Sheet 2. Field Raw Data Checklist 3. QA Findings/Recommendations 4. Response to QA Findings 5. SD/TFM Approval Page

# Corrected Pages Cont. ...





## Standard Operating Procedures (SOPs)

- Review your SOPs per your SOPs
- Be sure to include a completed signature page (FRD and RFC).
- Forward your SOPs, for the current filed season, to my attention.
- **It's important that we receive your SOPs on time. Not having your updated SOPs causes delay in getting your FDBs audited.**
- Be sure to include an index page. **This is a QA finding.**
- SOPs are posted on the IR-4 Intranet on the Quality Assurance page.



# Thank you!

