UC San Diego Health

Managing LDT Materials with MS Access – QA and FDA Compliance for the 21st Century

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How can use of a Product Database relate to the FDA LDT Final Rule?

Different kettles of fish?

Or natural partners?

Agenda

- Define tracking database
- Applications available in the market
- Demonstrate MS Access use as a tracking database
- Demonstrate use of MS Access for troubleshooting
- Benefits of having MS Access for Stage 1 of FDA LDT Ruling (5/6/2025)

What is an LDT tracking database?

- An application/software used to document all lots of materials, chemicals, solvents and standards used to prepare in-house calibrators, internal standards, mobile phases and reagents in the laboratory
- It is also used to document information on calibrators, quality controls and reagents purchased from a manufacturer

Applications that can be used as tracking database

Always think of user accessibility when choosing the right application for your lab!

MS Access

- Already included with Microsoft office
- User-friendly and no programming knowledge required
- ***UCSD CALM toxicology lab uses this***

LibreOffice – Base

- Compatible with different platforms such as Windows, macOS and Linux

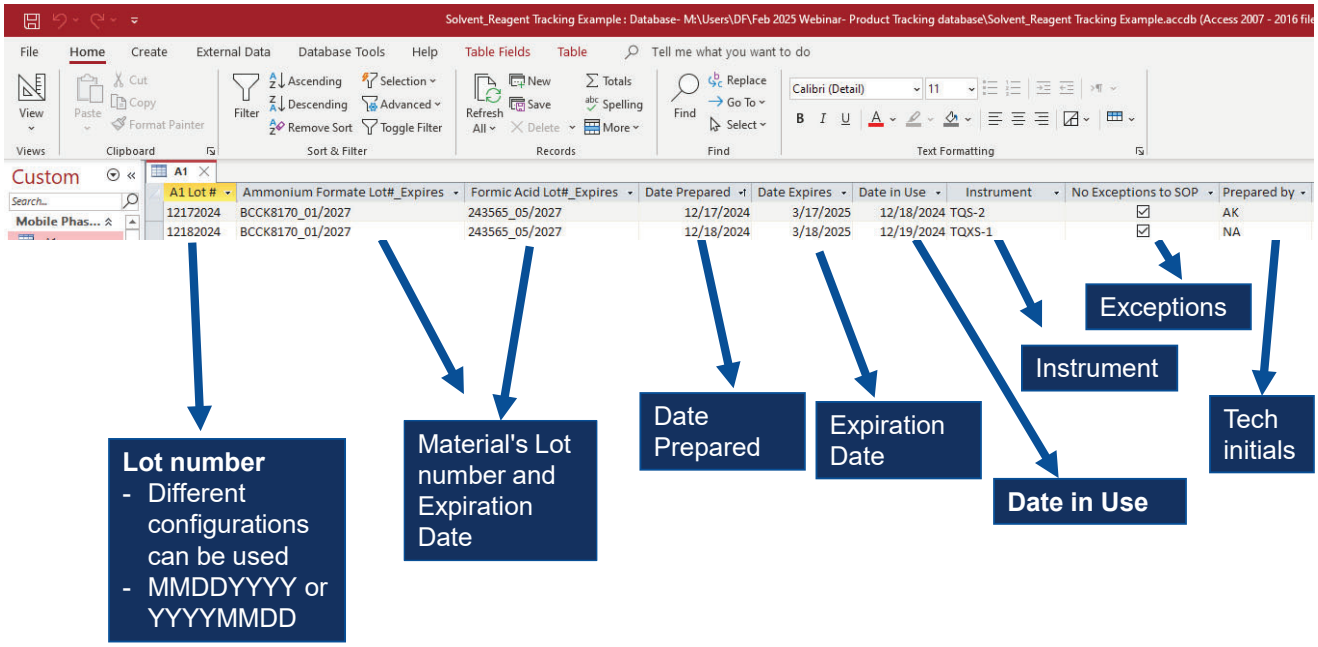
MySQL, mongoDB, etc.

- A lot of other options ranging from “easy to use“ to “sophisticated coding required”
- ***Consider lab resources and programming expertise***

Images from Wikipedia and https://www.trickyenough.com/most-popular-databases/

MS Access as an LDT materials tracking database

Basic fields to help track LDT materials:



MS Access as an LDT materials tracking database

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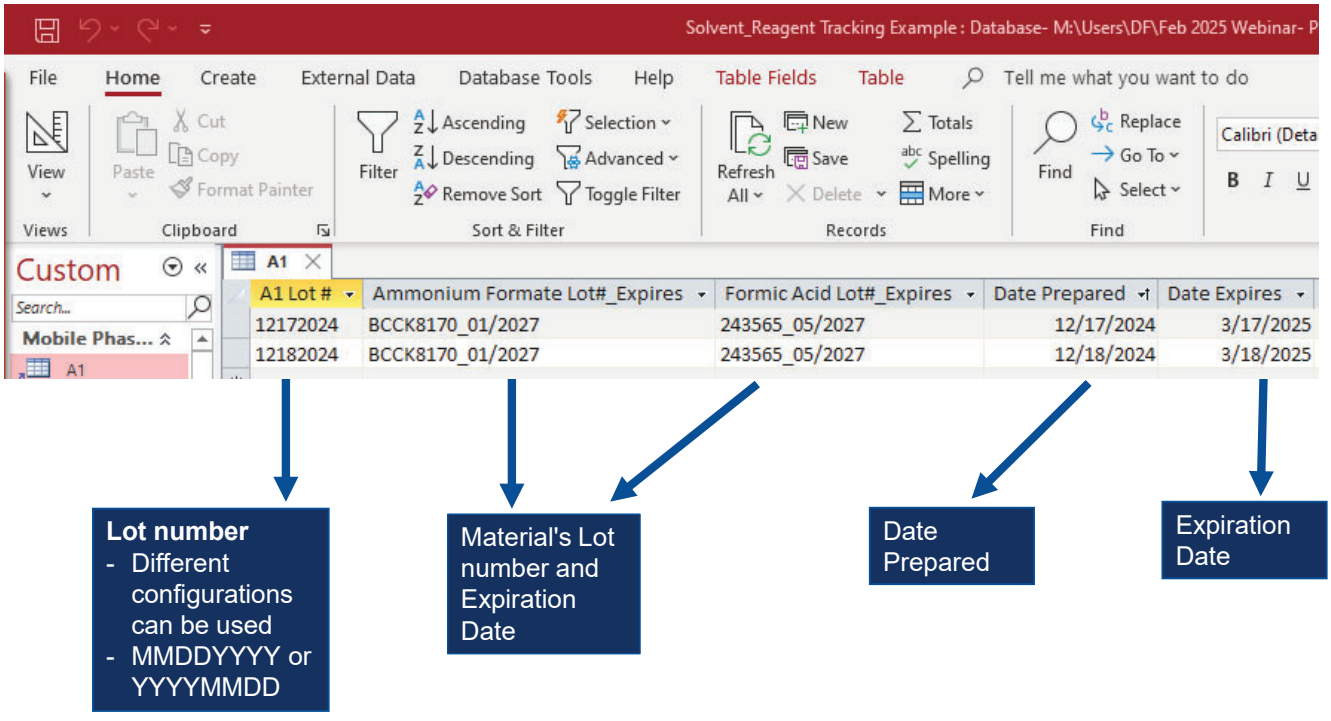

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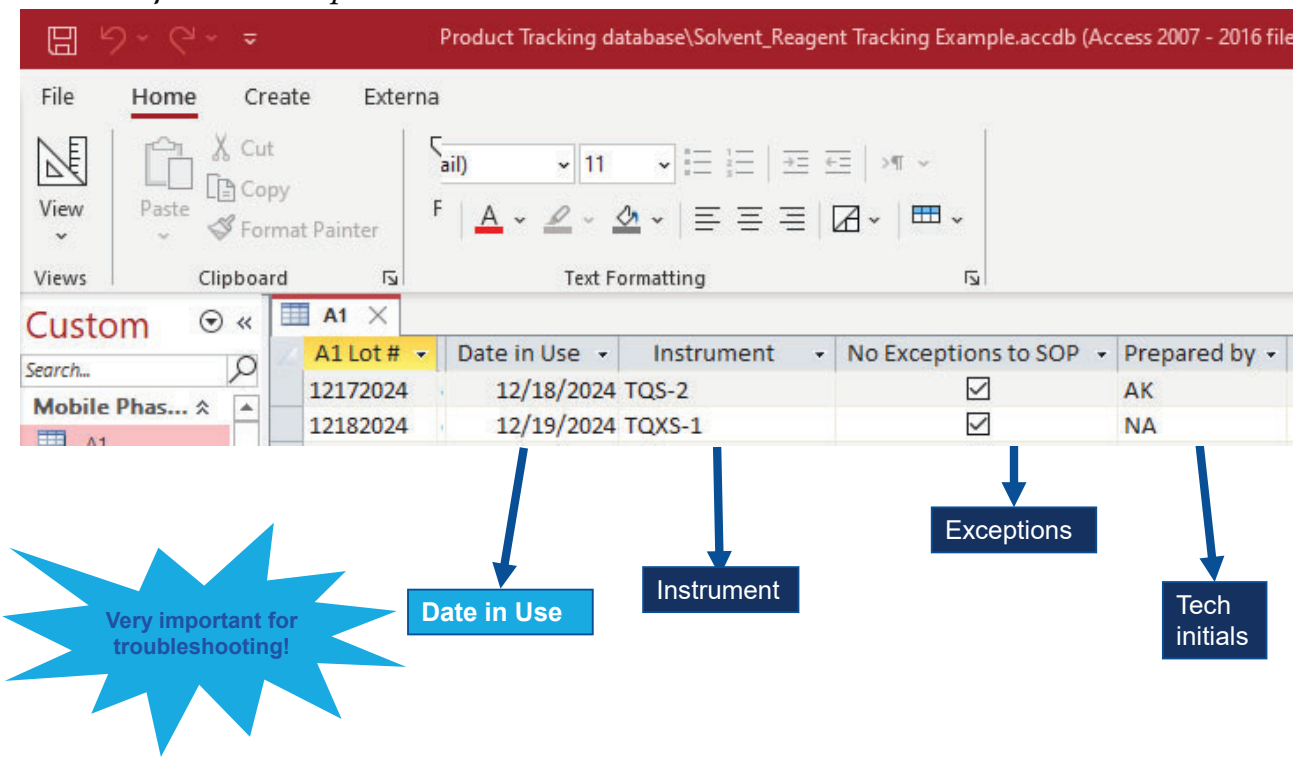
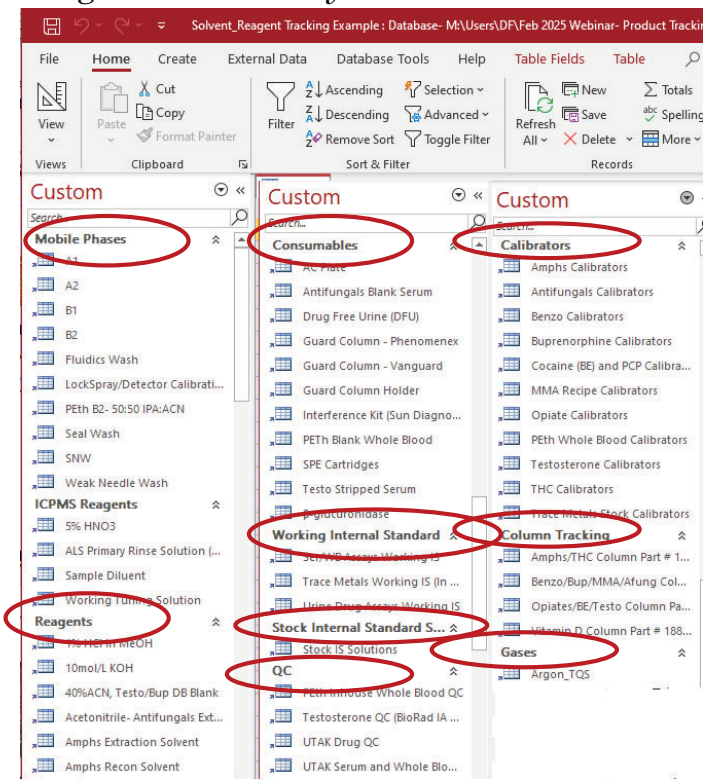


MS Access as an LDT materials tracking database

Organization is Key!

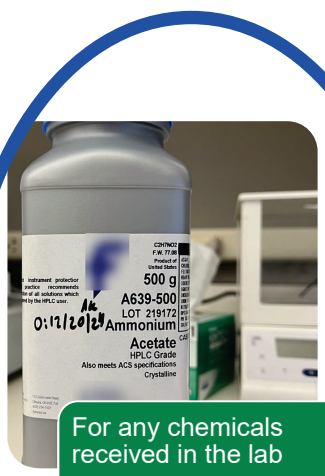


Organize reagents into subgroups:

1. Mobile Phases
2. Reagents (i.e. Extraction Solvent)
3. Consumables (i.e. SPE Cartridges)
4. Working Internal Standard
5. Stock Internal Standard
6. QC
7. Calibrators
8. Columns
9. Gases (i.e. Argon)

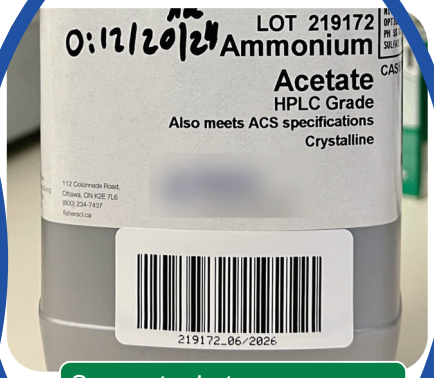
MS Access Database – Reagents

Make everything as user-friendly as possible – start with the materials!



For any chemicals received in the lab
- Download COA from manufacturer

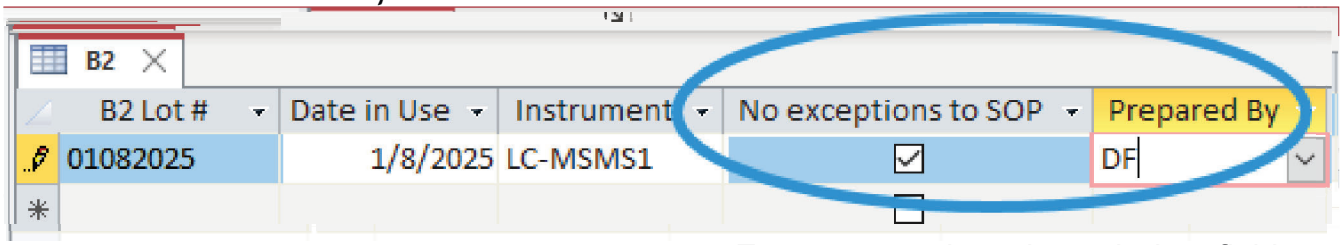
Create Barcodes
- Note lot number and expiration date from the COA
- Example format: Lot#_Expiration Date



Sequester Lot
- First one in, first one out

MS Access Database – Reagents

As an example, let's enter a newly prepared lot of 2mM Ammonium Acetate in Methanol with 0.1% formic acid



1. Enter Lot Number of Mobile Phase B2
2. Scan Methanol Lot & expiration date
3. Scan Formic Acid Lot & expiration date
4. Scan Amm. Acetate Lot & expiration date
5. Enter correct dates in each date field
6. Enter instrument where it will reside
7. Exceptions to SOP?
8. Tech who prepared the reagent

MS Access Database – Drug Standards

Organization is Key!

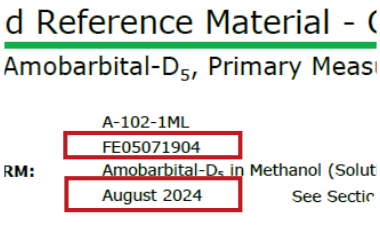
USE THIS

ID	Standards	BOX-COLUMN -ROV	BOX-COLUM	BOX-COLUM
371	Amobarbital-D5	5-6C		

Location	Lot #	Expires	Open/unopened?	Vial discarded	
5-6C	FE05071904	8/31/2024	Unopened	☐	(1)
				☐	(0)

For any new drug standards received in the lab

- Download COA from manufacturer



Enter in Access Database

- Note lot number and expiration date from the COA

Sequester Lot

- Organize each box by assay for ease of use

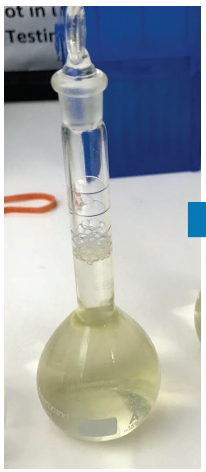
MS Access Database - Calibrators

Prep it and forget it????

Cocaine (BE) and PCP Calibrators

Calibrator Lot #	Prepared by	Date Prepared	Date Expires	No exceptions to SOP?
09202023	DF	9/20/2023	9/20/2027	☑

PCP Stock Std Lot#_Expiration	BE Stock Std Lot#_Expiration	DFU Lot#_Expiration
FE09152202_09/2027	FE03032102_03/2026	D2749_01/31/2025



After Preparing New lot of Calibrators:

1. **Enter Lot Number of Calibrator**
2. **Enter tech initials**
3. **Prep date and expiration dates**
4. **Exceptions to SOP (if applicable)**
5. **Stock standards lot numbers and expiration dates**
6. **DFU lot number and expiration date**

MS Access Database - Calibrators

Cocaine (BE) and PCP Calibrators

Calibrator Lot #	Prepared by	Date Validated	Date in Use	Batch Coversheet updated?	Sample Table template edited (1&2)?	
09202023	DF	10/9/2023	10/16/2023	☑	☑	(1)

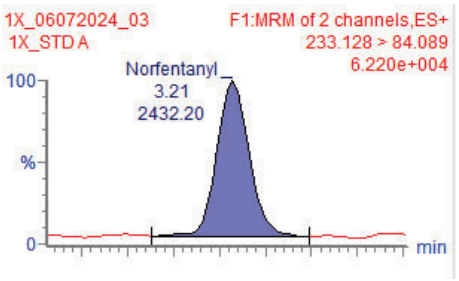
Once Validated then what???

1. Enter date validated
2. Enter date in use
3. Batch cover sheet and sample table updated
4. Attach scanned prep sheet

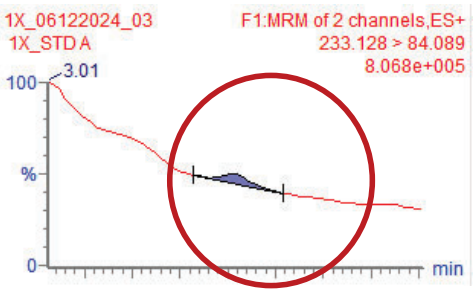
Troubleshooting using MS Access Database

***Problem**: During mobile phase validation, unknown interfering substance in Norfentanyl was observed affecting LLOQ (Non-Conforming Event)*

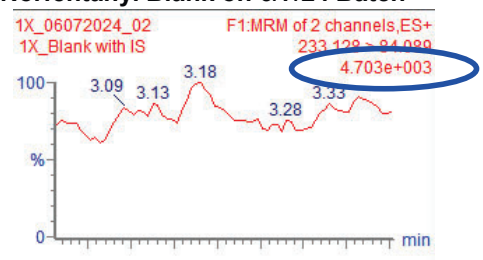
Norfentanyl LLOQ on 6/7/24 Batch



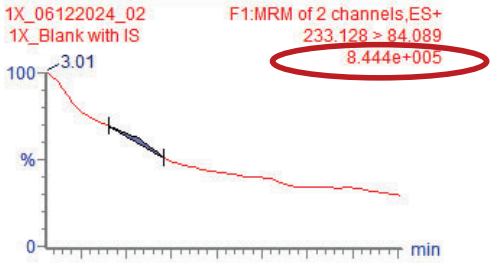
Norfentanyl LLOQ on 6/12/24 Batch



Norfentanyl Blank on 6/7/24 Batch



Norfentanyl Blank on 6/12/24 Batch



Troubleshooting using MS Access Database

Problem: *During mobile phase validation, unknown interfering substance in Norfentanyl was observed affecting LLOQ (Non-Conforming Event)*

#1

- Check MS Access database - what is new?
  - **New A1 Mobile Phase (Ammonium Formate in H_2O)!**

A1

A1 Lot #	Ammonium Formate Lot#_Expires	Formic Acid Lot#_Expires	Date Prepare	Date Expires	Date in Use	Instrument
03292024	BCCH5566_9/2025	232523_02/2026	3/29/2024	6/29/2024	4/3/2024	TQXS-1
04302024	BCCH5566_9/2025	232523_02/2026	4/30/2024	7/30/2024	5/1/2024	TQS-2
06112024	BCCH5566_9/2025	232523_02/2026	6/11/2024	9/11/2024	6/11/2024	TQXS-1
06132024	BCCH5566_9/2025	232523_02/2026	6/13/2024	9/13/2024	6/13/2024	TQXS-1
06142024	BCCK8170_01/2027	232523_02/2026	6/14/2024	9/14/2024	6/14/2024	TQXS-1
06182024	BCCK8170_01/2027	232523_02/2026	6/18/2024	9/18/2024	6/20/2024	TQXS-2
06242024	BCCK8170_01/2027	232523_02/2026	6/24/2024	9/24/2024	6/24/2024	TQXS-1

#3

#4

- Rule out DI H2O
  - Ran water injection on “clean” instrument – **no interference!**

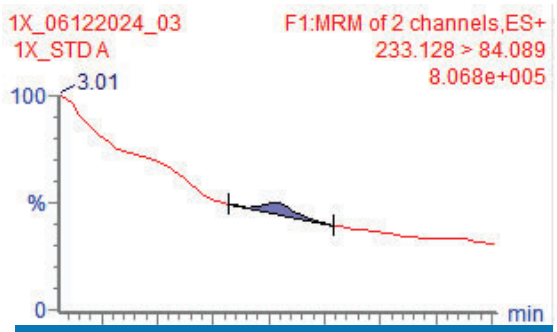
Hypothesis: *Ammonium formate is contaminated*

Troubleshooting using MS Access Database

Problem: *During mobile phase validation, unknown interfering substance in Norfentanyl was observed affecting LLOQ (Non-Conforming Event)*

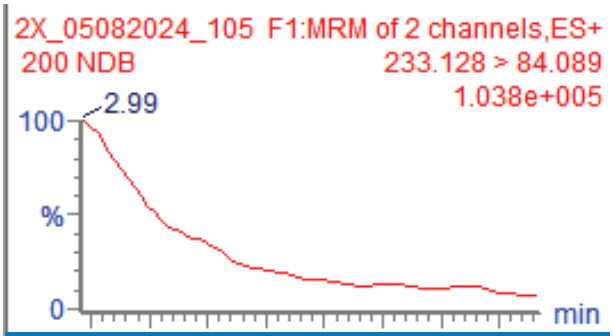
#5

- Re-trace troubleshooting steps
  - Profile of interferent very similar to NDB (bupivacaine metabolite) prepared for interference testing in May 2024
  - **When/How did contamination happen?**



1 ng/mL Norfentanyl LLOQ with contaminated A1 prepared in June 2024

VS



200 ng/mL Bupivacaine metabolite prepared in May 2024

Troubleshooting using MS Access Database

Problem: *During mobile phase validation, unknown interfering substance in Norfentanyl was observed affecting LLOQ (Non-Conforming Event)*

#7

- **What about the other materials used to make A1???**
  - Graduated cylinder
  - Weighing boat
  - **Spatula** – shared with all other reagent prep!

#8

- **Working Theory**: Spatula used to prep A1 was contaminated with NDB (bupivacaine metabolite)

#9

- Prepared A1 using cleaned spatula – **interference present!**
- Prepared A1 using disposable spatula – **interference present!**
- **Conclusion: Ammonium formate bottle is contaminated**

#10

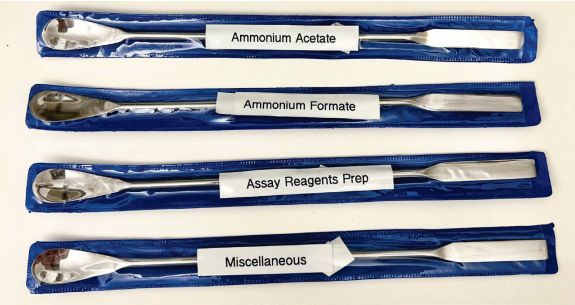
- **Buy new ammonium formate and new spatula!**
  - Prepared A1 using new spatula with new ammonium formate – **NO INTERFERENCE!**

Troubleshooting using MS Access Database

Conclusion and Corrective Action

Conclusion

Metal spatula used for preparing bupivacaine metabolite for interference testing somehow contaminated ammonium formate bottle in use, most likely metal spatula was not thoroughly cleaned



Corrective Action

Purchased new set of metal spatula and designated each set for mobile phase prep only, reagent prep only and miscellaneous prep to prevent cross contamination

The Right Tool for LDT Materials Management

Database storage of Materials Records

Hardcopy or MS Excel, MS Word, file storage

Strength and Weakness of MS Access Tracking Database

Strengths

- Troubleshooting
- Easily see trends
- Track reagent useability
- Traceability
- Easily customizable
- Macros can be created for easier archiving, in particular drug standards in ampoules
- At UCSD CALM – no $ to use MS Access (a component of MS Office, Professional)

Weaknesses

- Limited on what can be tracked

Generic Database advantages for FDA Compliance

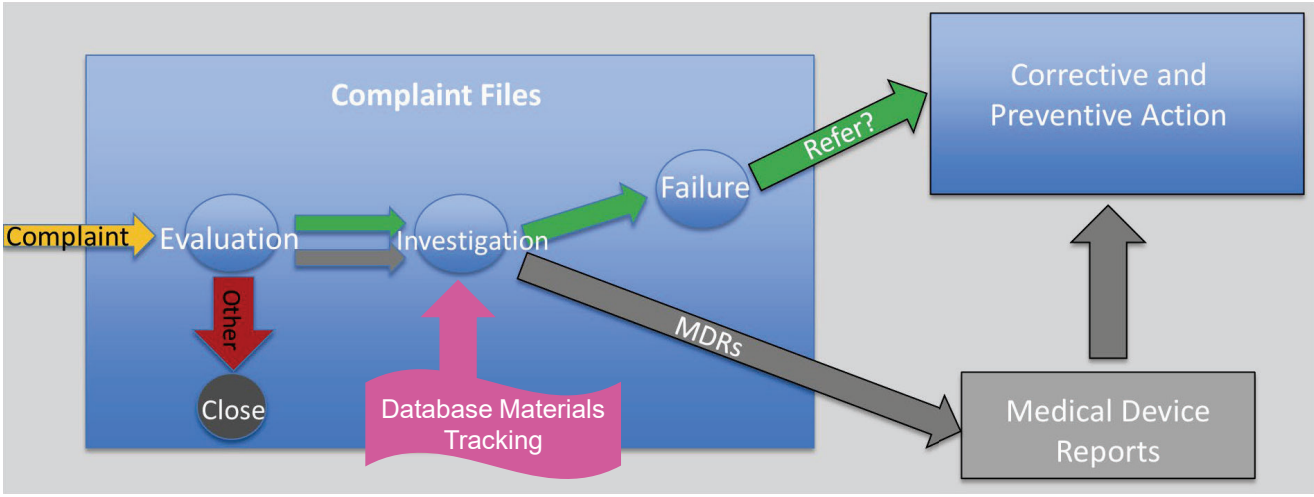
1. Finding records = faster
2. Tracking lot changes over time OR between different reagents = easier, more reliable, dependably comprehensive
3. Better standardization of entries (drop down menu vs free text)

FDA LDT Final rule & Database materials tracking

- Applicable to (chapter):
  - (6) Purchasing Controls
  - (7) Identification and Traceability
  - (8) Production and Process Controls
  - (9) Non-Conforming Product [Events] *(investigation)*
  - (10) Corrective and Preventative Action *(investigation)*
  - (11) Labeling (and Packaging)
  - (13) Records
  - (14) Complaints *(investigation)*

(From CLSI QSRLDT document)

Create a new Access file for Complaint tracking?



Complaint Files. Accessed 1/25/25. [Powerpoint Slides]. FDA. https://www.fda.gov/media/109411/download?attachment

Conclusions

Use of the Product Database at UCSD-CALM Toxicology Lab, since 2015 has:

- Streamlined operations for LDT production & QA
- Facilitated troubleshooting on numerous occasions
- Been optimized with modifications, queries, and additional features based on staff feedback
- Could be expanded with more functionality (if there was time!)

- ***We believe it can ease compliance with the FDA LDT Final Rule, Phase 1 and beyond***

If you are interested…..

- An SOP template for using MS Access as an LDT Materials Database is available for download on the MSACL-CAC webpage (*link*)
- An MS Access Materials Database template is available for download on the MSACL-CAC webpage (*link*)

MSACL-CAC Disclaimer: The functions provided in this database template are intended for general guidance only on recording and tracking laboratory test materials and are not guaranteed by MSACL. Regulatory rules, software functionality, and compliance requirements can vary significantly depending on the specific circumstances. It is essential to consult with a qualified IT professional who is familiar with this software and your specific situation to provide tailored guidance before using the content presented herein.

Special Acknowledgement

Thanks to Krista Pratico, MLS for original MS Access programming & design features of the UCSD CALM Toxicology Product Database

Thank you!

- *Dr. Robert Fitzgerald and Dr. Ray Suhandynata, Directors of Toxicology / Mass Spectrometry at UC San Diego Health CALM Lab*
- *Dr. Judy Stone and Dr. Jackie Hubbard, MSACL CAC Co-Chairs*
- *Heather Tone, Nicholas Asfour and Adam Kelsey, Toxicology / Mass Spectrometry team at UC San Diego Health CALM Lab*
- *Joshua Akin and Krista Pratico, former team members of the Toxicology / Mass Spectrometry team at UC San Diego Health CALM Lab*

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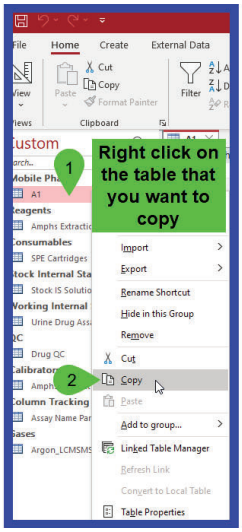
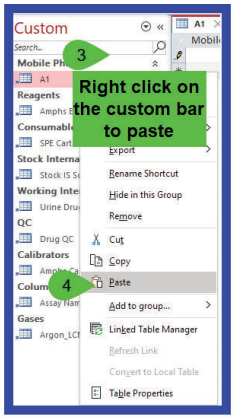
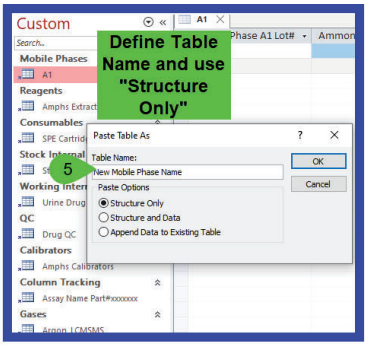
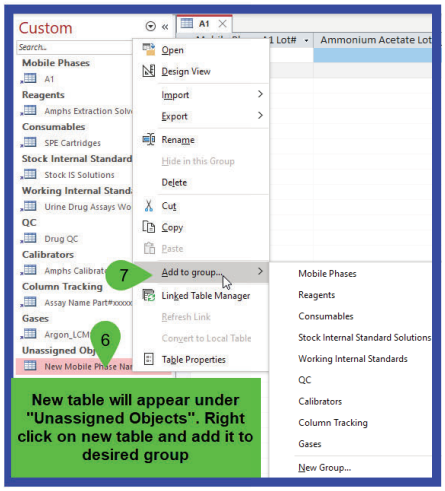
Demo - How to Create New Table in MS Access









Questions?

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