



Case example: Lifecycle issues of a Dossier long in the evaluation chain

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Dossier Process fact sheet

- ▶ Dossier submitted in 2021
- ▶ Not admissible yet without contentual reason
- ▶ Not published
- ▶ Light confidentiality check passed
- ▶ No confidentiality assessment performed
- ▶ NosID check was fine
- ▶ Two updates submitted:
 - Q1 2022 to overcome changed filtering rules in case of publication
 - Q2 2023 on request to overcome new validation rules and migration issues to achieve admissibility

Many examples like this exist

Dossier condition now

265 new Validation errors – partially on fields not existing at the time of last Dossier update

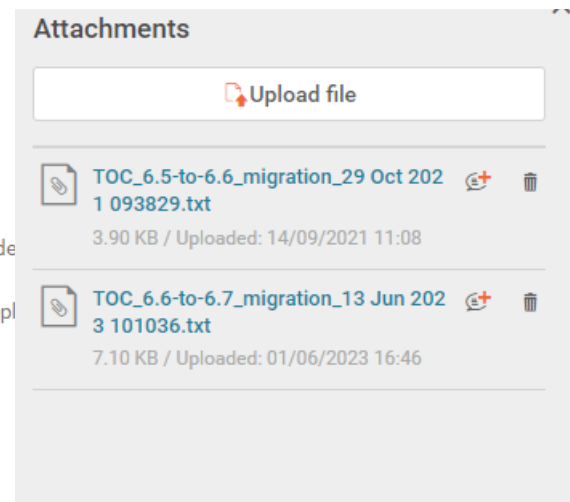
Dataloss in 40 individual documents

'Results and discussion' is not complete. You selected one of the following endpoint

- analytical methods
- methods for post-approval control and monitoring purposes
- methods for relevant impurities and/or metabolites of concern
- methods for the analysis of the (formulated) product
- methods to determine storage stability/shelf life

For each of the selected endpoint study record marked as 'key study' or 'weight of evidence', the tables 'Recovery' and 'Repeatability' under follow:

- Recovery, for each created entry the following information must be provided: Analyte, Matrix, MRM/ m/z, Fortification level, Number replicates and RSD (%)
 - Repeatability, for each created entry the following information must be provided: Analyte, Matrix, Number replicates and RSD (%)
- If none of the fields can be provided, an explanation must be provided in the field 'Remarks'.



Unpredictability of the process make Dossier update planning impossible

Next IUCLID update already in ~ 5 months - more issues can be expected and make current rework efforts potentially redundant

Potential for endless admissibility process

Evaluation process with IUCLID further complications from other processes



- For some evaluations the dRAR is nearly ready, but confidentiality assessment is not done
 - Dossier needs to be updated for public commenting
 - Confidentiality Assessment on the admissible version started – no changes to the Dossier should be applied during the assessment
- ⇒ If the Dossier update starts there is no chance to go back to the previous version

- For some dossiers responsibilities changed in companies – a pro-active Dossier update is triggered to add a new contact point
 - Nothing else should be changed for valid reasons
 - But several hundred new validation issues pop up
 - Is it ok to ignore them?

Each process may bring up new lifecycle issues

Evaluation process with IUCLID

Solutions to the challenges



- As discussed many times an element of lifecycle/Version management could support to overcome those issues and create more clarity but is not implemented yet

- Until then: Clear business roles needed to keep Dossier versions and timelines under control e.G.:
 - Guidance on when and when not to adress new validation errors (proposal: only once at the end of the process)
 - When to re-enter content removed by migration (Looking at the elements: Is it always necessary or even possible considering Dossier integrity)
 - Guidance on how to handle the confidentiality assesment in paralell to the evaluation and potential Dossier updates

Let us collaborate to come to a smoother and more timely process

Thank you



Time for questions and discussion

