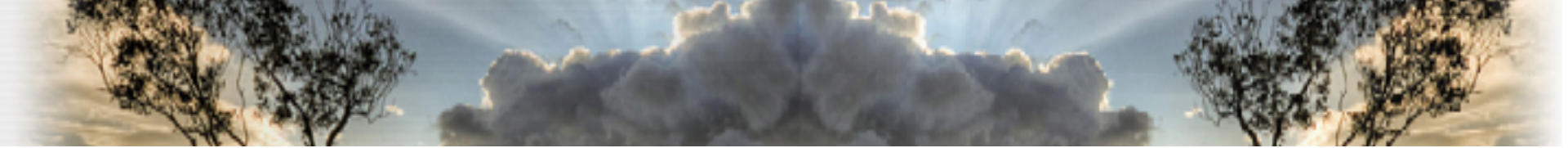


EBF

EBF Open Symposium

N° 13 From Cyberspace - Staying Connected

17-20 November 2020

Method Development Documentation:

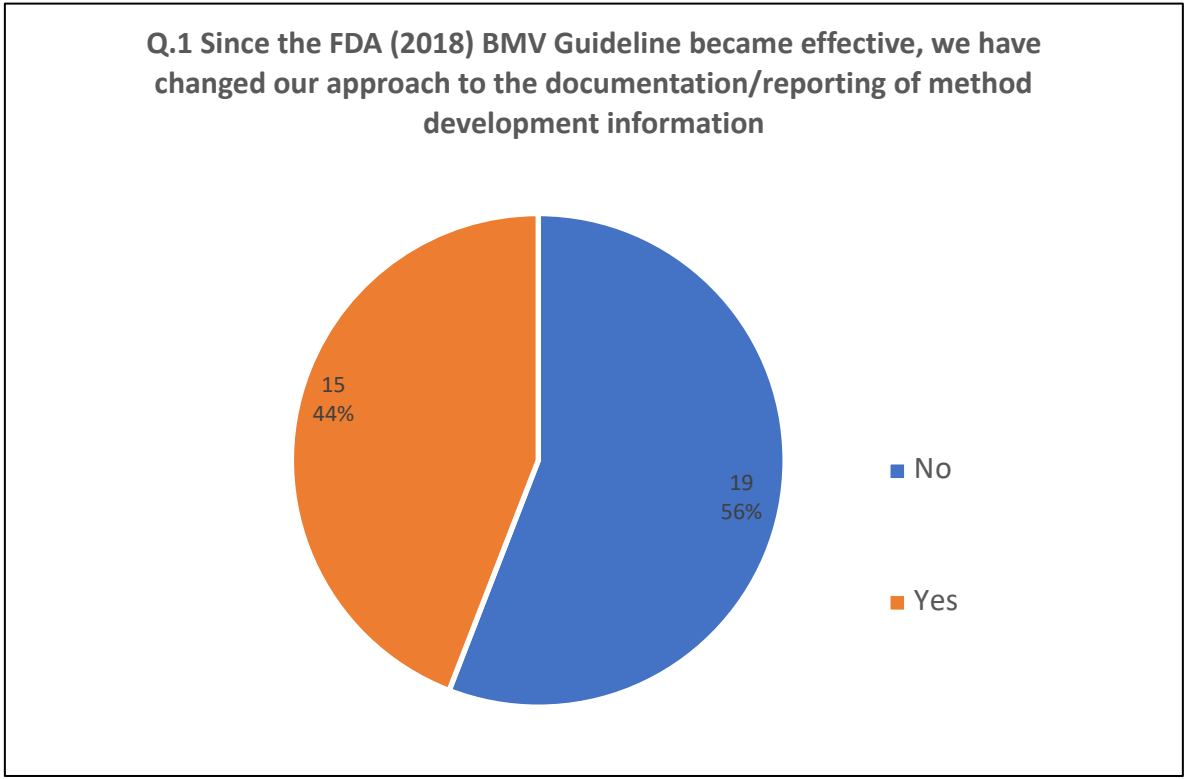
Interpretation of Guidelines

Steve White, on behalf of the EBF

Introduction

- Since 2018, increased discussion regarding method development documentation and interpretation of HA expectations
- At 11th EBF Open Symposium, feedback from FDA that the Agency expects "method evolution" information and **not** detailed method development reporting
- We continue to see industry uncertainty regarding level of detail required
- Concern that we as industry may be over interpreting HA expectations un-necessarily
- Survey to EBF members
  - 34 responses (19 CRO, 15 Pharma)

Survey Responses



Representative Comments from Question 1

Only for re-validated methods
We add a section in the study diary, Validation report describing what issues we experienced and what we are re-validating.

Brief description of key meth dev experiments (which are not repeated during validation) and/or changes from previous assay, are included in the validation report

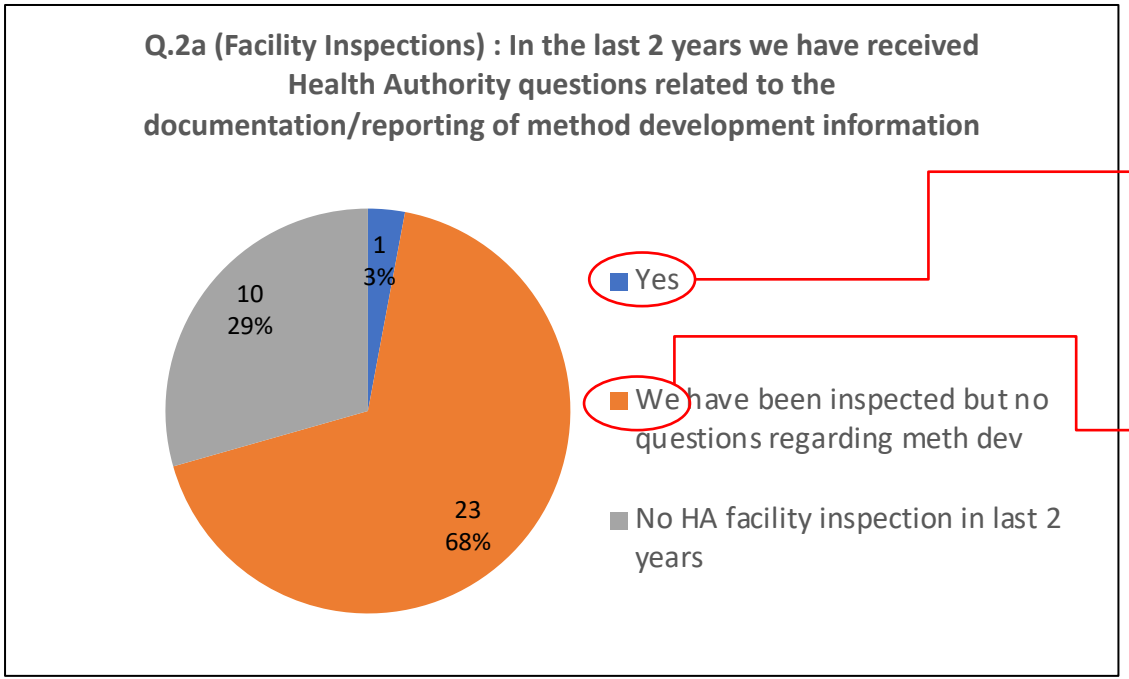
We include a ‘change of method’ description in the validation reports which shortly describe what the changes to the validated method were or the evulation of the method, respectively. No separate or dedicated MD reports are generated.

We have introduced method evolution summary.

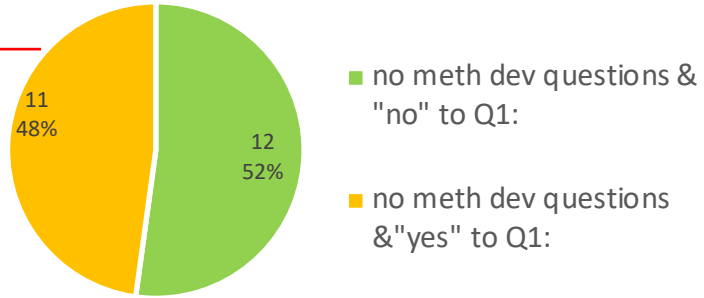
Include short summary of method development appended to Val report (1 page)

Although we have not changed our standard approach to MD reporting, we do see an increased interest of sponsors for separate MD reports, which we provide as an additional service, if so required. This happens occasionally, for both LC-MS and LBA studies

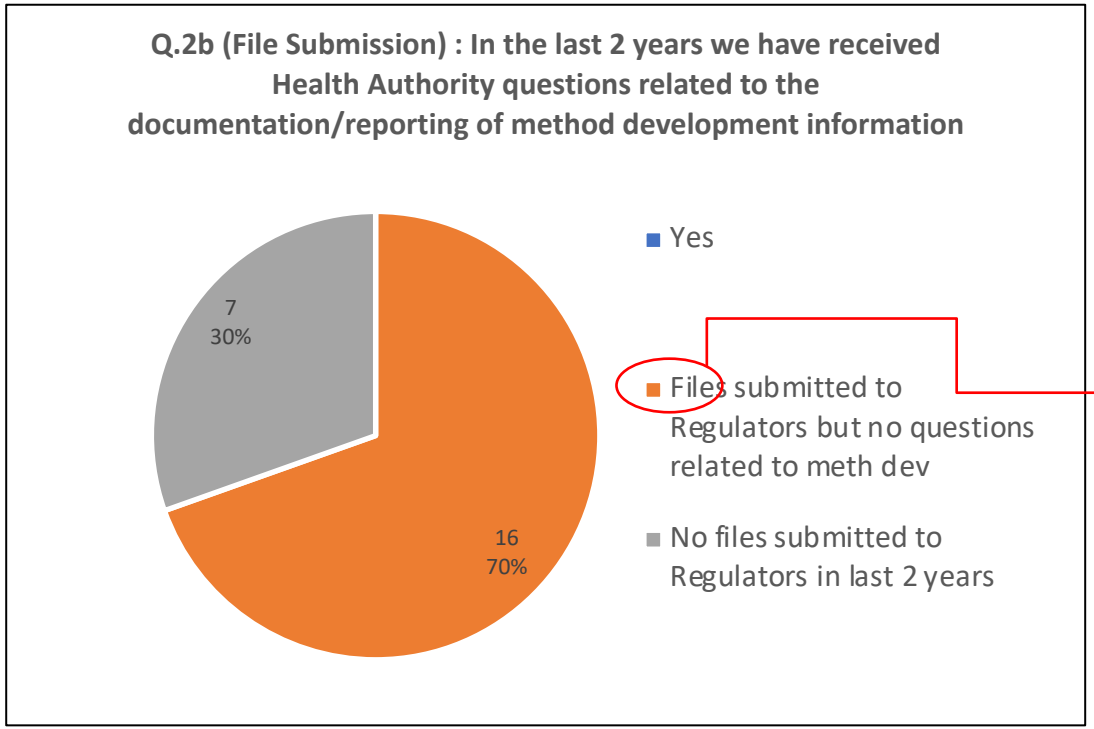
Survey Responses



"We did have an EMA inspection, approximately two years ago, which delved into method development projects but only in response to a specific audit finding. They did not come in with the intention of looking at the development work."



Survey Responses



Summary

- Currently around 50% of member companies have changed their approach to meth dev documentation & reporting, since the FDA (2018) BMV became effective
- Generally, any additional effort is limited to a brief summary of MD experiments and outcomes in the validation report
- Of the 24 companies inspected by Regulators in the last 2 years (facility inspections) one was asked about MD documentation - in response to a specific audit finding
- Of the 16 companies submitting files in the last 2 years, none received any meth dev questions
- **Are we worrying too much about this?**
- **Are we at risk of doing too much?**

For discussion during Q&A

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Contact Information

Questions: info@e-b-f.eu

European Bioanalysis Forum vzw

www.e-b-f.eu