Table 9: Software Considerations for Method Development and Data Evaluation

SESSION 1:
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SESSION 2:
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SCOPE:
Biopharma R&D and quality control operate on a wide range of analytical methods for the structural characterization of biologics and identification of impurities. The development of analytical methods and data handling require the use of specific software which not only has to fulfill technical but also data integrity requirements, depending on its intended use (GxP/non-GxP). This roundtable focusses on the evaluation of current laboratory practices, challenges and needs of analytical software regarding technical and compliance aspects.

QUESTIONS FOR DISCUSSION:
1. What are the main selection criteria for analytical software in a GxP, non-GxP or mixed environment?
2. What are the current challenges from a compliance perspective? In which areas do we need more vendor input, e.g. is compliant software available for all analytical techniques? Are the compliance requirements met with the software currently available?
3. Is current software suitable for platform-use? What are the advantages / disadvantages?
4. What are the current challenges from a technical perspective? Should data analysis require less user input (e.g. manual vs automated integration)? How comparable are data which were generated/processed by different software (e.g. missing values, protein grouping in MS software…)?

DISCUSSION NOTES:
Vision of optimal software:
- Audit trail, traceability and reproducibility in GMP are necessary as well as audit trail review support in the software.
- Data integrity should be controlled.
- Automatic processing and report generation tools would be optimal. I.e. possibility for generating templates for data processing and good options of handling of large amount of data.
- Data transfer between software from different vendors should be possible without addition data verification steps

Issues:
- Each new instrument brought into the laboratory comes with new software e.g. coupling CE and MS might require two different softwares.
- One software platform for several instrument types would be optimal. E.g. Empower was mentioned as an example of software that can control more types of instruments.

- With instrument specialized software there might be issues with locating and re-analyzing data years later after the equipment has been taken out of service. Readability of data years later when software or operating systems have been outdated was similarly also considered an issue. How can we ensure continuous of accessibility of data when softwares evolve.
- Automation software might solve some issues, but can the analytical procedures be validated. There are differences in needs between methods development (no validation) and QC methods. Automation might help validation procedures and data processing and reporting.

Knowledge sharing and informatics:
- When a single product is analyzed throughout its lifecycle e.g. research, CMC and production phase how can data and knowledge be captures across? Data might reside on different systems, different sites and different instruments. No clear solution on how to capture data and knowledge across.
- What data are important to capture and why. Raw file, processed data?
- Software to capture all data and integrate and extract meta-data would be optimal and replace local excel sheets. How to extract important information?
- Need a common definition of what industry needs in order to develop such a software.

Method development and DOE:
- Software to help DOE and develop analysis conditions in method development would be an advantage. This could support decision making in method development. Currently this is most often a manual decision and scientist (and experience) dependent.