Roundtable Session 1 – Table 3 – Recent Trends in Questions from Health Authorities

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Abstract:

This roundtable will offer attendees the opportunity to share trends on questions from FDA or other global health authorities during CASSS WCBP2025. We offer space for regulatory peers to come together to share insight on questions that are commonly arising, giving an opportunity to benchmark against other attendees' experience and share common practice. Discussion questions are suggested in line with observed trends however space will be made available for attendees to offer alternative discussion points. Time will also be given to consider how newer regulatory tools might support the sharing of intelligence on questions from health authorities to expedite speed to patient.

Discussion Questions:

1. What three trends in questions are you experiencing over the past 12 - 24 months?
e.g. specifications, analytics, document formatting (e.g. tabulation, structured data req'ments)

2. ICHQ12 established conditions have been implemented in US, Japan and China while other territories are in the process of doing so (E.g. Europe, Canada, Brazil, Mexico - have you made use of the guidelines and what has been your experience?

3. With respect to newer, innovative medicines, how well equipped have you found agencies to be to embrace these? Are more extensive justifications required, do you feel some territories are better prepared than others?

4. Geopolitics impacts what regulatory agencies will prioritize in their territory, do you experience this complexity in questions and in what what?

5. Future facing regulatory tools: have you/your organisation considered if any of the following might support how you deal with questions from health authorities...i) use of AI to spot trends in questions and mitigate for smoother submissions; ii) industry wide sharing of questions (anonymised) using, for example, a safe cloud technology platform for whole of sector insight; iii) use of reliance pathways to build a global dossier with sharing of questions/answers amongst multiple HAs?

Notes:

Gross content

- Companies getting asked for two sided range on DP gross content. In one case (liquid DP), an in process weight check was accepted. In another case, the release gross content test was required on CoA. More recently, the specification test is being required.

- Gross content limits may be wide in the case of weight-based dosing. May need multiple vial sizes.

In use studies

- Do you need to repeat at end of shelf life? In most cases, yes (differs among agencies). May not have it at time of submission, but would be in the protocol.

HCP – commercial kits

- Acceptability depends on sufficient coverage. No strict guideline. 75% likely ok. Definitely have to be better than 50%.
- Sponsor could consider using orthogonal methods (mass spec etc)

Leachables studies

- Number of lots used for commercial DP. Is three necessary? Three is gold standard. Justification for one will be difficult.
- For DS, risk assessment can be sufficient.

Increased number of questions related to deep technical detail, previously accepted practices. More requests for info in annual reports (risk assessments for changes, technical data on new equipment)

- Could be related to reviewers wanting to share collective knowledge across sponsors
- Could be related to agency prioritizing sponsors/facilities for inspection
- At FDA, annual report is not reviewed, it's assessed to determine whether changes are appropriately classified

One sponsor received an IR on a CBE30 months after submission. Another received a hold 4 months after CBE30 submission.

- Could be related to agency workload. Reviewer may need more time
- Fostering the relationship/collaboration with FDA project manager can be helpful. Some pm's are very responsive.
- If agency proposes very short timeline for response, helps to be clear on what info will be submitted when
- Sponsor couldn't meet timeline for PMC, asked for more time and was granted
- Sponsors should be mindful of when they submit (before holiday may not be advantageous etc)