Roundtable Session 1 – Table 10: Continuous Manufacturing - Continued Implementation of ICH Q13 Worldwide

Facilitator: Sydia Dunkley, *Hoffmann-La Roche Limited*

Scribe: Camilla Oxley, *Johnson & Johnson*

Abstract:

Following the final version of ICH Q13: Continuous Manufacturing of Drug Substances and Drug Products in November 2022, the Pharmaceutical Industry and Health Agency regulators have been collaborating to support Continuous Manufacturing (CM) technology and engage in active discussions to grow experiences in aid of successful implementation. The regulatory expectations concerning assurance of reliability, traceability, programmed processing, risk-based design, and relevance to product quality in a production setting are the same for batch and continuous processing. Moreover, as the years persists the Industry is abandoning traditional manufacturing practices in favor of integrated processes with reduced steps supporting faster response times, safer production with less bulky equipment and more enhanced development approach following quality by design. All these factors produce more efficient and easier changes in scale supporting supply needs globally and speed to patients.

This roundtable session will explore discussions on the implementation of Continuous Manufacturing worldwide, as well as the associated benefits and challenges.

Notes:

Hand full of Small Molecule processes out there have used continuous processing (like Vertex) but not for biologics. Members are researching to find cases out there.

Approval assessment not very defined, like perfusion processes not 'labelled' Continuous Manufacturing for example.

ICH Q13 guidance document for continuous manufacturing (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://database.ich.org/sites/default/files/ICH_Q13_Step4_Guideline_2022_1116.pdf), 3 bullet points for definition. Discussion about how to switch from batch to continuous. A few companies explored it and submitted; questions came up as to batch size. How to define a batch? Description in the ICH guidance is very broad.

Comparability is complex.

This is still a new topic in biologics.

Semi continuous processes are being developed where bottle neck steps being made continuous. However it was discussed that adoption of CM has been slow and below article came up.

https://www.sciencedirect.com/science/article/abs/pii/S0022354919304514

Footnote: Apart from the facilitator and scribe only 2 other conference attendees joined the table.

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