7 — Overview of the proposed ICH Q14 and current developments in Japan

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It is a great pleasure that this seminar afforded the Pharmaceutical Regulatory Science Team in the Dublin Institute of Technology an opportunity to extend a warm welcome to our esteemed and learned colleague Dr Yukio Hiyama on his return to Dublin to share his insights and knowledge with us.

In his closing address to the seminar delegates Dr Hiyama shared an overview of current developments in Japan with respect to medicinal product regulation. He began by addressing what is happening with the Submission/Approval process in Japan, confirming that the Japanese Medicines Regulator, PMDA, had commenced a trial in early 2018 of a new *Comparability Protocol* which was prompted by the international work of the ICH Q12 Post Approval Change Management Plan. In addition, the Ministry of Health Labour and Welfare (MHLW) has published a rational (simplified) *Description Rule for Test Methods* which will now be considered as approval matter within any submission.

Dr Hiyama then shared that within the regulatory process in Japan they have convened a QbD study group which actively contributes to new regulatory developments across a number of subgroups, including Active Pharmaceutical Ingredients (API), ICH Q12 and Post Approval Change Management, Continuous Manufacturing, Control Strategy and Analytical QbD. Both of the new work products included in the submission / approval process outlined above were based on outputs from this study group.

On the subject of what is happening in Japan with regards to the GMP Process, in 2014 the MHLW published a study based on an industry survey which showed that 30% of Japanese GMP Managers were not aware of the 2008 ICH Q10 *Pharmaceutical Quality System* (PQS) guideline. Arising from that, in 2016, the QbD study group developed a PQS-based model for continual improvement as well as producing an example of a typical *PQS Quality Manual*. This has now been adopted by the PMDA inspection division and earlier in 2018 they presented how they will evaluate each organisation’s PQS using this new *PQS Model*. To further strengthen the importance placed on the PQS, Dr Hiyama confirmed that it will be incorporated into the overall GMP Ordinance in 2019 or 2020. A final development shared was that a new revision of the Good Distribution Practice (GDP) guideline has recently been published by the MHLW study group.
Moving to his continued work with the International Conference on Harmonisation (ICH) Dr Hiyama has been appointed as rapporteur for an exciting new ICH topic which will involve two work streams: a revision of ICH Q2(R1) Analytical Validation and the development of a new ICH guidance entitled Q14 Analytical Procedure Development. The General Assembly of ICH approved Q2/Q14 (and Q13 Continuous Manufacturing) as new topics in their June 2018 meeting based on a proposal round which had started in early 2017. At that time the US FDA proposed the need for a Q2 revision while the MHLW proposed the need for a new guideline for Analytical Development. Consequently ICH Q2/Q14 will align both topics going forward. The final concept paper for Q2(R1)/Q14 has been prepared and the first face-to-face meeting of all parties is scheduled for the USA in November 2018.

His friends at colleagues within the PRST commend Dr Hiyama for his tireless dedication to the development of new knowledge which continues to drive improvement in the regulation and manufacture of high quality medicines to the benefit of patients around the world.

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