BRITISH PHARMACOPOEIA COMMISSION

Working Party AQbD: Analytical Quality by Design

SUMMARY MINUTES

A meeting of this working party was held via videoconference on the 9th December 2020.

Present: Dr G Cook (*Chairman)*, Dr K Barnett, Dr P Borman, Dr M Chatfield, Dr S Ellison, Dr M Hanna-Brown, Dr B Harrington, Mr S Jones, Dr P Nethercote, Ms E Razzano, Mr S Young

In attendance: Mr J Pound, Mr S Maddocks and Mr L Elanganathan. Ms A Thomson attended the meeting as an observer.

Apologies: None

66 **Introductory Remarks**

Welcome The Chair welcomed members to the sixth meeting of the Working Party AQbD: Analytical Quality by Design. And introduced changes to the Secretariat function supporting the working party.

67 **GENERAL MATTERS** **AQbD(20)01**

Confidentiality Members were reminded that all papers and minutes were confidential and should not be disclosed outside the BP Commission.

Declaration of Interests Members were thanked for providing their interests prior to the meeting. Members were reminded to inform the Secretariat of any changes to their interests throughout the year.

68 **Global updates** **AQbD(21)02**

Members provided updates on the development of ICH Q2, Q12 and Q14 Guidelines from an industry perspective.

69 **Atorvastatin Tablets monograph** **AQbD(21)03**

The Secretariat presented the draft BP monograph for Atorvastatin Tablets following the Analytical Target Profile (ATP) study to assess the suitability of the Assay method for compendial use. The Expert Advisory Group: Medicinal Chemicals 2 (MC2) approved the monograph to be placed on the BP Website for public consultation in Q1 2021, prior to publication in the BP 2022.

70 **Guidance and supporting information** **AQbD(21)04**

An outline for a BP Supplementary Chapter on Analytical Quality by Design techniques was presented to the group. Members discussed the drafted chapter outline and agreed that it should be produced for public consultation prior to publication in the BP 2022.

Members discussed other aspects of guidance that could potentially fit in to the chapter, and it was agreed that these aspects could form part of subsequent revisions to the Supplementary Chapter.

71 **The Analytical Target Profile** **AQbD(21)05**

The Secretariat introduced developments around the Analytical Target Profile, and discussed how it can be applied to the Pharmacopoeia. The Secretariat agreed to deliver project proposals for the group to deliberate and workshop at a future meeting.

72 **Further practical investigations (CQAs)** **AQbD(21)06**

The Secretariat presented discussion topics in order to progress the Working Party's work programme action point which aims to practically investigate the application of AQbD principles for other Critical Quality Attributes (CQAs) of pharmaceutical finished products and tests.

It was concluded that the application of AQbD principles would be most suitable for fully quantitative methods. As such, it was agreed that a practical project investigating the application of these principles for a Related substances test would bring most benefit to users.

73 **Developing Capabilities** **AQbD(21)07**

A number of areas for development of capabilities to allow the group to push forward on each of the strategic aims was presented to the members.

It was agreed that the Secretariat should present a full gap analysis of the Working Party membership to the Chair, as well as to reach out to specific members regarding software/IT infrastructure that would be beneficial.

74 **Engagement Strategies** **AQbD(21)08**

A number of events that the AQbD work was either presented at, or was to be presented at were introduced to members who also raised potential seminars.