

BRITISH PHARMACOPOEIA COMMISSION

Working Party AQbD: Analytical Quality by Design

SUMMARY MINUTES

A meeting of this working party was held via videoconference on the 11th May 2021.

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.

Apologies: None

75 **Introductory Remarks**

Welcome The Chair welcomed members to the seventh meeting of the Working Party AQbD: Analytical Quality by Design.

76 **GENERAL MATTERS**

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.

77 **Relevant updates**

The Secretariat informed members that a project exploring the applicability of an Analytical Target Profile would be initiated in the near future. Members were also notified that the joint BP-USP webinar would be held over 30 September and 01 October 2021.

Members gave updates on the development of ICH Q2/Q14 chapters and the USP's General Chapter <1220>.

78 **Supplementary Chapter**

The Secretariat presented comments on the draft Supplementary Chapter received during the stakeholder consultation. Several major changes were agreed based on the comments.

The supplementary chapter would be published in a future edition of the British Pharmacopoeia.

Several comments were made during the consultation period that suggested the Analytical Target Profile should be included, but it was felt that the concept of the ATP was not sufficiently defined for inclusion at this stage.

Lab project design: Related substances procedure

Several members declared an interest in this item and were invited to participate in the discussion.

The Secretariat presented a proposal following previous discussions held 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 agreed that an investigation into a Related substances test would bring most benefit to users, and the corresponding test in the family of Sumatriptan BP monographs had been identified as a suitable candidate.

A draft laboratory project had been presented, and members agreed to work with the Secretariat to develop a suitable experimental design to investigate a revision to the tests.

V**ANY OTHER BUSINESS**

The Secretariat informed members that a membership review was underway, and that an external call for expressions of interest was expected be carried out by June 2021.