

BRITISH PHARMACOPOEIA COMMISSION

Working Party AQbD: Analytical Quality by Design

SUMMARY MINUTES

A meeting of this Working Party was held at 151 Buckingham Palace Road, London SW1W 9SZ on Monday, 3rd October 2016.

Present: Dr G Cook (*Chairman*), Dr K Barnett, Prof M Hanna-Brown, Dr B Harrington (via web conferencing), Dr P Nethercote, Ms M Chatfield.

In attendance: Mr J Pound, Dr G Kemp, Mr S Young, Dr A Gardiner, Mr S Jones, Ms E Razzano, Mr A Gibb. Mr A Gibb attended the meeting for the item discussed under minute 48.

Apologies: Dr S Ellison, Mr P Crowley, Dr S Brown, Mr D Makohon.

35 **Introductory Remarks**

35.1 **Welcome** The Chairman welcomed members to the third meeting of Working Party AQbD: Analytical Quality by Design. Dr Harrington would participate during the meeting via web conferencing.

I **MINUTES**

36 The minutes and summary minutes of the meeting held on 18th September 2015 were confirmed.

II **Matters arising from the minutes**

37 The following matters arising from the meeting held on 18th September 2015 were noted.

Discussion 1 (minute 27) Members noted the proposed industry case study.

Discussion 2 (minute 28) Members discussed a recent trade/industry association meeting considering the application of AQbD and noted that companies developing small molecules were very well suited to AQbD concepts and these concepts were now moving into biologics.

Discussion 3 (minute 32) The Chairman noted that the investigation of interactions and method bias from the Design of Experiment (DoE) work had been completed and a report was to be presented later in the meeting.

Discussion 4 (minute 33) The Chairman noted a Subgroup had met to investigate measurement uncertainty approaches for qualification of the ATP. A report was to be presented later in the meeting.

Members agreed that a high-level summary document, detailing the actions of the meeting, would be useful if it were to be circulated soon after the meeting.

III **GENERAL MATTERS**

38 **Location** **AQbD(16)01**

Location and transport arrangements to the MHRA headquarters in London were

provided to members for information.

39 **Emergency Evacuation Procedure** **AQbD(16)02**

Members were presented with a paper on the emergency evacuation procedure.

40 **BP 2017** **AQbD(16)03**

The Secretariat noted that the BP 2017 had been published in August 2016 and would come into effect on 1st January 2017. Members were informed that they should receive their login details for the BP 2017 online shortly, which was the default product format for experts to the British Pharmacopoeia.

41 **BP Team Structure** **AQbD(16)04**

An updated organogram for the British Pharmacopoeia and Laboratory Services Group was provided for information.

42 **Membership** **AQbD(16)05**

Members were asked to confirm the contact details listed and to inform the Secretariat of any amendments required.

IV REPORTS AND CORRESPONDENCE

43 **Strategic Overview** **AQbD(16)06**

The Secretariat presented an overview of the strategic direction of the AQbD WP. Members discussed the scope of the project, learnings to date and ideas for future work.

44 **Industry Update** **AQbD(16)07**

Members provided presentations on the application of QbD principles to analytical methods from an industry perspective.

45 **USP Update** **AQbD(16)08**

Members presented an update from a USP perspective of AQbD application.

46 **Method Investigation Conclusions** **AQbD(16)09**

The Secretariat presented the conclusions of the Design of Experiment work investigating an assay method for Atorvastatin tablets. Members endorsed the conclusions and accepted the method.

47 **Feedback from the Analytical Technical Profile (ATP) Subgroup** **AQbD(16)10**

47.1 The findings of the ATP Subgroup were presented to the group. Five draft ATPs were presented. Dr Steve Ellison was acknowledged for his expertise in developing the presented ATPs.

47.2 A presentation on ATPs for dissolution methods was given to the group and members discussed the topic.

48 **Alternative Approaches to BP Biological Monographs** **AQbD(16)11**

The Secretariat presented a review of the work of the Biological and Biotechnological Products Expert Advisory Group with respect to a new monograph format. Members discussed the work and noted the overlap with the AQbD Working Party.

V ANY OTHER BUSINESS

49 None

VI DATE OF NEXT MEETING

The next meeting will be confirmed at a later date.