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 Friday, 18 September 2015.

Present: Dr G Cook (Chair), Dr K Barnett (via web conferencing), Dr S Brown, Dr S Ellison, Prof M Hanna-Brown, Dr B Harrington (via web conferencing), Dr P Nethercote.

In attendance: Mr P Crowley, Mr S Jones, Mr D Makohon, Mr J Pound, Ms E Razzano, Mr S Young, Dr K Courtney (BP Lab), Mr S Wilson (BP Lab).

18 **Introductory Remarks**

Welcome The Chairman welcomed members to the second meeting of Working Party AQbD: Analytical Quality by Design. Dr Barnett, a corresponding member, and Dr Harrington, an invited expert, would participate during the meeting via web conferencing.

Staff Changes Members were informed that following the retirement of Mrs Matilda Vallender, Mr James Pound had been appointed as the new Editor-in-Chief. Mr Alistair Gibb had been promoted to the role of Principal Pharmacopoeial Scientist and BP publications coordinator.

BP website Members were informed that the new BP website, www.pharmacopoeia.com had been launched. The new website consolidated both the publication and the content from the .co.uk and gov.uk websites.

Expense Claims Members were invited to contact Mr Wayne Jeffries for enquires concerning expenses claims.

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 reminded of the need to inform the Secretariat of any changes to their interests throughout the year and of the need to declare any specific interests at the start of relevant discussions during the meeting.

I MINUTES

19 The minutes and summary minutes of the meeting held on 16th September 2014 were confirmed.

II Matters arising from the minutes

20 The following matters arising from the meeting held on 16th September 2014 were noted.

Discussion 1 (minute 16) The Secretariat is to develop proposals on how further guidance on some of the principles outlined in the feasibility study could be included in aspects of the pharmacopoeia that provide general guidance.

III GENERAL MATTERS

21 **Location** **AQbD(15)01**

Location and transport arrangements to the MHRA headquarters in London were provided to members for information.

22 **Emergency Evacuation Procedure** **AQbD(15)02**

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

23 **BP 2016** **AQbD(15)03**

The Secretariat noted that the BP 2016 had been published in August 2015 and would come into effect on 01 January 2016. Members were informed that they should receive their login details for the BP 2016 online shortly, which was the default product format for experts to the British Pharmacopoeia.

24 **Secretariat Organisation** **AQbD(15)04**

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

25 **Membership** **AQbD(15)05**

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

26 **BP Website** **AQbD(15)06**

The Secretariat provided a brief overview demonstrating the new features of the BP website including navigation of the publication and how to use the updated BP Forum.

IV REPORTS AND CORRESPONDENCE

27 **Industry update** **AQbD(15)07**

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

28 **IQ Survey Overview** **AQbD(15)08**

Members discussed a summary of results from a survey investigating the implementation of AQbD concepts. This survey was conducted on behalf of a sub team from the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ).

29 **Regulatory update** **AQbD(15)09**

The current regulatory perdpective on the application of Quality by Design to analytical methods was discussed

30 **Pharmacopoeial update** **AQbD(15)10**

A summary of current compendial initiatives and policies with regards t Quality by Design was presented by the Secretariat

31 **Review of Atorvastatin Tablets Design of Experiments Report** **AQbD(15)11**

The Secretariat presented a road map describing the high level activities of the working group. The Secretariat then provided a summary of the experimental assessment which had been deferred from the previous Working Party meeting.

32 **Investigation of interactions and method bias identified from DoEs** **AQbD(15)12**

The Secretariat presented a summary of discussions concerning the key areas highlighted by the experimental assessment for further investigation.

33 **Next Steps** **AQbD(15)13**

Members discussed what the next steps were for the BP/MHRA project.

V ANY OTHER BUSINESS

34 Members discussed what additional expertise would complement the membership of the working party.

VI DATE OF NEXT MEETING

The next meeting will be confirmed at a later date.