

Working Party AQbD: Analytical Quality by Design

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 Tuesday, 16 September 2014.

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

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

1 **Introductory Remarks**

Welcome The Chairman welcomed members to the first meeting of Working Party AQbD: Analytical Quality by Design. Dr Barnett was a corresponding member and would participate in meetings via web conferencing.

Dr Nethercote and Mr Young were unable to attend in person due to other commitments. Both participated via web conferencing.

Expense Claims Members were invited to contact the BP Secretariat 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 **GENERAL MATTERS**

2 **Location** **AQbD(14)01**

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

3 **Emergency Evacuation Procedure** **AQbD(14)02**

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

4 **Introduction to the MHRA** **AQbD(14)03**

An overview of the role and structure of the Medicines and Healthcare Products Regulatory Agency was provided to members for information.

5 **Membership** **AQbD(14)04**

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

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14 **Introduction to the BP/MHRA Feasibility Study** **AQbD(14)13**

The Secretariat presented a summary of the British Pharmacopoeia/MHRA project to investigate industry initiatives regarding the application of QbD principles to analytical methods

15 **Review of Atorvastatin Tablets Design of Experiments Report** **AQbD(14)14**

It was agreed that this item would be deferred pending the completion of the statistical assessment of the DoE results.

16 **Discussion 1 - Introduction and initial discussion of the ATP concept (application to the pharmacopoeia)** **AQbD(14)15**

The Secretariat presented a number of published papers regarding the application of the ATP concept as well as a number of initial opening questions to stimulate debate and members discussed the concepts presented.

17 **Discussion 2 – The application of QbD to analytical procedures in the pharmacopoeia** **AQbD(14)16**

This item was deferred to the next meeting due to time constraints.

III ANY OTHER BUSINESS

NA

IV DATE OF NEXT MEETING

The next meeting will be conformed at a later date.