

BRITISH PHARMACOPOEIA COMMISSION

Working Party BIO-DPS: Alternative Approaches for Documentary and Physical
Standards for Biotechnological Products.

SUMMARY MINUTES

A meeting of the Working Party was held at 151 Buckingham Palace Road, Victoria, London SW1W 9SZ on Thursday 17th May 2018.

Present: Dr A M Brady (*Vice Chair*), Dr C Burns, Dr B Cowper, Dr L Both, Dr B Rellahan, Dr N Czeloth, Dr L Duhau, Dr M Wild, Mr C E Giartosio, Dr G Cook.

In attendance: Mr A Gibb, Mr J Pound, Dr A Gardiner, Dr K Radi.

Apologies for absence were received from Dr P Varley and Dr A Ramzan.

Opening Remarks

Welcome The Vice Chair welcomed everyone to the meeting. Members introduced themselves and gave brief overviews of their background experience in relation to the work of the working party.

1 General matters

BIO-DPS(18)01

Emergency exit The emergency evacuation procedure was confirmed.

Duties of members Members had been provided details of their duties as experts on a British Pharmacopoeia Working Party. These had been taken from volume one of the BP.

Working Party membership The Working Party membership and contact details had been provided.

Background to the MHRA and BP Members had been provided with a slide-deck containing background information regarding the BP and MHRA. These had been provided for information and were not presented in the meeting.

2 Overview – Putting the work into context

BIO-DPS(18)02

Background about the Agency's consultation on Strategy for Pharmacopoeial public quality standards for biological medicines was presented by the Secretariat. This work was supported by a Cross-agency group involving MHRA Licensing Department, NIBSC and the British Pharmacopoeia. The Working Party for Alternative

Approaches for Documentary and Physical Standards for Biotechnological Products (WP DPS) had been established as a result of the strategic work programme, published by the Agency following the consultation.

3 Performance and Class based Concepts **BIO-DPS(18)03 - 06**

Several potential performance and class based concepts were presented by members of the group. The Working party discussed the concepts, noting the overlap in ideas and terminology

4 Ways of working **BIO-DPS(18)07**

The Secretariat provided proposals for a roadmap which detailed a plan for progressing the work, including proposed steps and timelines.

An example matrix was presented, and workshop was used to discuss the possible candidates and projects to be assessed.

The Secretariat undertook to circulate high level meeting outcomes and the partially-complete matrix to the group for comment.