

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 via Teleconference on Monday 6th December 2021.

Present: Dr P Varley (*Chair*), Dr A M Brady (*Vice Chair*), Dr C Burns, Dr B Cowper, Dr L Duhau, Mr C E Giartosio, Dr A Ramzan, Dr B Rellahan, Dr F Plath.

In attendance: Mr A Gibb, Dr G Kemp.

Apologies: Dr V Ganeva.

Opening Remarks

Welcome The Chair welcomed everyone to the meeting.

I GENERAL MATTERS

- 19.1 **Expense Claims** Members were reminded to contact Mr Brian Delahunty on 020 3080 6144 (brian.delahunty@mhra.gov.uk) should they encounter any problems with their claims.
- 19.2 **Confidentiality** Members were reminded of the confidential nature of the papers, discussions and minutes of the meeting.
- 19.3 **Declaration of Interests** Members were reminded that they are required to inform the BP team of any changed to their interests.

II MINUTES

BIO-DPS(21)01

- 20 The minutes and summary minutes of the meeting held on the 27th November 2020 were confirmed.

III REPORTS AND CORRESPONDENCE

21 Recap: project aims and progress to date

BIO-DPS(21)02

The project was summarised and key milestones outlined.

22 Round robin data analysis

BIO-DPS(21)03

The data from the round robin experiments were presented and discussed. Members focussed discussions on the performance of the methods, particularly in terms of accuracy and precision.

23 Evaluation of draft standards

BIO-DPS(21)04

The data from the round robin experiments were assessed against previously drafted method performance and method capability standards.

24 Ph Eur Proposed Monoclonal Antibody Standards BIO-DPS(21)05

Proposed new and revised European Pharmacopoeia standards which had recently been published for public consultation (Pharmeuropa) were considered by members.

Members noted the shift to more flexible biological standards from global bodies.

25 ANY OTHER BUSINESS

26 NEXT MEETING

The date of the next meeting was to be confirmed at a later date.