BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group ATMP: Advanced Therapy Medicinal Products 8th Meeting

SUMMARY MINUTES

A hybrid meeting of this Expert Advisory Group was held in person and via MS Teams on Monday 29 September 2025 commencing at 10:00 AM and continuing into the afternoon.

Present in person: Jacqueline Barry (Chair), Christian van den Bos, Rehma Chandaria, Kimberley Gilmour, Alan Griffith and Ishtiaq Khaliq

Present online: Clare Blue, Chris Burns, Leanne Di Rollo, Janet Glassford, Lyn Healy, Claire Kerridge, Mark Lowdell, Keith McLuckie, Chaminda Salgado, Isobel Searing, and Caroline Weydert

In attendance: Ryan Smith, Kajetan Rakowski, and Rachael Feltham

Apologies received: Ian Rees, Steven Vinter, and Louise Bisset

Observing: Hayley Hall (in person)

1. General Matters ATMP(25)01

The BP Secretariat outlined recent MHRA changes, including the appointment of Professor Anthony Harndon as Chair from January 2025 and Lawrence Tallon as CEO since April 2025. Key updates included £6 million funding for the UK CERSI project to advance regulatory science and innovation, and the launch of a digital hub in Leeds, operational from October. Members were reminded about confidentiality, Freedom of Information processes, expense claims, and declaring interests, with queries directed to the BP Secretariat.

2. Minutes and Matters Arising

The BP Secretariat reviewed and confirmed the November 2024 meeting minutes, which were accepted without objections and will be published on the website. It was noted that work on CMC and GMP considerations for cryopreservation of cell products, discussed previously, has not yet started but remains a priority, with plans to begin by the end of Q1 2026 when resources allow.

3. Progress Report (General Update) ATMP(25)02

The BP Secretariat updated the group on the transition from working parties to an Expert Advisory Group (EAG), reflecting its more permanent status while individual working parties remain active for up to a year post-publication for urgent revisions. Guidance on replication competent virus (RCV) testing is set for release following consultation, and digital/qPCR protocols for vector copy number are expected by year-end. New working parties have been established for CRISPR Cas9 off-target effects, encapsidated DNA, and capsid protein characterisation, with progress resuming after recent reappointments. Plans for a GMP and CMC working party on cryopreservation of cell-therapy products remain delayed due to capacity but will commence once current guidance is published and resources allow.

4. Encapsidated DNA Characterisation ATMP(25)03

The Scientific Lead presented the draft Encapsidated DNA Characterisation guidance, outlining methodologies such as next-generation sequencing, qPCR, and digital PCR, along with their strengths, limitations, and regulatory considerations. The draft includes sections on terminology, methodology, and summary tables, and the group agreed it should focus on best practices and key considerations rather than detailed protocols to keep it current and accessible. The importance of patient and public involvement was highlighted, and the group will consult the MHRA patient engagement team to discuss the appropriateness of including these perspectives are reflected in the final guidance.

5. Capsid Protein Characterisation ATMP(25)04

The Scientific Lead updated the group on the Capsid Protein Characterisation guidance, focusing on methodologies, regulatory context, and challenges such as low assay throughput, high sample requirements, and inter-lab variability. The guidance will include sections on terminology, methodology, and summary tables, with efforts to keep best practice recommendations current. Alignment with the encapsidated DNA guidance was emphasised, with suggestions to add flow diagrams, checklists, and practical points for clarity. The impact of production platforms like baculovirus and HEK systems will be acknowledged, and future updates may incorporate emerging disruptive technologies to maintain relevance.

6. CRISPR Cas9 Off Target Effects ATMP(25)05

The Scientific Lead outlined early development of guidance on CRISPR Cas9 off-target effects, with the group agreeing on a conceptual, phase-based structure using summary tables rather than detailed protocols to keep it adaptable. The initial scope will focus on CRISPR Cas systems, with potential expansion to other gene-editing technologies like TALENs and zinc fingers. Ethical considerations and patient involvement were discussed, and the BP Secretariat will consult the MHRA patient engagement team to consider if it is appropriate to integrate these perspectives. The guidance may be published as an MHRA “points to consider” document.

7. Closing Remarks

The Chair and group agreed to tentatively schedule the next meeting for June 2026, focusing on horizon scanning to identify and prioritise emerging topics for future guidance. Updates from the cryopreservation work, yet to be initiated, and consideration of additional potential topics will also form part of the agenda, with the session intended to shape the direction of forthcoming guidance work.