

Volume 106

## **Evolving Scientific and Regulatory Perspectives on Cell Substrates for Vaccine Development**

Editors: F. Brown, A.M. Lewis, K. Peden, P. Krause

In September 1999, the cell substrate workshop entitled 'Evolution of Cell Substrates Used in the Manufacture of Biologicals' was held as a means to consider in depth the issues raised by the need to use neoplastic, i.e. continuous, cells as substrates for viral vaccine manufacture. Workshop goals included identifying the risks and concerns associated with the use of neoplastic cell substrates and determining the manner in which these could be assessed.

Volume 106 of *Developments in Biologicals* presents the edited proceedings of this workshop. It is the latest in a series of monographs that go back to 1967 and record the proceedings of meetings devoted to issues concerning the use of cells cultured *in vitro* as substrates for the manufacture of viral vaccines. The current workshop covered the following:

- a review of the history of cell substrate use in the production of biologicals
- scientific issues related to the development of the neoplastic state and tumorigenicity
- viral-viral and viral-cell interaction
- the oncogenic potential of residual cell substrate DNA
- adventitious agent testing
- ways to generate immortalized cells *in vitro*

The purpose of these discussions was to build on the concepts and precedents for the scientifically based regulatory management of viral vaccines documented in the earlier monographs.

It is the hope of the meeting organizers and sponsors that this volume will assist in generating confidence among vaccine developers, manufacturers, regulatory agencies and the general public that the use of neoplastic cell substrates, within an effective and reasoned regulatory approach, is feasible.

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Co-Chairs: *Elwyn Griffiths* (World Health Organization - WHO), *Martin Myers* (National Vaccine Program Office - NVPO)

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A Brief History of Cell Substrates Used for the Preparation of Human Biologicals: *L. Hayflick*

Major Issues Associated with the Use of Cell Substrates for the Production of Vaccines: *E. Griffiths*.

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Panel Chair: *Stephen Hughes* (FCRF/NCI)

Panel Members: *N. Rosenberg, S. Ruscetti, C. Patience, L. Evans, D. Purcell, P. Jolicoeur, R. Desrosiers, P. Berkhout, H. King, M. Linial, J. Kappes*

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Panel Members: *J. Sedivy, F. Fallaux, J. McDougall, M. Fried, S. Hughes, J. Löwer, D. Onions*

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A Defined-Risks Approach to the Regulatory Assessment of the Use of Neoplastic Cells as Substrates for Viral Vaccine Manufacture: *A.M. Lewis Jr., P. Krause, K. Peden*