

Summary of Session 3

- The origins of the present in vivo tests are in the earliest days of diagnostic virology and many come from the attempts to standardize preparations of poliovirus vaccine.
- In vivo tests offer amplification which a snapshot will not do.
- The systems introduce redundancy but do not detect all known viruses. The redundancy is a reassuring component of the assay

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- The volume of material that can be tested also limits assurances that all agents are detected. The volume is constant regardless of the size of the bioreactor. In general one detects agents present in $\sim 10^7$ cells.
- The assays have a certain defined failure rate of $<5\%$ though with multiple tests chance of disqualifying a lot is higher.

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- The catalogue of viruses keeps changing and makes certification a potentially changing target as new agents are discovered and new assays are developed
- Viral contamination has rarely been found but does occur most recently with CHO cells, examples reovirus and Cache Valley virus

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- Reagent and manufacturing controls decrease the likelihood of contamination.
- Testing can and should be targeted to the history of the cells and type of preparation. The current menu is not a fixed plate but rather a smorgasbord that can be altered with validated newer assays.
- There is real interest in the introduction of new assays.

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- The history of the current tests is reassuring and many new vaccines have been tested successfully based on the safety screening currently in place.
- Regulatory requirements and hence testing vary between Europe and the United States. Harmonization is to be desired.

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- PCR will prove a useful adjunct in defining new agents and offering redundancy. It is possible to screen for almost all DNA viruses at present. It can detect 10-100 copies per cell. Margin of safety depends on cells per dose.
- Experience with new cell substrates will drive innovation in the field. It is very difficult to change existing procedures; eg polio neurovirulence.
- There is not a good mechanism for long term safety monitoring of vaccine substrates