automating stem cell bioscience
from GMP to the clinic

Joint remedi/SCI transdisciplinary workshop

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Introduction: Andrew Webster, SCI Co-ordinator

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objective of the workshop

The principal objective of this Workshop is to discuss the primary role that different forms of process automation play and will play in making possible the clinical translation and commercial scale- up of stem cell based products and therapies, and the broader regulatory context within which they must operate.

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background

- Project on standardisation of biological markers
- Two views: managing and reducing variability across labs…but still need to allow local experimental protocols
- Push towards scale-up: from pre- to ‘Fordist’ mode of production of cell lines – developing the essential tools from a manual ‘cottage industry’ to automated process

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some central issues for debate

- securing repeatable cultures
- scalable cost effective GMP automation; when and how it may be achieved and what hurdles might be anticipated on the way.
- what is the relationship between our understanding of cells, the requirements for their use, and the measurement methods we use to characterise cells

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transdisciplinary questions: dealing with material culture

- When are material differences to be seen as a resource and when to be removed?
- Does material receive differing recognition: different views about automation of mouse fibroblast culture compared with hESCs because of clinical importance of latter
- Dealing with the materiality of hESCs in automation : e.g a) how do automated process technologies accommodate biological variation? b) hESCs tend to grow adherently which may mean scaling for product manufacturing is difficult

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and human cultures…

- Role and knowledge of technicians – what makes cells ‘happy’ – the technician's ‘gaze’
- Moving from tacit knowledge to codified knowledge: understanding technician’s knowledge of cells and lab practices

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…coping with innovation and regulation

- How to relate automation choices to business model – eg ‘product’ vs ‘service’ model?
- How much knowledge of stem cells do manufacturers need to have to design acceptable automation devices?
- What will be the regulatory demands made of automated processes

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outcomes of the workshop

- Identify role of automation
- Identify main issues relating to regulation and how these can be best managed
- Identify lessons for clinical translation and scale-up
- Ensure automation is a move that secures *clinical relevance* and *clinical utility*

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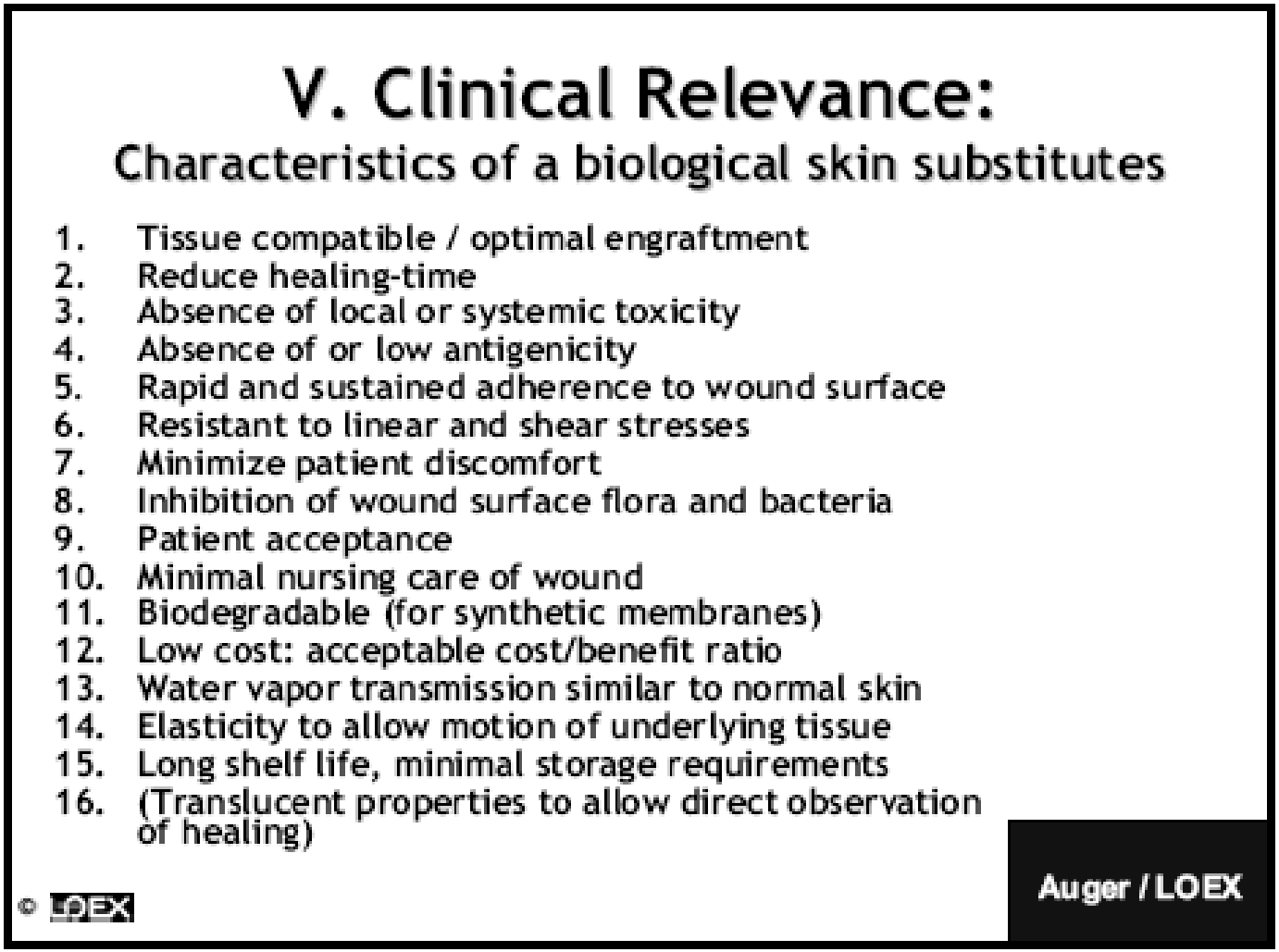

Factors determining clinical relevance of TE products (source: Laboratoire D'Organogenese Experimental, Canada, 2007)

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Clinical utility

- Acceptance only possible if new technology demonstrates clear benefit over current practice
- Utility is framed by context: e.g administration of the cell product (compare diabetes with spinal injury)
- Utility constructed within existing work practices, routines, infrastructures and constrained by resources

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