

Helios BioScience Inc.

**Human Platelet Lysate (hPL) for Clinical
Application of Mesenchymal Stem Cell Expansion**



HELIOS BioScience Inc.

Project Manager
惠韻如 / Doris Hui

Outline

- 全球細胞治療臨床現況
- 幹細胞產品國內發展現況
- 國內臨床試驗審查，常見之補件因素探討
- 影響MSC治療效能之關鍵因素
- 胎牛血清應用於人體細胞治療之瓶頸與風險
- USP<1043>**Ancillary Materials for Cell, Gene, and Tissue-Engineered Products**規範與風險分級
- 替代胎牛血清的新興產物-人類血小板生長因子

Trend for the MSC cell therapy

Rapidly growing market in global-Industrial Stem Cell Production



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EDITORIAL

Cell therapy industry: billion dollar global business with unlimited potential

Regen. Med. (2011) **6**(3), 265–272

“...the CTI is a distinct healthcare sector that is rapidly developing the capability and capacity to be a highly competitive, sustainable, multibillion dollar 21st century industry.”

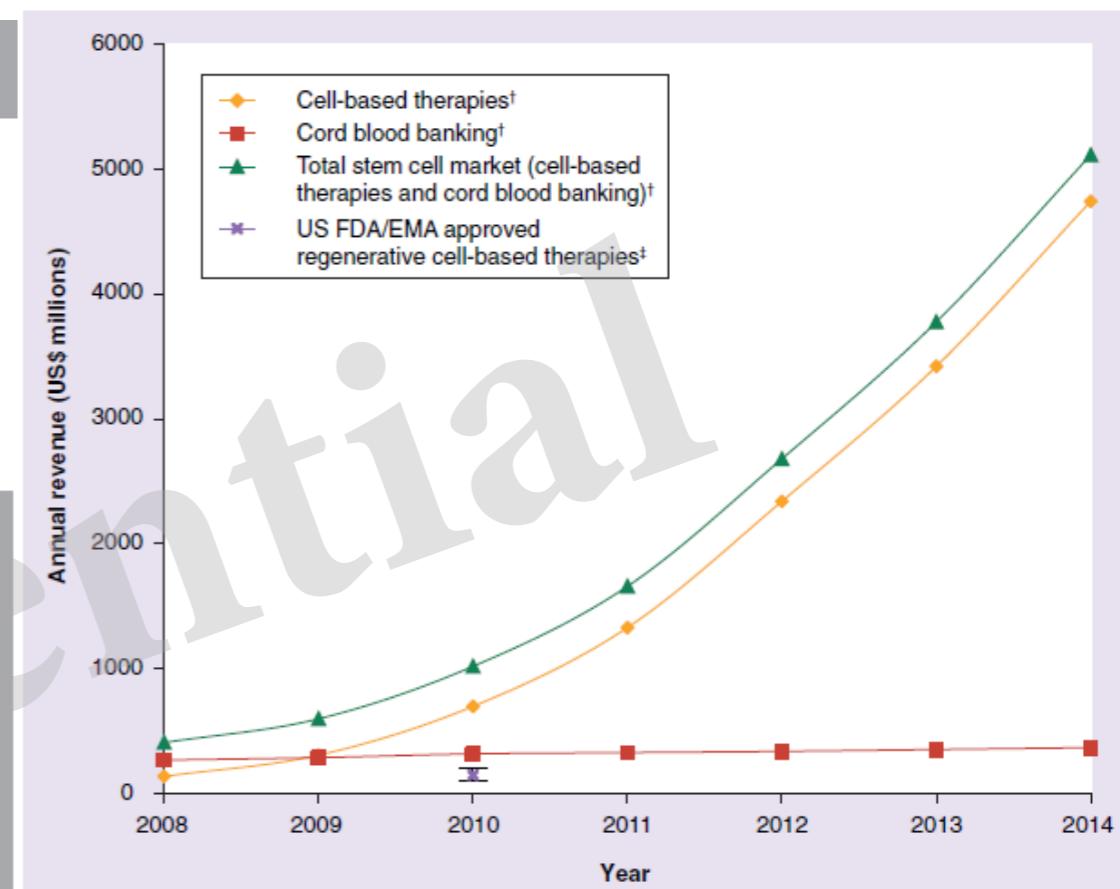
The cell therapy industry (CTI) has undoubtedly come of age with its international base, billion dollar per year turnover and broad spectrum of proven therapies ranging from conventional organ transplantation to advanced stem cell therapies. Now is, therefore, not the time to

Genome Sciences) [3]. From 2002 onwards, the term was increasingly embraced as political spin to distance the tissue engineering field from the disasters of its past – overambitious claims and wild research programs that resulted in billions of dollars of squandered investment, zero



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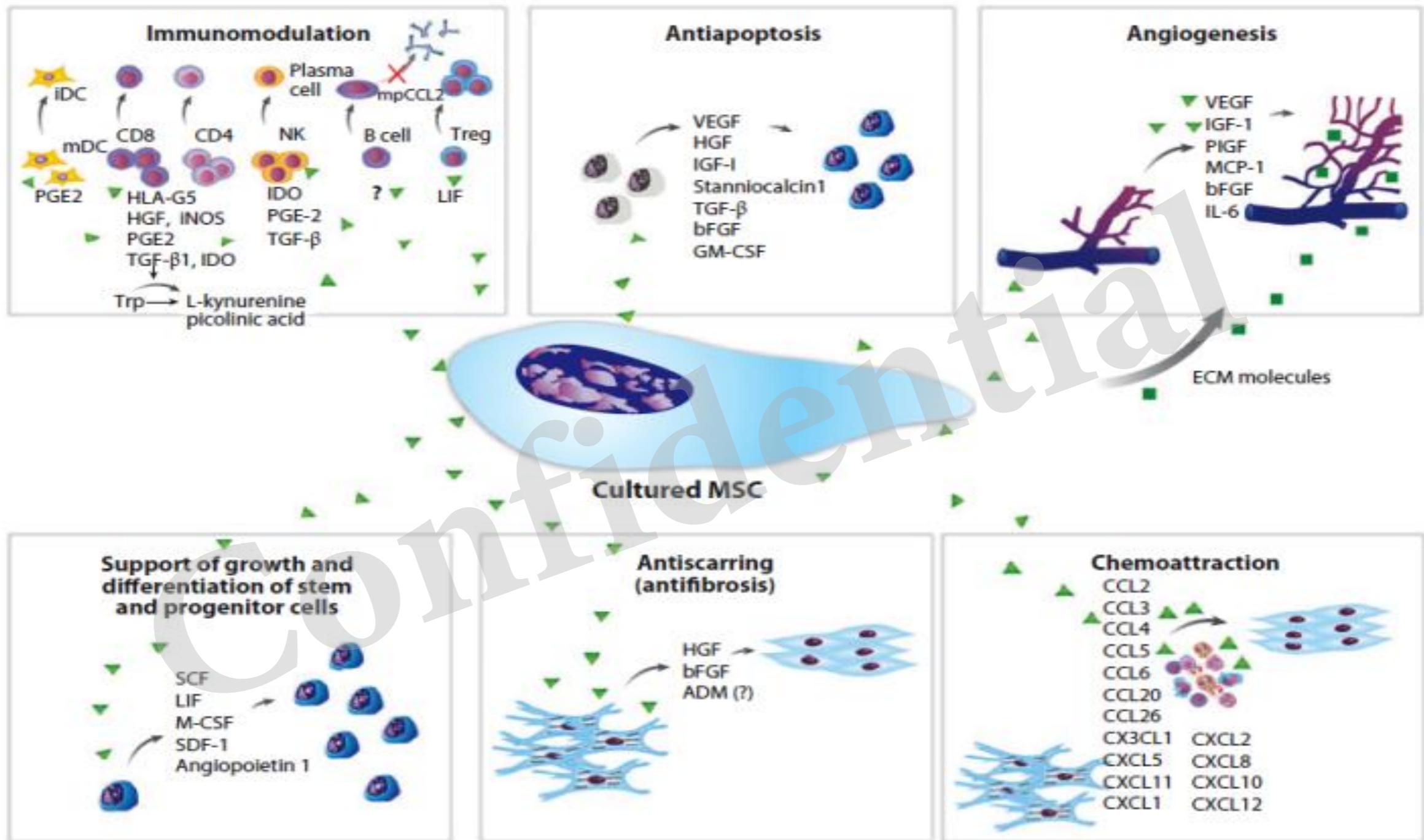
Top 50 most influential people on Stem Cells today

3

Prof. Chris Mason
Stem Cell & Regenerative Medicine
Bioprocessing Unit, ACBE
University College London

USD 5B Global Market in 2014

MSC intrinsic features-Paracrine



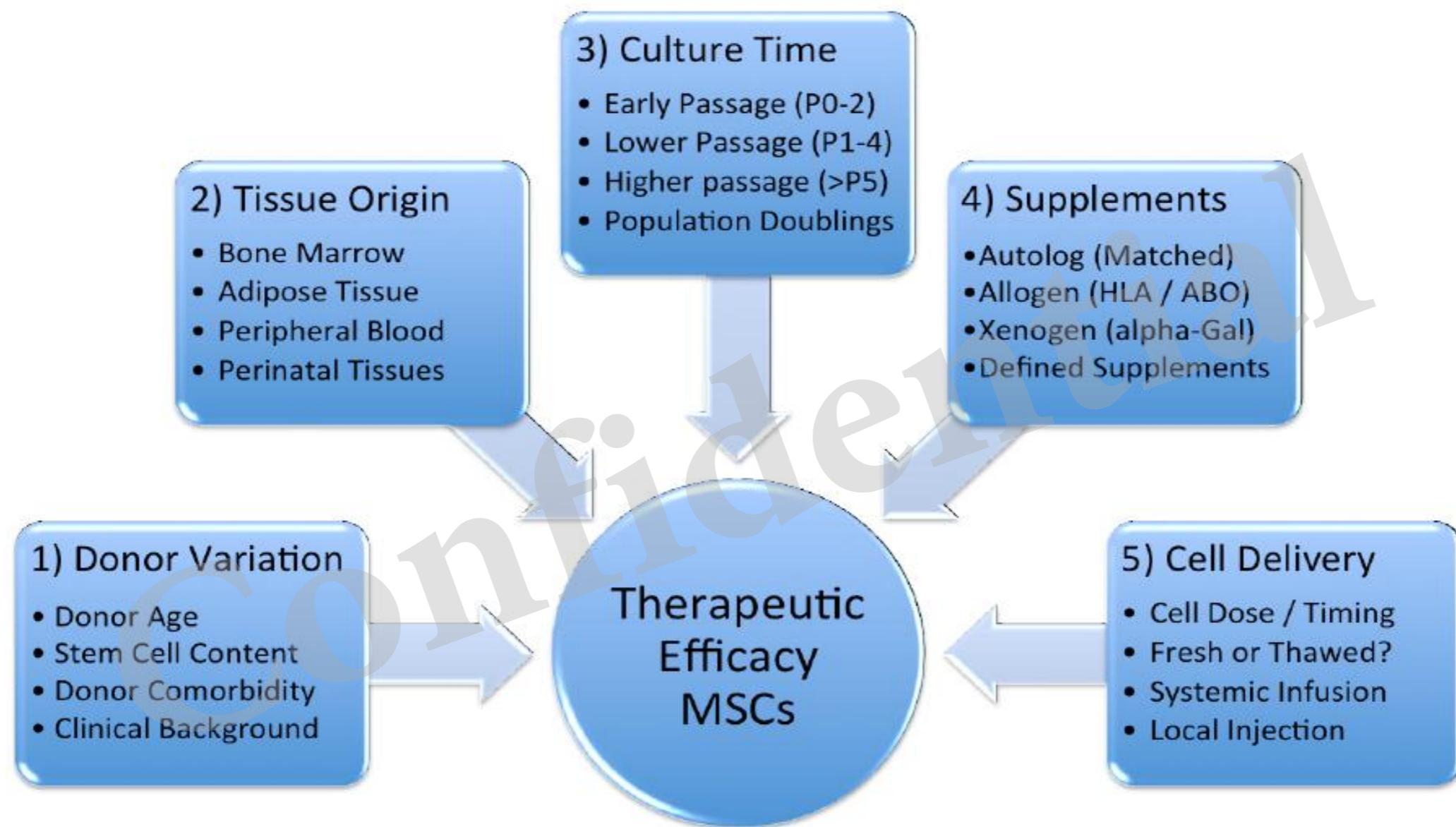
Source: Singer and Caplan, 2011

幹細胞治療產品的國內發展現況

- 2002年2月19日衛生福利部公告「胚胎幹細胞研究的倫理規範」
- 2002年12月衛生署公告「人體細胞組織優良操作規範(Good Tissue Practice, GTP)」
- 2007年8月9日衛生福利部公告「人類胚胎及胚胎幹細胞研究倫理政策指引」
- 2010年以前，衛生福利部將體細胞以新醫療技術方式列管，自食品藥物管理署(TFDA)成立後，大多數體細胞治療臨床試驗申請由醫事司轉移至TFDA(臍帶血移植仍由醫事司進行規範)
- 2011年2月TFDA公告「體細胞治療臨床試驗基準(草案)」、「體細胞治療及基因治療臨床試驗計畫申請與審查作業規範(草案)」
- 2014年9月正式公告「人類細胞治療產品臨床試驗申請作業及審查基準」
- 2014年12月5日台灣細胞醫療促進協會(TACT)成立

Critical successful factors

Potential parameters affecting therapeutic efficacy of MSCs



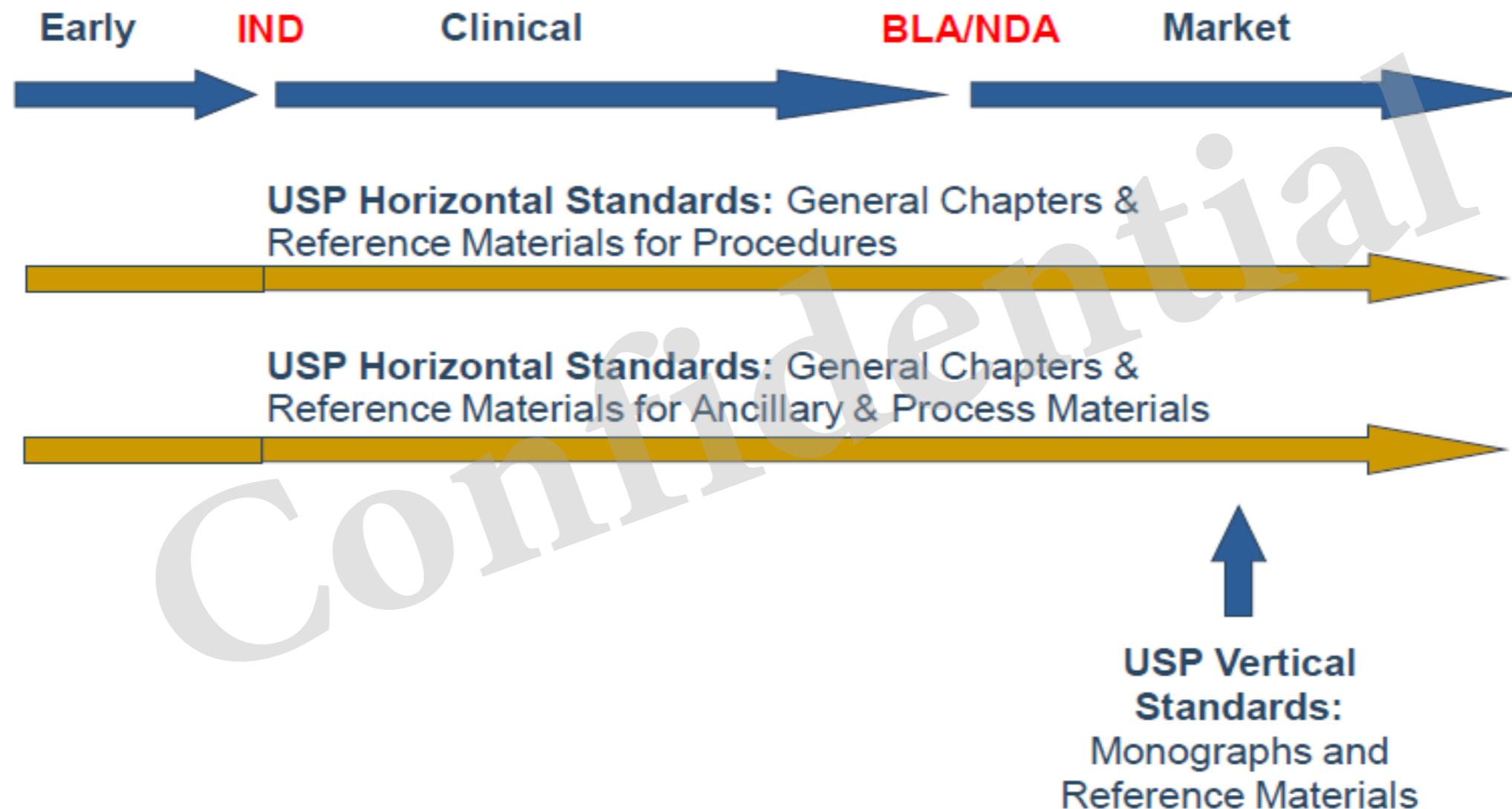
Guido Moll, Karolinska Institute Stockholm, Sweden 2013

USP <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products

USP 1043 Ancillary Material

Cell/tissue source	Ancillary Material	Excipient	Device (or Other) Component of Combination Product
<ul style="list-style-type: none">Source of cells that are processed to become the active ingredient in the final product	<ul style="list-style-type: none">Material that comes into contact with product during manufacturing, but is <u>NOT intended to be in the final product</u>May be active or inert	<ul style="list-style-type: none">Inactive ingredient that IS intended to be in the final product	<ul style="list-style-type: none">Material normally classified as device (or drug) that IS intended to be part of final product<i>e.g., structural component or delivery device</i>

USP Standard in the Biopharmaceuticals Life cycle



Performance-UC-, BM-, AD-MSCs

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Thank You

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