Axol Bioscience and the new ISSCR (International Symposium for Stem Cell Research) **Standards Document**

We are delighted to see the release of the new ISSCR Standards Document 2023.

Our quality and scientific team have reviewed the guidelines and are pleased to report on the following compliance statement.

*"There is a **strong history** through Roslin Cells' involvement with EBiSC (European Bank for Induced pluripotent Stem Cells) and the UK Stem Cell Bank, in the early days of developing stem cells. We are **deeply rooted in compliance and quality**, having been part of the consortium setting the standards for quality-controlled stem cell lines. Several of us were involved in the **early foundational work** for these guidelines, so we are delighted to see the publication of the Standards Document along with **Axol's continued compliance** to these high standards."*

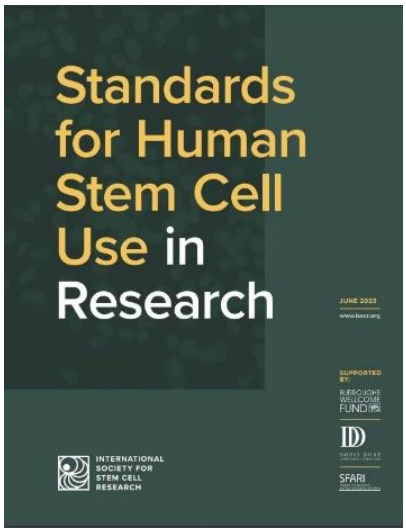
John Gardner
Manufacturing Operations Manager at Axol's Roslin site.

Committed to quality and consistency

Given the enormous potential for human iPSCs in building more human-relevant disease models, we prioritize the consistency and quality of our products. Our Quality Management System is the bedrock for our daily work, driving quality and consistency for every one of our customers.

Our Quality Management System

- Bulk / same batch manufacturing and storage are available
- Our manufacturing facilities are ISO 9001:2015 accredited
- We conduct in-depth iPSC characterization, both pre- and post-differentiation
- Our Certificate of Analysis inserts report on the quality testing methods and result
- We provide full batch control and options of ownership
- There is full traceability of material origin and source
- We utilize a Q-Pulse Quality Management System for compliant audit-trail operation



The ISSCR Standards Document 2023

We have over a decade of experience supplying high-quality products and services to biopharma organizations. We therefore welcome the publication of the ISSCR Standards Document 2023 and are pleased to report on our compliance with the individual components overleaf.

Test and Stage of Process	ISSCR Standard Required	AXOL
Acquisition of Materials	MTA	Meeting and/or exceeding
	Consent	Meeting and/or exceeding
	Licensing Agreements	Meeting and/or exceeding
	GDPR	Meeting and/or exceeding
	Comply with Regional and international regs	Meeting and/or exceeding
Cell Line Biobanking for Preservation	MCB with characterization	Meeting and/or exceeding
	WCB with characterization	Meeting and/or exceeding
	SOPs	Meeting and/or exceeding
	Documentation -traceability- batch records cell line history	Meeting and/or exceeding
	Equipment monitoring, validation, and servicing	Meeting and/or exceeding
	Work to GLP	Meeting and/or exceeding
	Off-site Storage	Meeting and/or exceeding
Cell Line Authentication	STR Analysis from Origin	Meeting and/or exceeding
	STR at MCB Stage	Meeting and/or exceeding
Nomenclature -Unique Identifier-Registration	hPSCreg	Meeting and/or exceeding
Reprogramming Transgene Elimination	Sendai clearance by qPCR	Meeting and/or exceeding
Cell Hygiene	Viral testing	Meeting and/or exceeding
	Mycoplasma	Meeting and/or exceeding
	Sterility	Meeting and/or exceeding
Pluripotency - Undifferentiated State - Assessment	Flow Cytometry	Meeting and/or exceeding
	Mesoderm -Scorecard	Meeting and/or exceeding
	Ectoderm -Scorecard	Meeting and/or exceeding
	Endoderm -Scorecard	Meeting and/or exceeding
	Downregulation of undifferentiation -Scorecard	Meeting and/or exceeding
	Morphology	Meeting and/or exceeding
Developmental State	Flow Cytometry	Meeting and/or exceeding
Genomic Characterisation	G-Banding	Meeting and/or exceeding
	aCGH	On request
Cell-Based Systems	Cell Line History	Meeting and/or exceeding
	Batch Records	Meeting and/or exceeding
	QC Records - Testing and Data	Meeting and/or exceeding
	Phenotype- Computational -molecular data - various	On request
	Image analysis	On request
	Antibody panels	On request
	Proteomics	On request
	Metabolics	On request
	Transcriptomics	On request
	Epigenome profiling	On request