Article

Compliance with Good Manufacturing Practice in the Assessment of Immunomodulation Potential of Clinical Grade Multipotent Mesenchymal Stromal Cells Derived from Wharton's Jelly

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Table S1. Severity rating for the FMEA analysis.

Severity level	Qualitative severity level	Potential impact of the failure
1	Negligible	Will not alter CQA
2	Minor	Unlikely to alter CQA
3	Moderate	Likely to alter CQA and will potentially result in regulatory incompliance
4	Critical	Undesirable CQA, will result in regulatory incompliance and will alter product safety
5	Catastrophic	Highly alter the product safety

CQA: Critical Quality Attribute

Table S2. Occurrence rating for the FMEA analysis.

Occurrence level	Qualitative severity level	Potential impact of the failure
1	Negligible	Will not alter CQA
2	Minor	Unlikely to alter CQA
3	Moderate	Likely to alter CQA and will potentially result in regulatory incompliance
4	Critical	Undesirable CQA, will result in regulatory incompliance and will alter product safety
5	Catastrophic	Highly alter the product safety

CQA: Critical Quality Attribute

Table S3. Detection rating for the FMEA analysis.

Detection level	Qualitative detection level	Description of consequences
1	Direct detection method	Controls systems, in process controls that will be used as direct method for identifying the failure
2	Highly detectable	Existing controls that are likely to detect the altered CQA
3	Medium detect-ability	Controls may detect the altered CQA
4	Low detect ability	Very unlikely that current control may detect the altered CQA
5	Undetectable	No available controls for the determination of a variation of CQA

CQA: Critical Quality Attribute

Table 4. Potential failures in the production of WJ-MSC.

Process
Materials and reagents
Equipment
People
Environment
Documentation

Table S5. **Potential failures regarding product's dose.** Complete Failure Mode and Effects Analysis for cell number, cell viability and volume.

Table S6. **Potential failures regarding product's impurities.** Complete Failure Mode and Effects Analysis for sterility, *Mycoplasma*, endotoxins, and adventitious viruses.

Table S7. **Potential failures regarding product's identity.** Complete Failure Mode and Effects Analysis for phenotype and karyotype.

Table S8. **Potential failures regarding the immunopotency of WJ-MSC.** Complete Failure Mode and Effects Analysis for immunomodulation potential.