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Biotechnology — Cell counting —

Part 1: General guidance on cell counting methods

Biotechnologie — Dénombrement des cellules —

*Partie 1: Lignes directrices générales relatives aux méthodes de
dénombrement des cellules*



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Foreword

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This document was prepared by ISO/TC 276, *Biotechnology*.

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Introduction

Cell counting (or cell enumeration) is a fundamental measurement that broadly impacts many aspects of biotechnology, from biomanufacturing to advanced therapy. The cell count (or discrete number of cells) is often expressed as cell concentration (i.e. cell count per volume) when in suspension and area density of cells (i.e. cell count per unit area) when adhered to a surface. Cell count is critical in evaluating potency and efficacy for cell-based therapy. The cell concentration within a bioreactor can serve as a quality assurance metric in cell-based manufacturing processes. Many cell-based bioassays need to be normalized to the respective cell count to allow data inter-comparability. This document (which is Part 1 of a multi-part standard on cell counting) defines terms and provides general guidance for the cell counting measurement process, including method selection, sample preparation, measurement, qualification and validation, and data analysis and reporting.