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# Biotechnology — Gene delivery systems —

## Part 1: Vocabulary

*Biotechnologie — Systèmes de transfert de gènes —*

*Partie 1: Vocabulaire*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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# Foreword

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*, Subcommittee SC 1, *Analytical methods*.

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# Introduction

Modern and emerging biotechnology is underpinned by the ability to manipulate the genes and genomes of living systems. Gene delivery systems are foundational to genome engineering. Gene delivery technology is evolving rapidly with numerous types of gene delivery systems providing a comprehensive set of tools and capabilities for in vitro or in vivo targeted delivery.

The ISO I6921 series consists of multiple parts to provide common understanding, guides, and analytical methods for characterizing these emerging biotechnology tools. This document provides terms and definitions to enable common understanding. Other parts of the ISO I6921 series will focus on measurements for various gene delivery systems.

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# Biotechnology — Gene delivery systems —

# Part 1: Vocabulary

## 1 Scope

This document defines terms related to gene transfer for mammalian systems, including the use of viral and non-viral gene delivery systems and via mechanical mechanisms.

This document is applicable to the development, measurement, and use of gene delivery systems for all applications.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

### 3.1 General terms

**3.1.1**
**electroporation**
action or process of introducing nucleic acids into cells using a pulse of electricity to briefly open pores in the cell membrane

**3.1.2**
**exosome**
subtype of *extracellular vesicles* (3.1.3) of endosomal origin generated by cells that can carry nucleic acids, proteins, lipids, and metabolites

Note 1 to entry: Usage of this term is discouraged unless subcellular origin can be demonstrated. See Reference [1] for additional information.

**3.1.3**
**extracellular vesicles**
particles that are released from cells, are delimited by a *lipid bilayer* (3.4.3), and cannot replicate on their own

Note 1 to entry: See Reference [1] for additional information.

[SOURCE: Minimal information for studies of extracellular vesicles (MISEV2023)[1]]

**3.1.4**
**gene amplification**
process whereby a defined DNA sequence in the genome is increased exponentially in number of copies using methods such as PCR or bacterial amplification

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**3.1.5**
**gene cloning**
technique of identifying a *gene of interest* (3.1.10), isolating the gene, and amplifying a gene that can be incorporated into a *gene delivery system* (3.1.6)

**3.1.6**
**gene delivery systems**
systems to introduce foreign nucleic acid into target or host cells

Note 1 to entry: Foreign nucleic acid to be delivered are commonly known as *transgenes* (3.1.27).

**3.1.7**
**gene editing**
techniques for *genome engineering* (3.1.13) that involve nucleic acid damage, repair mechanisms, replication and/or recombination for incorporating site-specific modification(s) into genomic DNA

Note 1 to entry: Gene editing is a subclass of *genome editing* (3.1.12).

[SOURCE: ISO 5058-1:2021, 3.1.1, modified — changed “into a gene or genes” to “into genomic DNA” and removed Note 2 to entry.]

**3.1.8**
**gene expression**
process of gene transcription and translation, in which the product is RNA or protein

[SOURCE: ISO/TS 16843-6:2022, 3,27, modified — Example removed.]

**3.1.9**
**gene gun**
mechanical *gene transfer* (3.1.11) method for transfecting cells with foreign nucleic acid or other biological molecules where a payload is coated on to high-density microcarriers, accelerated to high velocity by a gas pulse, and driven through cell walls and membranes to enter a target cell

**3.1.10**
**gene of interest**
**GOI**
nucleic acid sequence that encodes for the protein of interest

**3.1.11**
**gene transfer**
**gene delivery**
process by which foreign nucleic acid is introduced to target or host cells through mechanical, chemical, or biological approaches

Note 1 to entry: There are various gene transfer methods (see Figure 1).

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